COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

OFFICE OF THE
EXECUTIVE VICE PRESIDENT FOR RESEARCH

SPONSORED PROJECTS HANDBOOK

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1.

I. INTRODUCTION

A. Purpose of Handbook

This Handbook has been created to give practical guidance to faculty and administrative staff of Columbia University (**Columbia** or the **University**) in the management of sponsored projects funded by both governmental and private organizations. This will enable faculty and staff to administer and conduct research and other externally funded projects in accordance with University and sponsor policies.

In accepting sponsored project funding, University faculty and staff who conduct sponsored projects have an important fiduciary responsibility to manage such projects carefully. This Handbook will serve as a reference guide to the research policies and procedures of the University for all faculty, staff and students involved in research.

Readers should be advised that recent policy enhancements or changes in sponsors' policies and regulations may be more current than the contents of this Handbook. While every attempt will be made to keep the Handbook up-to-date, ultimately the most current information will be found in the government regulations and specific sponsor documentation and award documents, as well as the University's numerous websites and the Administrative Policy Library at http://policylibrary.columbia.edu/. Where a policy exists, links have been provided throughout the Handbook for ease of navigation to take the user to that specific policy.

B. Other Resources

1. Clinical Research Handbook

The University's Clinical Research Handbook is designed to give practical guidance to clinical research coordinators in the management of clinical research conducted at Columbia, and to serve as a general reference guide for faculty, staff and students who are involved in clinical research. It covers in greater depth than in this Handbook topics of particular interest to clinical researchers and should be seen as a companion volume to this Handbook. It is available online and in pdf at http://evpr.columbia.edu/content/clinical-research-handbook.

2. Animal Research Handbook

The University's Animal Research Handbook is designed to be a reference guide for faculty, staff and students who are involved in research using animals. It covers in greater depth than in this Handbook topics that are of particular interest to researchers conducting research with animals and should be seen as a companion volume to this Handbook. It is available online and in pdf at http://evpr.columbia.edu/content/animal-research-handbook.

3. Research Radiation Safety Handbook

The University's Research Radiation Safety Handbook is designed to be a reference guide for faculty, staff and students who are involved in research using radiation or radioactive materials. It covers in greater depth than in this Handbook topics that are of particular interest to researchers conducting research with radiation or radioactive materials and should be seen as a companion to this Handbook. It is available online and in pdf at http://evpr.columbia.edu/content/research-radiation-safety-handbook.

4. CUMC Administrators' Manual

The CUMC Administrators' Manual is intended to provide guidance to administrators at the University's College of Physicians and Surgeons (**P&S**), School of Nursing, College of Dental Medicine and Mailman School of Public Health and to serve as a reference for all administrative staff at Columbia University Medical Center (**CUMC**). It covers a wide range of departmental administrator activities. The Manual is available online at https://admin-manual.cumc.columbia.edu/administrators-manual. Questions can be sent to cumcadmmanual@columbia.edu.

C. Glossaries

1. Glossary of Handbook Acronyms

For ease of reference, **Annex A** contains a Glossary of Acronyms used in this Handbook.

2. Federal Agency Glossaries

For more formal grant definitions and terms, you can refer to the following NIH and NSF links:

NIH Glossary and Acronym List

http://grants.nih.gov/grants/glossary.htm

NSF Glossary

http://www.nsf.gov/about/glossary.jsp

D. Sponsored Projects

1. Sponsored Projects vs. Gifts

In carrying out its various missions, the University derives its revenues from a variety of sources, including tuition, gifts, clinical activities and grants and contracts. A question that arises regularly is how to differentiate a gift from a sponsored project. In some cases, making this determination may require a legal assessment. In most cases, the

distinction can be made by considering the attributes associated with each of these types of funding. As articulated in the University's Policy on Distinguishing Gifts from Sponsored Projects:

Sponsored projects include research, instruction and training, public service, fellowships and other scholarly and creative activities conducted under the direction of Columbia faculty and staff and funded by an outside source in accordance with award instruments containing one or more of the following provisions:

- The proposed work binds Columbia to a specific line of scholarly or scientific inquiry, which usually requires a statement of work, grant application or proposal.
- The submission (and approval) of a budget is required.
- The funds are given to accomplish specific research objectives (as opposed to providing support for a general area of research) within a specific time frame.
- Funds are to be used only for activities approved in advance by the sponsor.
- There is a requirement for technical or detailed financial reports (e.g., by cost category) or for some other outcome or product of the activity, to be delivered to the sponsor during or at the completion of the activity.
- A time period is specified during which activities are to be conducted and completed.
- There are requirements for audits by or on behalf of the funding source.
- Terms for the disposition of rights in tangible or intangible property (data rights, copyrights and inventions) developed or obtained during the activity are included.
- The requirement for unexpended funds to be returned to the sponsor at the completion of the activity is specified.

Gifts are voluntary, irrevocable, gratuitous transfers of money or other property to support Columbia programs or activities. Gifts can be unrestricted or restricted. Generally, funds from private, non-governmental sources are to be administered as gifts when the funding source neither expects nor requires the performance of contractual obligations or the delivery of products in return for the transfer of funds to Columbia.

If the proposal is for a sponsored project, it must be processed through Sponsored Projects Administration (**SPA**), the Clinical Trials Office (**CTO**) or Columbia Technology Ventures (**CTV)**. When assistance is required in making a determination as to whether a particular source of funds is a gift or a sponsored project, SPA or the appropriate Development Office should be contacted.

2. Types of Sponsored Projects

It is important to understand that funding for sponsored projects is provided to the University through a variety of funding instruments. The primary distinction that needs to be made is whether the funding provides assistance or is payment for completion of a

specific scope of work that has been requested (procured) by the sponsor. Grants and cooperative agreements are forms of assistance awards while contracts are used to provide procurement funding.

Grants may have fewer conditions than other types of sponsored funding, but they are nonetheless legal agreements that detail the terms and conditions under which the funding is being provided by the sponsor. A sponsor awards a grant to support research or other activities described by a Principal Investigator (**PI**) in a proposal submitted often, but not always, in response to a solicitation (frequently called **Funding Opportunity Announcements – FOAs, Requests for Application – RFAs** or **Program Announcements – PAs**). The proposal describes what the PI hopes to accomplish (the **project scope**) with the award and outlines a general course of inquiry. Within the scope specified in the formal grant agreement, the PI controls the direction of the inquiry process. The sponsor agrees to provide assistance to the PI to undertake the proposed scope of work. Ordinarily, grants do not include commitments to provide specific products or deliverables, beyond reports detailing the progress or outcome of the work. Grants may support research or other activities including conferences, symposiums, training, program activities, maintaining a collection of scientific specimens, etc.

Cooperative agreements are also assistance agreements, but typically involve a significant level of sponsor participation in the administration of the project. PIs can expect that there will be ongoing and regular communication with the sponsor's programmatic personnel often including regular meetings and site visits.

Contracts are issued by sponsors to procure one or more specific deliverables. They are usually issued in response to detailed requests from sponsors (**Requests for Proposals - RFPs**) that require that the PI undertake a specific course of action and provide data, analysis, devices or other specified deliverables within a set time frame. Payment is dependent on the satisfactory completion of these activities within the timeline detailed in the terms of the contract.

E. Primary University Offices Involved in Sponsored Research: Office of the Executive Vice President for Research (EVPR)

The Office of the EVPR has overall responsibility for the University's research enterprise at all locations: the Morningside and Manhattanville campuses, CUMC, Lamont-Doherty Earth Observatory (**Lamont**) and Nevis Laboratories (**Nevis**). The Office establishes and administers the policies governing the conduct of research at the University and oversees the management of its research programs. It assists investigators seeking external funding, promotes interdisciplinary research and provides seed money for early stage investigations through the Research Initiatives in Science and Engineering Program. It also works to promote an institutional environment that sustains the high quality of the University's research programs and maximizes their productivity.

Reporting to the EVPR, the Vice President for Research Operations has overall responsibility for managing the administration of research at the University. In addition, the Vice President works with the EVPR to define the University's research policies; enhance the services and resources that support the University's research mission; identify new research opportunities; and strengthen the University's relationships with external research collaborators.

The Office the EVPR also includes an Executive Director for University Research Planning and Development, who works with investigators and administrators on formulating and implementing medium- and long-term planning for research. The Executive Director's responsibilities also include working with the Office of Alumni and Development to expand private fundraising efforts for research.

The offices described in this **Section E** constitute all of the operating units of the Office of the EVPR. Additional information about the Office of the EVPR, the offices it manages and general research resources is available at www.evpr.columbia.edu. See also the Quick Guide to Research at Columbia University for an overview of offices that support Columbia's research enterprise.

1. Office of Research Administration (ORA)

ORA is comprised of the operations of both Sponsored Projects Administration and the Clinical Trials Office.

• Sponsored Projects Administration (SPA)

SPA coordinates the submission of proposals for sponsored projects to external funding sources and provides some post-award services for those projects that are funded. It also ensures that project proposals and awards comply with University and sponsor policies. All sponsored research proposals and resulting awards (other than (a) industry sponsored clinical research and clinical trial proposals and agreements for which the CTO has signatory authority and (b) certain industry sponsored non-clinical research agreements for which CTV has signatory authority) must be signed on behalf of the University by certain officers in SPA who have been designated by the Trustees. Vice presidents, deans, directors, department chairs or other officers are not authorized to act in this capacity.

Each department is served by a dedicated Project Officer, who assists with proposal development and submission, and by a Financial Analyst, who assists with certain aspects of post-award management. The Project Officer is the key point of contact in SPA for investigators and administrators and serves as the conduit between Columbia and external sponsors.

A directory of these officers and additional information on SPA may be found at www.spa.columbia.edu.

• Clinical Trials Office (CTO)

Clinical trials are a subset of clinical research. The most commonly used definitions of clinical research and clinical trials can be found in the NIH Grants Policy Statement Glossary (http://grants.nih.gov/grants/glossary.htm), where they are defined as follows:

Clinical Research: patient oriented research, including epidemiologic and behavioral studies, outcomes research and health sciences research. Patient oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual unless the research involves a clinical investigation of a medical device.

Studies falling under 45 CFR 46.101(b)(4) are not considered clinical research for purposes of this definition. 45 CFR 46.101(b)(4) studies are defined as "research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

Clinical Trial: a biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices or new ways of using known drugs, treatments or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective.

Industry Sponsored Clinical Research and Clinical Trials

The administrative responsibility for promoting and assisting investigators in managing industry sponsored clinical research and clinical trials rests with the CTO. The CTO negotiates contracts for all industry sponsored clinical trials and clinical research. The finance office of the CTO assists in financial management of clinical trials. All invoicing, collection and reconciliation of funds relating to industry sponsored clinical trials is conducted by the finance office. The CTO also provides regulatory guidance, education and training in FDA-regulated research for the research community.

In the CTO, each department is served by a dedicated Budget Analyst, who assists with the review of proposals and development of budgets, a Project Officer, who is responsible for the negotiation of industry contracts, and a Financial Analyst, who is responsible for setting up accounts.

The CTO is advised by a Clinical Trial Advisory Committee (**CTAC**) composed of administrators and clinical research faculty jointly appointed by the University and NewYork-Presbyterian Hospital (**NYP**). The CTAC is responsible for advising on

policy issues that may arise with respect to clinical trials and on matters relating to the promotion of clinical trials.

Additional information on the CTO and the programs it manages is available at https://cto.cumc.columbia.edu/.

2. Office of Research Compliance and Training (RCT)

RCT ensures that the University is in compliance with the complex web of regulatory requirements that govern research. It fulfills that mission in collaboration with the other offices discussed in this Handbook. RCT administers the University's policies on financial conflicts of interest in research, research misconduct, international research and export controls, and serves as a resource on compliance questions on a variety of issues, including effort reporting. It also promotes an understanding among the faculty and staff of the requirements they must observe in conducting research through the development of integrated educational programming on compliance across the University. Its web site at http://www.columbia.edu/cu/compliance/ contains detailed information about both the research compliance requirements under which the University operates and RCT's training programs.

3. Office of Research Initiatives (ORI)

ORI works across disciplines, schools and campuses to foster interdisciplinary research collaboration, and supports efforts to secure funding for such collaborations. It identifies opportunities and strategies for enhancing Columbia's research presence and its status as a prominent research institution. It also administers Columbia's internal review and nomination processes for those funding opportunities that limit the number of proposals any one institution is permitted to submit, and works to improve Columbia's track record in securing such awards. Finally, it assists the faculty in securing and managing research computing resources on the Morningside campus. For more information on limited submissions, see **Preparing a Sponsored Project Proposal: Developing a Proposal – Other Resources** (**Chapter IV, Section G(5)).**

Additional information on ORI is available at http://researchinitiatives.columbia.edu/

4. Human Research Protection Office (HRPO)/Institutional Review Boards (IRBs)

The HRPO is the administrative office that supports the University's IRBs and implements the functions and goals of the University's Human Research Protection Program (**HRPP**).

The HRPP is charged with the responsibility of ensuring that all human subjects research is performed ethically, in compliance with applicable laws, regulations and University policies and in a manner that promotes the protection of human subjects in research. Protections for human participants must also meet or exceed the standards of

accreditation as set forth by the Association for Accreditation of Human Research Protection Programs (**AAHRPP**). The Columbia HRPP covers all entities, offices and individuals engaged in and/or responsible for the review and conduct of human subjects research at Columbia and NYP (at CUMC).

The IRBs review study protocols and modifications to study protocols, conducts continuing reviews at least annually for non-exempt research, audits studies and, if necessary to protect subjects, can suspend projects.

For further information about the HRPO and the IRBs, see the Clinical Research Handbook. In addition, there is a wealth of information about the HRPO and the IRBs, applicable regulations, the review process, etc. on the HRPO/IRB website: Http://www.cumc.columbia.edu/dept/irb/.

5. Office of the Institutional Animal Care and Use Committee (IACUC)

The IACUC is responsible for reviewing all protocols involving live vertebrate animals, ensuring compliance with federal regulations and guidelines, inspecting animal facilities and laboratories and overseeing training and educational programs. The overall role of the IACUC is to ensure the humane and ethical care and use of laboratory animals. The IACUC works closely with the Institute of Comparative Medicine (**ICM**) which manages the animal facilities and veterinary services at the University

For further information on the IACUC, see the Animal Research Handbook and the IACUC website: http://www.cumc.columbia.edu/dept/iacuc/.

6. Office of Environmental Health and Safety (EH&S)

EH&S is committed to establishing and maintaining a healthy and safe work environment for our staff, students, neighbors and surrounding communities. Through the recognition, evaluation and control of personal and environmental hazards, EH&S strives to eliminate individual risk and reduce the environmental impact of its activities. EH&S offers a broad range of services and actively develops partnerships with faculty and departmental personnel to ensure a safe work environment and compliance with applicable local, state and federal regulations and University policies in the most efficient manner possible. These endeavors are realized through programs such as personnel training, chemical hygiene planning, biological safety, environmental safety, fire safety and occupational safety. Consultation is also available for laboratories that wish to discuss hazards relating to specific materials or techniques.

The Columbia Radiation Safety Program is managed as a unit within EH&S and is responsible for assisting its constituent communities in the safe use of ionizing radiation, including radioactive materials and x rays. The Radiation Safety program is designed to protect users, staff, patients, the general public and the environment from radiation exposure and to ensure the safe receipt, handling, use and storage of radioactive

materials. The mission of the Radiation Safety Program is to facilitate safe conditions for the proper use of radiation, maintain radiation exposures As Low as Reasonably Achievable (**ALARA**) and to ensure that operation are in compliance with applicable city, state and federal regulations.

The Radiation Safety Program is integrated, but has two components. One component includes the Morningside and Manhattanville campuses, Lamont, Nevis and Barnard College. The other component includes CUMC, NYP and New York State Psychiatric Institute (**NYSPI**).

7. Office of Postdoctoral Affairs (OPA)

OPA enhances the educational and training experiences of the University's postdoctoral appointees (**postdocs**). In addition to providing professional development workshops and networking events for postdocs, the Office also serves as an advocate for postdocs through the provision of administrative support, the development of communication among postdocs, faculty and administrators and the promotion of consistency among all postdoc-related University policies. The Office has authored a Postdoctoral Officers Handbook that can be accessed on the OPA website.

For further information, go to http://www.columbia.edu/cu/postdocs/ or email OPA directly at postdocaffairs@columbia.edu.

F. Other University Offices Involved in Sponsored Research

The following offices are not part of the Office of the EVPR, but provide important support to Columbia's research enterprise.

1. Columbia Technology Ventures (CTV)

CTV is the University's technology transfer office. Through technology transfer, Columbia inventions and innovations may be incorporated into products and services that directly benefit people across the globe. The University itself also benefits, as technology transfer brings in licensing revenues that are reinvested to enhance the quality and breadth of education and research at Columbia.

If a member of the Columbia community (investigator, staff or student) believes that he/she may have an invention, it is both in his/her own best interests and his/her obligation to report the invention to CTV. CTV has more than 20 years of experience evaluating, protecting and commercializing Columbia's intellectual property. It triages more than 300 new invention disclosures, executes 40-50 license agreements, and helps launch 10-12 start-up companies each year.

CTV provides the full spectrum of technology transfer-related services for Columbia faculty, staff and students, including:

- Material and Data Transfer Agreements
- Confidentiality Agreements
- Patent Filing and Prosecution
- Technology Marketing
- Technology License Agreements
- Industry Sponsored Non-Clinical Sponsored Research Agreements (**SRAs**) (in collaboration with SPA)
- Inter-Institutional Collaboration/Sharing Agreements
- Entrepreneurship and Start-Up Advising
- Commercialization Grants Advising (SBIR, STTR, etc.)

The majority of SRAs are handled by SPA, consulting with CTV, as needed, on intellectual property issues. CTV handles some SRAs, as agreed to with SPA and with notice to the applicable department. CTV does not handle any industry sponsored clinical research or clinical trials.

For more information on any of CTV's services or to report a potential invention, send an email to techventures@columbia.edu, or call CTV at (212) 854-8444. Additional information on CTV is available at www.techventures.columbia.edu/.

2. Office of the Controller

The Office of the Controller is responsible for the overall fiscal administration of sponsored projects. Two departments within the Office of the Controller carry out these responsibilities: Sponsored Projects Finance (**SPF**) and Research Policy and Indirect Cost (**RPIC**).

SPF is the University's central office for sponsored project post-award administration. SPF provides PIs and departmental administrators post-award financial administrative support for most types of sponsored projects. SPF's primary objective is to facilitate compliance with both sponsor and University policies on all components of post-award administration.

Each academic department is assigned a SPF Project Manager, who acts as the single point of contact for principal investigators and departmental administrators for projects assigned to their department on matters of financial reports to sponsors, billing of sponsors, collection of payment from sponsors and application of cash to projects upon receipt. SPF maintains signatory authority for financial documents submitted to sponsors on behalf of the University.

Specific administrative functions that SPF is responsible for include:

- Preparation and submission of financial reports to sponsors
- Preparation and submission of invoices to sponsors
- Guidance on allowable and non-allowable costs
- Monitoring of cost sharing and cost transfers

- Management of sponsor financial audits
- Final reconciliation and closeout of terminated projects
- Development and delivery of training materials relating to post-award management

RPIC is responsible for the following activities:

- Coordination of compliance with the federal regulations relating to effort reporting, including the annual certification of salary, and review of requests for retroactive cost transfers.
- Development and negotiation of the University's Facilities and Administration (**F&A**) and fringe benefit rates
- Monitoring of capital assets relating to grant activity
- Preparation of expenditure based reports and Schedule of Federal Financial Assistance and review of subrecipient Uniform Guidance Subpart F reports.

Additional information is available at http://finance.columbia.edu/content/sponsored-projects-finance

3. Office of Alumni and Development

The Office of Alumni and Development (which includes the CUMC Development Office) provides, in keeping with University fundraising priorities, essential services to schools, departments, faculty, investigators and physicians with regard to developing strategies and implementing fundraising plans, preparing cultivation and solicitation letters and materials, and identifying prospective donors. In addition, the Office successfully solicits significant supplements to investigators' sponsored research funds.

The Office works closely with SPA in determining if awards are gifts or sponsored research. For an explanation of the distinction between a gift or sponsored research, see **Sponsored Projects – Sponsored Projects vs. Gifts** (**Section D(1))** above.

Gift Systems at the Office of Alumni and Development works with SPA and SPF to record sponsored research gifts in both the development system (**Advance**) and the University's financial system, Accounting and Reporting at Columbia (**ARC**). The Office's Advance record is used to maintain an historical record of gifts to the University, issue receipts acknowledging each payment, house gift documentation and track philanthropic gift income in development totals.

Additional information on the Office of Alumni and Development and the CUMC Development Office can be found at http://alumni.columbia.edu/ and http://giving.cumc.columbia.edu.

4. Center for Digital Research and Scholarship (CDRS)

CDRS is part of Columbia University Libraries/Information Services and uses innovative new media and digital technologies to empower Columbia's research community with the online tools necessary to make the most of scholarly communication, collaboration, data-sharing and preservation. CDRS was established in 2007 to address the ongoing evolution of researchers' and scholars' needs as new technologies, policies and systems of knowledge exchange arise.

CDRS services include publications support, Columbia's online repository Academics Commons, conference support, video team services and collaboration support. CDRS is also developing services focused on supporting research data management. The Center's Scholarly Communication Program hosts events, provides resources about transformations within the realm of scholarly communication and open access policies and manages the Columbia Open Access Publication Fund (COAP).

Additional information can be found at http://cdrs.columbia.edu/cdrsmain/ or email CDRS at info@cdrs.columbia.edu.

G. Overview of Principal Investigator and Departmental Administrator Roles and Responsibilities

As described above, the purpose of this Handbook is to facilitate the work of PIs and administrative staff by providing a comprehensive reference guide covering the entire spectrum of activities associated with sponsored projects – from obtaining funding to closing out awards.

While sponsored projects are awarded to the University, the actual management of those projects rests with each PI and the support provided by his/her department.

1. Principal Investigator (PI)

The PI bears the primary responsibility for the success of his/her sponsored project. In addition to his/her academic and scholarly duties, the PI has managerial and oversight responsibilities for the administrative aspects of a project. The PI's particular duties include:

- assuming overall responsibility for the management of the study;
- determining study feasibility;
- ensuring that all the information in the proposal is presented in a manner that is complete, accurate and developed according to the practices commonly accepted within the scientific community;
- ensuring that all required approvals are obtained and University forms and certifications are completed in a timely manner;
- for sponsored research, knowing and abiding by the terms and conditions of the award;

- conducting the work on the project according to the research protocol or statement of work that was submitted with the original proposal or as subsequently modified by the sponsor in agreement with the PI and the University;
- ensuring that all work meets the highest ethical standards and is conducted without real or apparent conflicts of interest, in accordance with the University's policies;
- ensuring that all work performed is conducted in compliance with applicable federal, state and local laws and regulations and with University policies and requirements;
- ensuring that all key personnel are qualified and have met necessary training requirements;
- managing the project's budget so that funds are spent correctly, taking into account any restrictions imposed by the sponsor and avoiding cost overruns;
- ensuring that all financial records and reports are accurate and auditable;
- monitoring the activities of subrecipients, if any;
- submitting reports on the research in a timely manner and according to the sponsor's requirements; and
- completing the formal closeout of the project.

The PI's responsibilities are delineated in the University's Faculty Handbook and the Policy on
Principal Investigator Responsibility for Financial Oversight of Grants and Contracts

The Faculty Handbook also contains information on the following topics:

- Fundamental Principles Governing Externally Funded Research
- Research Misconduct
- Eligibility to Act as a Principal Investigator
- Offices Relating to Research Management and Compliance
- Technology Development and Transfer
- Conflicts of Interest

Selected policies relating to such topics are included in the Faculty Handbook as Appendices.

For a summary of PI responsibilities, see Quick Guide for Principal Investigators.

See also **Preparing a Sponsored Project Proposal: PI Eligibility** (**Chapter IV, Section C**) for a description of eligibility requirements to act as a PI at Columbia.

2. Departmental Administrator (DA)

The DA is responsible for the administrative aspects of a sponsored project and is a key individual in the management of the project. While the University places the primary

responsibility for the conduct of a sponsored project in all of its aspects on the PI, it is the DA who will be the most involved in the day-to-day administration of the project. Therefore, it is imperative that the PI and the DA interact closely and frequently to review and discuss financial and administrative matters. The DA is responsible for, among other things:

- working with SPA, the CTO or CTV to make sure that budgets and awards are created accurately in the University's financial systems in accordance with the approved award after reviewing a notice of award or contract;
- discussing with the PI any special award or contractual requirements;
- understanding the sponsor's restrictions on costs and discussing them with the PI;
- processing charges to the study based on guidance from the PI;
- monitoring the award or contract on a regular basis, including monthly reconciliation of accounts;
- confirming that charges to awards or contracts are appropriate and accurate in adherence to University policies and in compliance with applicable laws and regulations;
- monitoring subrecipient expenditures and work;
- assisting with the preparation of Financial Status Reports;
- assisting with the monitoring effort reporting and compensation to ensure that they are consistent; and
- planning the administrative and financial closeout of the project.

See also **Introduction: Roles and Responsibilities** (**Chapter I, Section G)** of the **Clinical Research Handbook** for a description of additional responsibilities of the PI, Clinical Research Coordinator (**CRC**), DA and sponsor when conducting clinical research.

H. General University Guidelines

The University is committed to operating with integrity and in compliance with applicable laws, regulations and policies. The University expects the highest standards of ethical conduct from members of its community and is dedicated to upholding its reputation as of the preeminent academic and research institutions in the world.

The principles embodied within the Statement of Ethical Conduct and the Administrative Code of Conduct guide and govern interactions at the University and promote an environment of respect that is central to its success and that of the individuals who work at the University.

1. Statement of Ethical Conduct

Columbia expects all officers, support staff and students to maintain the highest standards of ethical conduct.

The basic principles of Ethical Conduct are:

- Be honest, ethical and truthful
- Obey the law. If you are uncertain about what the law or applicable regulations require, seek assistance from your supervisor.
- Follow University policies and procedures. Make sure you understand your responsibilities. If you have questions about specific issues, you should ask your supervisor. Select University policies are listed in the "Where should I go with a concern?" and "To learn more" sections.

The Statement also sets forth procedures for reporting concerns, and states that failure to live up to these principles may result in disciplinary action.

The Statement of Ethical Conduct can be found at http://policylibrary.columbia.edu.

2. Administrative Code of Conduct

The Administrative Code of Conduct articulates the principles that govern interactions at the University and some of the basic expectations that flow from those principles. The Code can provide sound advice and direction for all interactions between members of the Columbia community. It applies to Officers of Administration, applicants for positions as Officers of Administration and vendors working on behalf of Officers of Administration.

The Administrative Code of Conduct is organized around four basic principles:

- Respect for governance;
- Respect for others;
- Respect for information; and
- Respect for property.

The Administrative Code of Conduct can be found at policylibrary.columbia.edu.

I. Regulatory Oversight

Sponsored research is heavily regulated, particularly by the federal government, which provides most of the sponsored research funding in the United States. Many of the University policies and procedures described in this Handbook have been established to conform to federal regulations overseen by various government agencies and have been extended to non-federally funded sponsored projects.

1. Uniform Guidance

The Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (the **Uniform Guidance**), issued by the Office of Management and Budget (**OMB**), governs how the University must manage federally sponsored projects. The Uniform Guidance became effective on December 26, 2014, replacing OMB Circulars A-21, A-110 and A-133. Federally sponsored projects awarded on or after December 26, 2014 are subject to the Uniform Guidance. Awards issued prior to December 26, 2014 are subject to the previous OMB Circulars.

The Uniform Guidance is codified in the Code of Federal Regulations (**CFR**) in Title 2, Subtitle A, Chapter 2, Part 200 (2 CFR 200) and is divided into the following subparts:

Subpart A (200.0 – 200.99) – Acronyms and Definitions
Subpart B (200.100 – 200.113) – General Provisions
Subpart C (200.200 – 200.211) – Pre Award Requirements
Subpart D (200.300 – 200.345) – Post Award Requirements
Subpart E (200.400 – 200.475) – Cost Principles
Subpart F (200.500 – 200.521) – Audit Requirements (includes Appendices I-XI)

The Uniform Guidance is divided into the following three areas:

Administrative requirements. Subparts B through D set forth the uniform administrative requirements for grants and cooperative agreements. It sets forth standards ranging from pre-award requirements such as agency funding announcement requirements and treatment of pre-award costs, to post-award requirements, including standards for financial management systems, payment terms, cost sharing, program income, budget revisions, property management and procurement standards and financial reporting requirements.

Cost Principles. Subpart E established principles for determining the allowable costs incurred under federal awards. The sections of this Subpart that have the greatest impact on PIs and administrative staff in carrying out their financial management responsibilities are those relating to:

- Allowability of costs;
- Allocability of costs;
- Reasonableness of costs;
- Consistency in how costs are treated;
- Consistency in how costs are estimated, charged and reported to sponsors; and
- Accounting for unallowable costs.

Single Audit Requirements and Audit Follow-up. Subpart F sets forth audit requirements in accordance with the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), including the annual compliance audit of federally sponsored projects. While the audit itself is coordinated through the Office of the Controller, PIs and DAs overseeing sponsored projects or specific transactions that are selected by the auditors often need to interact with the auditors during the course of the audit. Such interactions are generally coordinated by the Office of the Controller.

2. Other Regulations

In addition to the Uniform Guidance and the previous OMB Circulars that govern all federal projects, many federal and other sponsors, including voluntary health and welfare organizations, have their own sponsor-specific requirements, and it is the responsibility of PIs and administrative staff to be familiar with those requirements as well. It is beyond the scope of this document to reference each of these documents. However, given the large proportion of project support from the NIH and NSF, the following links will direct you to the policies of those two agencies:

NIH Grants Policy Statement

NSF Proposal and Award Policies and Procedures Guide

J. University Compliance Hotline

Columbia expects members of the University community to inform the appropriate contacts if they have observed unethical, illegal or suspicious activity. Those who have concerns about possible noncompliance with federal, state or local laws and regulations or University policies are expected to report promptly. The University prohibits retaliation against individuals who in good faith report or seek guidance on possible ethical or compliance issues. The University Non-Retaliation Policy can be found at policylibrary.columbia.edu.

There are a number of resources available to individuals who have concerns. You may discuss the concern with a supervisor or another responsible person in your own school or department, or with one of the many specialized compliance offices at the University. Employees with concerns stemming from possible noncompliance or irregularities may also anonymously report them to the University Hotline. Compliance reports may be submitted 24 hours a day at (866) 627-3768 or via the Internet. For more information about the hotline and to file a report online, please follow the links found at the University Compliance website at: http://compliance.columbia.edu/hotline.

For additional information on University compliance programs, including select policies and compliance training links, please visit the University Compliance website at: http://compliance.columbia.edu.

K. Visitors in Research-Related Activities

The University benefits from the presence of many visitors who come for limited periods of time to receive research training or observe research activities. In may cases, such visitors are appointed as Officers of Research or Officers of Instruction or designated as Visiting Scholars or Visiting Scientists. In a few exceptions, short-term visitors have no appointment, formal affiliation or other designation within the University (**Short-Term**

Visitors). Short-Term Visitors may include high school students, undergraduates, post-baccalaureates and other observers or trainees.

The University has issued Guidelines for Short-Term Visitors in Research-Related and Clinical Activities (the **Short-Term Visitors Policy**) that spell out in detail the requirements relating to visitors, some of which are summarized below.

1. Registration of Short-Term Visitors

Short-Term Visitors must register with the appropriate office of the University by completing a Visitor Registration Form prior to arrival, which must be countersigned by the person sponsoring the visitor, the applicable Chair, Dean or Director and the Associate Provost for Academic Appointments who will submit it to the Human Resources Office. At CUMC, the Form should be submitted to the Director of the Office of Faculty Affairs.

If the Short-Term Visitor is a minor (under the age of 18), a Minor Visitors Parental Consent Form must be submitted with the Visitor Registration Form.

2. Training

All Short-Term Visitors must attend the applicable training sessions identified in the Research Compliance Training Finder described in **Training: Research Compliance Training Finder (Chapter III, Section B)** or otherwise identified by the applicable PI or DA.

3. Other Requirements and Restrictions

See the Short-Term Visitors Policy for information on additional requirements and certain restrictions on the activities of Short-Term Visitors.

II. FINDING FUNDING

A. Introduction

Columbia University has a number of resources available to assist faculty, postdocs and staff in identifying funding for research and training. As objectives, opportunities and constraints can and do change among the federal and state agencies and private foundations that provide the vast majority of our outside research funding, many investigators have found it worth the investment to acquaint themselves with the tools available and to ensure they are on various alert systems and email lists. In addition, certain Columbia entities provide seed funding from time to time.

Some funding opportunities from public or private sources require the University to limit the number of applicants. Many of these are targeted at junior faculty. Some grants focus on interdisciplinary opportunities and/or shared instrumentation. Information and support on these kinds of grants can be obtained from ORI. Finally, if you are new to Columbia and/or searching for funding opportunities, you may wish to review the "Resources for Junior Faculty" described in **Resources for Junior Faculty (Section H)** below and the services offered by OPA.

B. Web-based Search and Alert Tools: InfoEd SPIN

SPIN (**Sponsored Programs Information Network**) is part of the InfoEd suite of web-based modules for grants management that the University uses. See **Preparing a Sponsored Project Proposal: University IT Systems Used in Proposal Development and Submission (Chapter IV, Section F)** for more information regarding InfoEd and other University systems. The URL is https://www.infoed.columbia.edu/. To access SPIN, all you need is your UNI and password to be able to log into the system. If you are unable to log in, call the InfoEd Help Desk at (212) 851-4368 or email SPA-eBiz@columbia.edu .

SPIN is a searchable database of funding opportunities from current national and international government and private funding sources, including fellowships, research grants, publication support, sabbatical support, curriculum development and more. SPIN can be used to conduct manual searches of funding opportunities. SPIN has an Advanced Search tool, so that users can identify finding by specific scientific keywords, grant types, locations of research and sponsors.

With SPIN, the user can create email alerts of new opportunities based on saved search criteria. For more information on SPIN, including a Getting Started guide, you can refer to SPA's website at http://spa.columbia.edu/funding/search-funding-spin.

C. Sources of Federal Funding

1. Grants.gov

Grants.gov is a central portal to find and apply for federal government grants. The U.S. Department of Health and Human Services (**HHS**) is the managing partner for Grants.gov. It provides access to the 26 grant-making HHS agencies, where federal grant and contract opportunities can be found. You can search by agency, keyword, funding opportunity number or category.

To search for grants on Grants.gov, go to: http://www.grants.gov/web/grants/Search-grants.html

It is sometimes beneficial to view what HHS grant opportunities are in the planning stages, but have not been formally announced, in order to learn who might provide future opportunities.

To search for future funding opportunities, go to: http://www.grants.gov

2. National Institutes of Health (NIH)

While you can locate all NIH opportunities on Grants.gov, it is helpful to explore the NIH site to stay current on upcoming opportunities.

NIH's Funding Opportunities and Notices Search Page:
http://grants.nih.gov/grants/guide/index.html

You have the ability to save NIH funding searches and receive emails when future postings match your search. By conducting an Advanced Search, the results page will offer you an opportunity to "Save this Search" and requests your email address and the frequency of emails you would like to receive. To conduct this type of search, go to:
http://grants.nih.gov/searchGuide/search_guide.cfm

You can sign up for the NIH Guide to Grants and Contracts, which announces new NIH grant opportunities on a weekly basis. Sign up for their email listserv:
http://grants.nih.gov/grants/guide/listserv.htm

NIH Institutes, Centers and Offices:

Depending on your specific area of interest, browse the specific NIH Institutes, Centers and Offices website for recently cleared concepts or upcoming solicitations. This website presents key information, including the objectives and descriptions of future solicitations and a direct link to NIH staff contacts. The listing of potential future initiatives is meant to provide the earliest possible alert to potential applicants in order to maximize application preparation time. For a listing of NIH Institutes, Centers and Offices, go to http://www.nih.gov/icd/ and then search for recently cleared concepts.

3. National Science Foundation (NSF)

The NSF promotes and advances scientific progress in the United States by competitively awarding grants and cooperative agreements for research and education in the sciences, mathematics and engineering.

The NSF website (http://www.nsf.gov) is the most comprehensive source of information on NSF Directorates (including contact information), programs and funding opportunities. In addition, National Science Foundation Update, which has replaced "My NSF", is an information delivery system that includes subscription options for documents that were available in My NSF, as well as new content categories such as Images and Videos, Events and Upcoming Due Dates for Funding Opportunities. "National Science Foundation Updates" is available on NSF's website at: http://service.govdelivery.com/service/multi_subscribe.html?code=USNSF&custom_id=823.

4. Department of Energy (DOE)

The Office of Science of the DOE is the single largest supporter of basic research in the physical sciences in the United States. It oversees – and is the principal federal funding agency of – the nation's research programs in high-energy physics, nuclear physics and fusion energy sciences.

An entity within DOE – the **Advanced Research Projects Agency-Energy** (**ARPA-E**) was established by Congress in 2007 under the America Competes Act "to overcome the long-term and high-risk technological barriers in the development of energy technology" and the 2009 American Recovery and Reinvestment Act provided its first funding. Its focus is on research that is both "transformational" and "translational" (i.e., breakthrough research that can move swiftly toward applications).

To search the Office of Science for DOE opportunities: http://science.energy.gov/grants/

5. Department of Defense (DOD)

The DOD supports University research through several agencies and programs.

The DOD branches generally indicate their areas of interst through the issuance of annual Broad Agency Announcements. If a researcher finds that his/her research might be responsive to the needs expressed in such an Announcement, he/she should contact the relevant DOD Program officer to determine whether it is of interest to the DOD.

The **Defense Advanced Research Projects Agency** (**DARPA**) is the central research and development organization for the DOD. It manages and directs selected basic and applied research and development projects for the DOD.

To search for DARPA opportunities: http://www.darpa.mil/Opportunities/Solicitations/DARPA_Solicitations.aspx

The armed services have the following science and technology providers:

- Department of the Air Force: **Air Force Office of Scientific Research (AFOSR)**

To search for AFOSR opportunities: http://www.wpafb.af.mil/Welcome/Fact-Sheets/Display/Article/842050

- Department of the Army: **Army Research Laboratory (ARL)**

To search for ARL Opportunities: http://www.arl.army.mil/www/default.cfm?Action=6&Page=8

- Department of the Navy: **Office of Naval Research** (**ONR**)

To search for ONR opportunities: http://www.onr.navy.mil/02/baa/

To search for DOD's **Congressionally Directed Medical Research Programs**: http://cdmrp.army.mil/funding/.

6. National Oceanic and Atmospheric Administration (NOAA)

The mission of NOAA is to understand and predict changes in earth's environment and conserve and manage coastal and marine resources to meet the nation's economic, social and environmental needs. NOAA provides funding for research that will improve understanding of the role of the oceans, coasts and atmosphere in the global ecosystem.

To search for NOAA opportunities: http://www.ago.noaa.gov/quicklinks/grantee.html

7. National Institute of Standards and Technology (NIST)

As part of the Department of Commerce, NIST's funding for extramural research focuses on "advancing measurement science, standards and technology". While it will fund early research, there must be a clear line between the potential research outcome and practical application. NIST seeks to fund research that is complementary with other agencies and can be used for tools and platform technologies. Its own laboratories include: Manufacturing Engineering, Nanoscale Science and Technology, Materials Science and Engineering, Chemical Science and Technology, Information Technology, Electronics and Electrical Engineering, Physics, and Building and Fire Research. NIST typically awards money under a contract rather than a grant.

To search for NIST funding opportunities: http://www.nist.gov/director/grants/grants.cfm

8. Other Federal Resources

The Catalog of Federal Domestic Assistance

There are currently 15 types of assistance available, including surplus equipment, training, guaranteed loans and grants. www.cfda.gov

Federal Business Opportunities

Commercial vendors seeking federal markets for their products and services can search, monitor and retrieve opportunities solicited by the entire federal contracting community. These opportunities can also be accessed through SPIN. http://www.fedbizopps.gov/

U.S. Small Business Administration (SBA) Office of Technology

The SBA Office of Technology administers the Small Business Innovation Research (**SBIR**) Program and the Small Business Technology Transfer (**STTR**) Program. Through these two programs, SBA ensures that the nation's small, high-tech, innovative businesses are a significant part of the federal government's research and development efforts. Eleven federal departments participate in the SBIR program; five departments participate in the STTR program awarding $2 billion to small high-tech businesses. NSF administers the sbir.gov website on behalf of the federal government.

To search for SBIR/STTR opportunities: https://www.sbir.gov

Federal Register

The Federal Register is the official daily publication for rules, proposed rules and notices of federal agencies and organizations, as well as executive orders and other presidential documents. This publication can also be accessed through SPIN. https://www.federalregister.gov/

D. Sources of New York State Funding

1. New York State Department of Health

The New York State Department of Health is comprised of a number of offices that provide funding for research that will address healthcare issues affecting New Yorkers.

To search for New York State Department of Health opportunities: http://www.health.state.ny.us/funding/

2. New York Stem Cell Science (NYSTEM)

NYSTEM was created for the purpose of administering grants for basic, applied, translational or other research and development activities, and facilitates the acquisition and development of specialized equipment, that will advance scientific discoveries in fields related to stem cell biology.

To search for NYSTEM opportunities: http://stemcell.ny.gov

3. Empire State Development (ESD)

ESD is New York's chief economic development agency. The mission of ESD is to promote a vigorous and growing economy, encourage the creation of new job and economic opportunities, increase revenues to the State and its municipalities and achieve stable and diversified local economies. Through the use of loans, grants, tax credits and other forms of financial assistance, ESD strives to enhance private business investment and growth to spur job creation and support prosperous communities across New York State.

To search for ESD opportunities:
http://www.esd.ny.gov/CorporateInformation/RFPs.html.

4. New York State Energy Research and Development Authority (NYSERDA)

Through collaborations with industry, academia and governmental and non-governmental organizations, NYSERDA seeks to develop a diversified energy supply portfolio, improve market mechanisms, and facilitate the introduction and adoption of advanced technologies that will help New Yorkers plan for and respond to uncertainties in the energy markets.

To search for NYSERDA opportunities: http://www.nyserda.ny.gov/Funding-Opportunities.aspx

E. Sources of Non-Governmental Funding

1. The Foundation Center

We encourage the use of SPIN for all non-federal funding searches.

However, The Foundation Center can also provide information about the foundations and corporations that provide grants. The Center has the Foundation Finder that offers basic information on sponsors in the United States, including private foundations, community foundations, public charities and corporate giving programs.

To search the Foundation Finder: http://foundationcenter.org/find-funding

2. The Foundation Directory

The Foundation Directory is a database of 80,000 grantors and 500,000 awards.

To search the Foundation Directory: http://foundationcenter.org/find-funding/fdo-quick-start

F. Sources of Seed Funding within Columbia for Investigators, Departments and Schools

1. Research Initiatives for Science and Engineering (RISE)

Each year, the Office of the EVPR sponsors a competition for RISE funding. These seed monies enable researchers to initiate a project to develop a novel theory or idea in order to gather the data necessary to then secure external funding. Interdisciplinary projects are favored. These formal announcements are sent via email to the University community, and contain the details on proposal submission, availability of funds, eligibility and deadlines.

For more information about RISE:
http://researchinitiatives.columbia.edu/funding/research-initiatives-science-and-engineering-rise.

2. Academic Quality Fund (AQF)

The Deans on the Morningside Campus have the opportunity to apply to the Provost for support from the AQF to help initiate new programs central to a school's mission or to bolster significantly a program with a one-time modest injection of funds. Such programs should support core academic functions, and may be interdisciplinary.

3. Irving Institute for Clinical and Translational Research

The Irving Institute for Clinical and Translational Research (the **Irving Institute**) at CUMC is funded in part by a NIH Clinical and Translational Science Award (**CTSA**). The Irving Institute offers seven pilot funding programs designed to provide incentives to young clinical and translational investigators, as they obtain pilot data prior to submitting funding applications, and to more senior investigators who may not otherwise engage in multi- and interdisciplinary research. These programs include:

- **Collaborative and Multidisciplinary Pilot Research Awards (CaMPR)** – A two-phase program that provides planning ($15,000 for three months) and start-up funding ($75,000 for one year) to newly-configured investigative teams involving both senior and junior faculty from at least two of the four CUMC schools to support the planning of novel, cross disciplinary projects. A second school selected from the Morningside campus may be an option.
- **Collaborative and Multidisciplinary Pilot Research Award for Basic Science and Clinical/Translational Investigators (CaMPR-BASIC)** – A two-phase program including a letter of intent and full application that provides one-year, $40,000 awards to form a new collaborative team consisting of two principal investigators at the Assistant Professor level: one from a basic science department and one from a clinical department.
- **Community-Based Participatory Research Raining and Pilot Awards Program (CBPR) –** A key capacity building opportunity for University faculty and administrative staff from non-profits serving Upper Manhattan. The program is free to all admitted participants and consists of a course, Introduction to Community Based Participatory Research, and competitive pilot funding. At the

conclusion of the course, participants will be eligible to apply for a one-year pilot award of up to $40,000. Funding will be awarded to studies that have the potential to apply for larger federal funding opportunities in CBPR research.

- **Health Practice Research Awards –** Co-sponsored by the Department of Biomedical Informatics, this individual, one-year health practice research award provides funding ($25,000 in addition to $25,000 "in-kind" DBMI faculty support) for junior investigators to pursue an informatics-based project in an operational clinical setting.
- **Imaging Pilot Awards –** Provides one year of funding (ranging from $5,000 – $10,000) for junior investigators in magnetic resonance imaging (MRI), optical imaging, PET tomography, single photon emission computed tomography/computed tomography (SPECT/CT) and ultrasound.
- **Irving Institute/Clinical Trials Office Pilot Award –** Co-sponsored by the CTO, this program provides one-year, $50,000 awards ($25,000 cost-shared by the applicant's home department) for junior faculty from P&S to conduct pilot studies leading to future independent funding.
- **Precision Medicine Pilot Awards –** Provides one-year, $100,000 awards ($50,000 cost-shared by the applicant's home department) for research proposals focused on approaches to tailor medical care (prevention, diagnosis and/or treatment) to the individual patient. Studies may include use of biomarkers, genomic data, aggregated clinical data and/or patient reported data to develop personalized medical care.

For additional information, see
http://irvinginstitute.columbia.edu/research_ops/pcsr.html.

4. Irving Scholars Program

Recognizing the critical importance of training young clinical investigators, Herbert and Florence Irving earmarked a major portion of their endowment of the Irving Institute for the Florence and Herbert Irving Clinical Research Career Awards, usually referred to as the Irving Scholar Awards. The program is open to applicants from all clinical departments at P&S, who hold the rank of assistant professor and are starting a career in clinical research. Scholars are selected on the basis of research proposals that reflect independent, well-developed scientific initiative in clinical investigation. These three-year awards provide substantial salary support ($60,000/year) allowing the Irving Scholar more time for clinical investigation.

Please note that, due to the overlap in the terms of the Irving Scholars Program and the Louis V. Gerstner, Jr. Scholars Program, faculty are eligible to hold only one of these awards at any one time.

For additional information, see:
http://irvinginstitute.columbia.edu/research_ops/irving_scholars.html.

5. Louis V. Gerstner, Jr. Scholars Program

This program is designed to support young physician-scientists who conduct translational research to bring new treatments to patients. To be eligible, applicants must hold current appointments at Columbia at the postdoc, instructor or beginning assistant professor level. The Program provides $60,000/year for up to three years to be used for salary or laboratory support. Applicants must be committed to spending at least 50% of their time on translational research.

6. Columbia-Coulter Translational Research Partnership

Through the Columbia-Coulter Translational Research Partnership, selected teams receive funding and guidance to advance nascent ideas from conception to proof-of-concept. The partnership aims to better position these ideas for partnering with a commercial entity that will invest the necessary resources to bring the concept to market.

Projects that propose to undertake discovery research will not be selected. Successful proposals must be translational in nature, i.e., they must focus on efforts to translate research into practical clinical application.

For additional information, go to http://www.columbia-coulter.com.

7. Individual School and Center Seed Funds

Many centers and schools offer seed funding as well from time to time. Examples are Columbia University Population Center and the Earth Institute. You may wish to contact central administration at your center or school to inquire about the existence of such opportunities.

G. Limited Applicant Competitions from Government and Private Organizations

For certain awards, a sponsor will only accept institutional nominations and/or limit the number of applications that an institution may submit. In such cases, ORI coordinates the selection process. Ad hoc committees are appointed to review applications and assist in the selection of the University's nominees. To allow adequate time for a review and selection of final candidates, and to enable the nominee(s) to complete the final application, internal deadlines must be set well in advance of official sponsor deadlines.

There are two ways faculty and students may find out about such opportunities:

For an updated list of these opportunities, and for specific instructions, go to: http://researchinitiatives.columbia.edu/funding/limited-submission-funding-opportunities.

ORI maintains several email list-serves through which it announces programs. If you do not receive such emails and wish to (or conversely, prefer not to receive such emails), please contact researchinitiatives@columbia.edu.

H. Resources for Junior Faculty

1. Search Tools for Related Research

To begin a funding search, it helps to check whether the topic that you would like to explore has already been studied by others. This can be done by searching online for projects that have been awarded to see what other projects with a topic similar to yours have been funded.

- NSF has an Award Search database, where you can find the abstracts of projects funded by NSF by PI name, scientific keyword and grant type. Go to http://www.nsf.gov/awardsearch/.

- Research Portfolio Online Reporting Tool (**RePORT**) has comprehensive funding information for NIH grants and contracts. This new, user-friendly system combines NIH project databases and funding records, PubMed abstracts, full-text articles from PubMed Central, and information from the U.S. Patent and Trademark Office with a robust search engine, allowing users to locate descriptions and funding details on NIH-funded projects along with research results that cite the NIH support. Please note that RePORT replaces CRISP (Computer Retrieval of Information on Scientific Projects). To search through RePORT, go to http://projectreporter.nih.gov/reporter.cfm.

2. NIH Information

NIH Peer Review Process

The Center for Scientific Review offers a primer for new applicants about what happens to your grant application at NIH.

http://public.csr.nih.gov/Pages/default.aspx

NIH Review Process Video

NIH has several videos to give applicants an inside look at the NIH review process. http://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx

National Cancer Institute (NCI)

NCI publishes the NCI Grant Guide: http://deainfo.nci.nih.gov/extra/extdocs/gntapp.pdf

National Institute of Neurological Disorders and Stroke (NINDS)

NINDS publishes a Funding Overview: http://www.ninds.nih.gov/funding/index.htm and a Guide to Common Mistakes in NIH Applications: http://www.ninds.nih.gov/funding/grantwriting_mistakes.htm.

3. NSF Information

Through its merit review process, the NSF ensures that proposals submitted are reviewed in a fair, competitive, transparent and in-depth manner. The goal of the Merit Review website is to provide a better understanding of the review process. http://www.nsf.gov/bfa/dias/policy/merit_review/

See also NSF's How to Prepare and Submit your Proposal: http://www.nsf.gov/funding/preparing

I. Fellowships

SPIN can be used to search for fellowship opportunities. In addition, the following resources are available for identifying different types of fellowships:

Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty: http://www.hhmi.org/educational-materials/lab-management/for-early-career-scientists

The F Kiosk: Individual Fellowships at NIH: http://grants.nih.gov/training/F_files_nrsa.htm

NSF: Find Funding tool: http://www.nsf.gov/funding/

National Center for Environmental Research Fellowships: http://epa.gov/ncer/fellow/

American Society for Engineering Education: http://www.asee.org/fellowship-programs

The Life Sciences Research Foundation: http://www.lsrf.org

The Leukemia & Lymphoma Society, Career Development Program: http://www.leukemia-lymphoma.org/all_page?item_id=11618

III. TRAINING

A. Introduction

The University believes that all personnel involved in research conducted at Columbia should have a certain base knowledge of the regulations and policies governing the conduct of research, whether the person is a PI, a member of the research team, a DA or other administrative staff, a student or a trainee. As a result, the University supports a number of training initiatives, some of which are required in order to conduct research and others of which are available as resources, but are not mandatory. This chapter summarizes both types of trainings.

B. Research Compliance Training Finder

For help identifying which research compliance trainings you may be required to complete, visit the Research Compliance Training Finder at http://www.columbia.edu/cu/compliance/docs/training/trainingfinder.html?mode=interactive. Using a series of research-related questions, the Finder creates a personalized training chart of required and recommended trainings and responsible offices. In addition, an overview of training requirements broken down by research roles can be found at http://www.columbia.edu/cu/compliance/pdfs/Training_Chart.pdf.

C. Mandatory Training

1. Human Subjects

The following lists the principal training courses required for personnel involved in human subjects research.

- **Human Subjects Protection:** All Columbia investigators and key personnel, including faculty, staff and students, conducting human subjects research and all other persons conducting human subjects research under the auspices of the University must complete the online course *TC0087: Human Subjects Protection Training* (http://www.rascal.columbia.edu/login/tc0087/) using the Collaborative Institutional Training Initiative (**CITI**) set of modules prior to participating in research. In addition, refresher training is required every three years. This requirement applies to all personnel conducting behavioral research, as well as clinical or non-clinical biomedical research. The IRB will not approve the inclusion of an individual listed on the protocol's Rascal Data Sheet for an initial human subjects research protocol, or a modification or renewal of an existing protocol, unless such individual has completed the Training.

Under the CITI program, research personnel are required to complete a total of seven modules – five core modules and two additional modules. Depending on the type of research, the individual will be placed in the appropriate "Learner Group". Some Learner

Groups will specify all seven required modules. However, most Learner Groups will afford the learner the opportunity to select one or two of the seven modules and thus choose the modules most applicable to his/her research.

Most modules include a brief quiz and a cumulative score of at least 80% is required to receive credit. In order to ensure documentation in Rascal, research personnel must access the course via the Rascal Training Center at https://www.rascal.columbia.edu/login/tc0087/. Completion data are transferred from CITI to Rascal once each business day, after which they should appear in "My Rascal" under "My Test History".

The FDA-regulated research module is required for researchers included in a research project that involves a drug, device, biologic or other biomedical intervention to study its potential therapeutic use, or a diagnostic test or procedure to study its potential clinical utility. This module is accessible within the CITI Human Subject Protection Training Program and should be accessed through the Rascal Training Center.

If the study population includes children, completion of the CITI Biomedical Research with Minors module is required. This module is accessible with the CITI Human Subjects Training Program and should be accessed through the Rascal Training Center.

See also **Getting Started: Training: Mandatory Training-Human Subjects Protection (Chapter III, Section B(1)**) in the **Clinical Research Handbook**.

- **Other Required Courses:** The following lists additional training courses required for personnel involved in human subjects research. Additional information about the training courses can be found at the links included below.
    - **GCP Training for NIH-Funded Clinical Trials**: **Chapter III, Section B(2)** in the **Clinical Research Handbook**
    - **Privacy and Security Training** (**HIPAA**) (http://www.rascal.columbia.edu/login/tc0019/)**: Chapter III, Section B(4)** in the **Clinical Research Handbook**.
    - **Clinical Research Training** (http://www.rascal.columbia.edu/login/tc0098/): **Chapter III, Section B(5)** in the **Clinical Research Handbook** (for certain Clinical Research Coordinators only)
    - **Genetic Research Training**: **Chapter III, Section B(6)** in the **Clinical Research Handbook** (for certain Clinical Research Coordinators only)
    - **FDA Sponsor-Investigator Training** (http://www.rascal.columbia.edu/login/tc0096/): **Chapter III, Section B(7)** in the **Clinical Research Handbook** (for faculty holders of INDs or IDEs only).

2. Research with Animals

The following lists the principal training courses required for personnel involved in research using animals. Additional information about the training courses can be found in the following sections of the **Animal Research Handbook**.

- **Laboratory Animal Regulatory Training: Chapter II, Section B(1)**
- **Introduction to the Institute of Comparative Medicine: Chapter II, Section B(2)**
- **Species Specific Training: Chapter II, Section B(3)**
- **Rodent Wet Lab Training: Chapter II, Section B(4)**
- **Rodent Surgery Training: Chapter II, Section B(5)**
- **Mouse Barrier Training: Chapter II, Section B(6)**
- **Facility Specific Orientation: Chapter II, Section B(7)**

3. Financial Conflicts of Interest and Research for PHS Researchers

Columbia University researchers who are funded by the U.S. Public Health Service (**PHS**) or who plan to apply for such funding must complete online training in Financial Conflicts of Interest and Research at least once every four years. (Other research sponsors also may require that this training be completed. Contact your SPA Project Officer for an updated list.) This training requirement can be met by completing in Rascal either *TC0087: Human Subjects Protection Training* or *TC1450: Financial Conflicts of Interest and Research for PHS Researchers* at https:www.rascal.columbia.edu/login/tc1450.

Researchers can fulfill the refresher training requirement by completing *TC0087: Human Subjects Protection Training* or *TC1455: Refresher FCOI Training for PHS Researchers.*

4. Responsible Conduct of Research

Columbia is dedicated to the highest standards of research integrity and is committed to responsible and ethical conduct for all those involved in research. Several federal funding agencies, such as the NIH and NSF, require certain individuals participating in projects funded by those agencies to receive training in the Responsible Conduct of Research (**RCR**), as follows:

- **NIH:** The NIH requires all trainees on NIH training grants – typically junior faculty and postdocs – to take at least eight hours of in-person training covering nine RCR topics. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html.

- **NSF:** The NSF RCR requirement applies to all undergraduates, graduate students and postdoctoral researchers who are funded by NSF projects, including competitive renewals. PIs are responsible for assuring that all such personnel working on their studies complete RCR training. In general, training should be completed within one month after the individual begins work on a project. RCT will coordinate the collection and maintenance of compliance information, including identification of affected individuals, collection of training completion data and reporting to PIs and DAs. See http://www.nsf.gov/bfa/dias/policy/rcr.jsp.

See the RCT website for more information on RCR: http://www.columbia.edu/cu/compliance/docs/training/Responsible_Conduct_of_Research/index.html

The University has established multiple options for satisfying RCR requirements:

- **Online.** *TC0094: Responsible Conduct of Research* is available through Rascal at https://www.rascal.columbia.edu/login/tc0094/. This training is managed by CITI and satisfies the NSF RCR requirements.

  NIH trainees may use the CITI training in partial satisfaction of the NIH RCR requirement, but must also complete some in-person training.

- **In Person.** The University offers several established RCR courses, that satisfy both the NIH and NSF requirements. Two popular coursed are:

  - **Research Ethics** (http://sps.columbia.edu/bioethics/courses#PS5450) (given on the Morningside campus; permission of instructor required)

  - **Responsible Conduct of Research and Related Policy Issues** (http://www.researchethics.cumc.columbia.edu/) (given at CUMC)

  - **School/Departmental Offerings** Some schools and departments offer RCR training that satisfies the NIH and NSF requirements if approved by RCT and if the trainer maintains appropriate compliance documentation.

5. Environmental Health and Safety

The following lists the principal training courses required for research personnel using hazardous materials. All initial training must be taken prior to commencing work with the hazardous materials. For a complete list of safety training courses, see **Determining Your Safety Training Requirements @ Columbia University** attached as **Annex B.** Additional information about the training courses can be found at the EH&S Website at http://ehs.columbia.edu. Schedules for classroom trainings and all online courses on Rascal can be accessed at http://ehs.columbia.edu/Training.html.

Investigators can review the training records of their staffs by creating a Laboratory Assessment Tool and Chemical Hygiene Plan (**LATCH**) within the EH&S Laboratory Information Online Network (**LION**).

Laboratory Safety, Chemical Hygiene and Hazardous Waste Management

All University faculty, staff and students using hazardous materials in a laboratory setting are required to take Laboratory Safety, Chemical Hygiene and Hazardous Waste Management training. This course covers general laboratory safety, working with chemicals and management of hazardous waste. The initial training must be taken during one of EH&S' regularly scheduled classroom sessions.

Refresher training is required every two years and may be completed by taking the Rascal online course: *TC0950: Lab Safety, Chemical Hygiene and Hazardous Waste Management*.

Biological Safety/Bloodborne Pathogens/Infection Control

Except as noted below, all University faculty, staff and students working with human blood, body fluids, cell lines or unfixed tissue, microorganisms or viral vectors are required to take Biological Safety/Bloodborne Pathogen training. The initial training must be taken during one of the EH&S' regularly scheduled classroom sessions.

Refresher training is required on an annual basis and may be completed by taking the Rascal online course: *TC0509: Biological Safety/Bloodborne Pathogen Training.*

For personnel working in clinical settings, the following Rascal online course is required: *TC0025: Bloodborne Pathogens/Infection Control Training for Personnel in Human Research Studies and Clinical Settings*. It details what one must do to reduce his/her risk of exposure to blood and bodily fluids capable of transmitting bloodborne diseases such as HIV, Hepatitis B and Hepatitis C.

Viral Vectors

Personnel conducting research with viral vectors must take the Rascal online course *TC1150: Viral Vector Research – Handling and Biosafety* and pass a test with a score of 80% or better prior to submitting a protocol to the Institutional Biosafety Committee.

A refresher course is required every two years.

Biosafety Cabinet Training

Personnel using a biological safety cabinet must take the Rascal online course *TC3550: Biological Safety Cabinet Training* and pass a test with a score of 80% or better.

A refresher course is required every two years.

Recombinant DNA

Personnel conducting research with recombinant DNA must take the Rascal online course *TC0508: Recombinant DNA Training* prior to submitting a protocol to the Institutional Biosafety Committee.

A refresher course is required every three years.

Shipping Biological Materials

National and international regulations require that anyone who ships "biological materials" (human or animal materials or any substances that may contain infectious microorganisms) be provided with specific training. Taking the Rascal online course *TC0507: Shipping Biological (Infectious and Potentially Infectious) Materials and Genetically Modified Microorganisms* and passing a test with a score of 80% or better, fulfills this requirement.

Refresher training is required every two years.

Shipments of samples with dry ice are not covered by this training; shippers should refer to the following paragraph.

Shipping Non-Hazardous Materials with Dry Ice

Dry ice is used to refrigerate samples being transported by air is considered a "Dangerous Good" under U.S. Department of Transportation regulations. Personnel using dry ice must take the Rascal online course, *TC0076*: *Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods,* and pass a test with a score of 80% or better.

Refresher training is required every two years.

Laser Safety

Personnel using Class 3b or 4 lasers must take laser safety training. The initial training must be taken during one of EH&S' regularly scheduled classroom sessions.

Refresher training is required every two years and may be completed by taking the Rascal online course: *TC1600: Laser Safety Training*.

Formaldehyde/Xylene Safety

This training is required for all University faculty, staff and students using formaldehyde, paraformaldehyde or xylene. The initial training must be taken during one of EH&S' regularly scheduled classroom sessions.

Refresher training is required annually and may be completed by taking the Rascal online course: *TC0016: The Safe Use of Formaldehyde.*

Hydrofluoric Acid Safety

This course is to educate personnel in hazard recognition, safe use and proper handling of hydrofluoric acid. Taking the Rascal online course, *TC1650: Hydrofluoric Acid Training* and passing a test with a score of 80% or better, fulfills this requirement.

Refresher training is required ever two years.

Cyanide Safety

This course is to educate personnel in the safe use and proper handling of cyanide. Taking the Rascal online course, *TC0085: Cyanide Safety*, and passing a test with a score of 70% or better, fulfills this requirement.

There is no required refresher training.

Pyrophoric Materials

This course is to educate personnel in the safe use and proper handling of pyrophoric materials. Taking the Rascal online course, *TC1850: Pyrophoric Materials Training*, and passing a test with a score of 80% or better, fulfills this requirement.

There is no required refresher training.

Shop Safety Training

General Shop Safety Training is required for students, faculty and staff planning on working in academic machine shops or other area with machinery. The Rascal online course is *TC0600: Shop Safety Training* and users must pass a test with a score of 70% or better. In addition, machine-specific training must be provided by the department managing the shop prior to using machinery. Machine-specific training frequency is defined by the department managing the shop. This training is not required for Facilities or Machine shops as defined by the University's Academic Machine Shop Safety Policy (http://ehs.columbia.edu/AcademicMachineShopSafety.pdf).

There is no required refresher training.

Controlled Substances

Prior to the purchase and/or use of controlled substances in *in vitro* or animal research, individuals must successfully complete the Rascal online course entitled *TC0502: Controlled Substances Use and Management in Research.* The course covers all aspects

of proper use and management of controlled substances under state and federal regulations, including license/registration application, purchasing, storage and security, recordkeeping and disposal.

Refresher training is required every two years.

6. Radiation Safety

The New York City Department of Health regulations require radiation safety training for all personnel whose work brings him/her into contact with ionizing radiation or who works in the immediate vicinity of a radiation source and is likely to receive a dose in excess of 10% of the limits specified in the New York City Health Code.

At Columbia, the Radiation Safety Program offers classroom training to first-time users of radioactive materials and to individuals who have had training and experience at other institutions. The class includes, among other topics, types and forms of radiation, interactions with radiation, best practices to reduce exposure, methods for surveying laboratories and proper waste disposal procedures, following which an online test must be taken.

See a further description of the required training in **Getting Started: Authorizations and Training – Training – Initial Training (Chapter IV, Section C(1))** in the **Research Radiation Safety Handbook.**

Refresher training is required annually and may be completed by taking one or more of the four courses and completing the online test referred to in **Getting Started: Authorizations and Training – Training – Refresher Training (Chapter IV, Section C(2))** in the **Research Radiation Safety Handbook**.

7. Effort Reporting

All Officers of Instruction, Officers of Research (except postdoctoral Officers of Research), Officers of Administration and Officers of the Libraries who participate in sponsored projects and are self-certifiers or PIs must complete a mandatory Rascal online training course. Research personnel in the sciences, including the basic sciences, engineering and biomedical research (clinical and non-clinical) should take the Rascal online course *TC0068: Effort Reporting Training* (http://www.rascal.columbia.edu/login/tc0068) and non-science personnel should take the Rascal online course *TC0501: Effort Reporting for Individuals in Non-Science Departments* (http://www.rascal.columbia.edu/login/tc0501/).

Administrators who are Effort Coordinators for their departments, divisions, centers or institutes must attend in-person training given by RCT and SPF.

8. Scientific, Budgetary and Commitment Overlap

Investigators may not accept awards or execute contracts with the New York State Department of Health (**NYSDOH**)/Wadsworth Center for projects that have scientific, budgetary or commitment overlap. Therefore, all recipients of NYSDOH/Wadsworth Center funding are required to take the Rascal online course *TC1400: Understanding Scientific, Budgetary and Commitment Overlap.* This course defines the three areas of overlap and outlines policies and procedures in identifying overlap.

9. Contractor Business Ethics

Any investigator participating in a research study that is conducted pursuant to a federal contract in an amount in excess of $5 million and with a term of more than 120 days (or any subaward under such a contract) is required to take the Rascal online course *TC0504: Columbia's Code of Conduct and Contractor Business Ethics* which introduces the University Code of Conduct and satisfies the federal requirement for training in ethical business practices.

D. Additional Training Resources

A number of University offices provide training related to the conduct or administration of sponsored projects.

1. RCT

Columbia University Certification in Administration of Sponsored Projects

The Columbia University Certification in Administration of Sponsored Projects is a certificate program for Columbia administrative staff involved in sponsored projects. The certificate program provides appropriately-trained individuals with a credential that attests to their knowledge and understanding of the policies and processes relating to the administration of sponsored projects at Columbia. The program presents training in four key areas of pre-award and post-award administration:

- Research compliance and regulatory requirements;
- Research roles and responsibilities at Columbia;
- Operational procedures and best practices for proposal development and financial management; and
- Resources available for compliance and operational support.

The program is open to Research Administrators, DAs, Research Coordinators, Effort Coordinators, Grants Managers and other administrative staff involved with sponsored projects.

In order to receive the Certification in Administration of Sponsored Projects, you must complete all of the following requirements:

- **Research Compliance Foundations** (see below)

(http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/Foundations.html). Certification requires attendance at all classroom sessions.

- **Sponsored Projects Essentials** (see below)

(http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/Essentials.html). Certification requires attendance at all classroom sessions.

- **Review of Online Case Studies** (http://www.rascal.columbia.edu/login/tc0504. A series of detailed case studies related to the Responsible Conduct of Research for Research Administrators.
- **Completion of Rascal Online Test** (For CUMC: http://www.rascal.columbia.edu/login/tc0097; for Morningside campus and Lamont: http://www.rascal.columbia.edu/login/tc0505. Required to demonstrate mastery of the material by successfully completing a test in Rascal.

For information, see http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/index.html.

Research Compliance Foundations Course for Research Administrators

RCT, in collaboration with other research related offices, offers a course on Research Compliance Foundations for Research Administrators. The eight-week course provides an overview of the University's research-related offices, as well as institutional policies and procedures. Experts from the responsible Columbia offices share important compliance information, valuable insights and tips on how to ensure a smooth process. There is plenty of opportunity to ask questions of the people best positioned to answer them.

The course is open to all University administrators who are involved in research, including DAs, Project Managers/Coordinators, Grants Managers/Administrators, Research Coordinators and administrators whose responsibilities include research-related activities. The 90-minute sessions are offered at both the Morningside campus and at CUMC.

Participating offices, in addition to RCT, include: SPA, the CTO, SPF, RPIC, CTV, HRPO, IACUC and EH&S.

For information, contact RCT at research-compliance@columbia.edu. See also the RCT website: http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/Foundations.html.

Sponsored Projects Essentials

Sponsored Projects Essentials is a five-week course for administrative staff working in research that provides detailed information on creating and managing sponsored projects at Columbia. The course has been developed by RCT, SPA, the CTO and SPF. The

course is designed to increase understanding among sponsored projects administrative professionals of the policies and processes that govern the pre- and post-award phases of sponsored projects at Columbia. It is open to Research Administrators, DAs, Research Coordinators, Effort Coordinators, Grants Managers and other administrative staff involved with research who have previously participated in the Research Compliance Foundations course. The 90-minute sessions are offered both on the Morningside campus and at CUMC.

Representative topics include: Proposal Preparation, Budget Creation, Award Acceptance and Program Monitoring, Financial Management, Accounting and Monitoring and Project Closeout.

For information, contact RCT at research-compliance@columbia.edu. See also http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/Essentials.html

Data Management

RCT, through its ReaDI Program (see **Programmatic Management of Sponsored Project: Research Integrity and Data Integrity (ReaDI) Program (Chapter IX, Section E(1)**) and the University Libraries, through their Scholarly Communication Program, created the following Rascal courses that although not required, are recommended for researchers responsible for managing data:

- *TC2650: Best Practices for Data Management When Using Instrumentation:* a tutorial on effective data collection, saving and processing methods http://www.rascal.columbia.edu/login/tc2650.
- *TC2651: Good Laboratory Notebook Practices:* a tutorial on notebook best practices for maintaining organization of data and research integrity during the conduct of research http://www.rascal.columbia.edu/login/tc2651.
- *TC2800: Managing Research Data, Part 1: Responsibilities:* Part 1 of a 2-part course on research data management:
  - Why research data management is both recommended and required
  - What research data are
  - Who is responsible for research data management

  http://www.rascal.columbia.edu/login/tc2800.
- *TC2801: Managing Research Data, Part 2: Practicalities:* Part 2 of a 2-part course on research data management:
  - When research data management activities occur
  - How research data management activities are carried out

  http://www.rascal.columbia.edu/login/tc2801.

Optional Good Clinical Practice (GCP) Training

Training in GCP, while not required by the University, is recommended for all clinical personnel. For further information, see **Getting Started: Training – Additional**

Training Resources – Optional CGP Training (Chapter III, Section D(2)) in the **Clinical Research Handbook.**

2. HRPO

The HRPO has a number of training and educational programs that are described on the HRPO website and summarized below. See http://www.columbia.edu/cu/irb.

IRB 101

The HRPO conducts quarterly informational sessions for the human subjects research community. While attendance is not mandatory, these sessions provide useful information for new investigators and CRCs, including discussions of the following topics: human subjects protection and the ethical principles that guide human subjects research, federal regulations for the protection of human subjects in research, criteria for IRB review, tips for IRB submission, tips for using Rascal and special considerations for vulnerable populations.

Monthly IRB Investigators Meetings

The HRPO hosts monthly meetings for the research community that address human subjects protection issues.

Rascal Workshops

The HRPO provides training workshops on how to effectively submit to the IRB using Rascal. The workshops cover creating a new protocol, submitting modifications and continuing reviews and creating an Informed Consent Document using the Rascal Consent Builder.

3. SPA

Research Administration Forums

SPA hosts regular Research Administration Forums for grants administrators to provide ongoing training and updates on a wide variety of grants management topics. For additional information on the Forums, see http://spa.columbia.edu/resources-administrators/forums-administrators.

In addition, SPA holds ad hoc trainings on a variety of topics or online systems. To be notified on such event, grants administrators may sign up for the 'grants-cumc-da@lists.columbia.edu' or 'grants-morningside-da@lists.columbia.edu' by contacting the SPA Communication and Outreach Director.

IV. PREPARING A SPONSORED PROJECT PROPOSAL

A. Introduction

The submission of a proposal is the usual means of approaching potential sponsors for support of research and other projects. The investigator who will be designated as the PI will be primarily responsible for developing the proposal and preparing the necessary documentation. The PI is often assisted in this process by his/her DA.

As a preliminary matter, the scope, methods and objectives of the proposed project must be evaluated by the PI before a decision is made to respond to a RFP or submit a grant application. Personnel, equipment, facility and other support requirements must be estimated and discussed with the department chair to assure consistency with departmental objectives and availability of resources. If the project is interdisciplinary, discussions must also take into account faculty and chairs of other departments.

B. Funding Through Columbia

Please note that the University administers all sponsored project proposals and awards for which faculty serve as PIs. Therefore, faculty may not prepare or submit proposals for outside funding through an institution other than Columbia without first obtaining permission from the Provost. Any faculty member with a joint appointment at Columbia and NYSPI should consult with his/her DA to determine which institution should submit the proposal and administer the award.

C. PI Eligibility

For each sponsored project, one investigator is typically designated as the PI. The PI bears ultimate responsibility for academic decisions as well as for financial, administrative and compliance matters of the project. Other individuals with significant involvement may be listed as "Co-Principal Investigator" or "Co-Investigator".

Federal agencies permit more than one PI on a project. This presents an important opportunity for investigators seeking support for projects or activities that clearly require a "team science" approach. As the rules differ from agency to agency, for more information about the multiple PI model, please refer to the website for the particular agency to which you are interested in submitting a grant application.

In order to maintain academic standards and in recognition of the University's assumption of liabilities under sponsored projects, the University limits the eligibility of persons who may serve as PIs.

A PI normally must have a full-time appointment and must be an:

- Officer of Instruction in the rank of:

  - Professor
  - Associate Professor
  - Assistant Professor
  - Instructor

or an

- Officer of Research in the rank of
  - Senior Research Scientist/Scholar
  - Research Scientist/Scholar
  - Lamont Research Professor
  - Lamont Associate Research Professor
  - Lamont Assistant Research Professor

Persons with appointments carrying other titles, including those in a visiting or adjunct grade, may act as co-PIs with officers in one of the instructional or research grades cited above. However, individuals who do not meet the above criteria may not serve as the sole PI without the approval of their department chair or director and dean or vice president, as well as the Provost.

The Provost has delegated the authority to make such exceptions as follows:

- For those holding appointments at CUMC, the Executive Vice President for Health and Biomedical Sciences;
- For those holding appointments at Lamont, the Director; and
- For those holding appointments elsewhere in the University, the EVPR.

Officers seeking an exception to this policy should submit a request through SPA, the CTO or CTV, as applicable. Approval may be requested on a project-by-project basis or for all projects of the officer. The request must include confirmation that the department will provide appropriate non-sponsored support to cover proposal writing and other non-sponsored activities of the individual for whom the waiver is being sought. The request must be countersigned by the appropriate chair or director and dean or vice president in order to acknowledge the financial responsibility of the department and school for the proposed project or projects. In addition, the request must include the individual's curriculum vitae and, if it relates to a specific project, an abstract of the project.

Note: For non-sponsored research studies involving human subjects, a similar waiver request must be submitted to the HRPO if the PI on the IRB protocol does not meet the qualifications indicated above.

D. Types of Proposals

Proposals are generally classified in two ways:

1. By Function

Research

Most Columbia projects involve basic research that fits within the mission of the funding agency. Sometimes applied, demonstration or clinical research is performed.

Basic research involves the acquisition of fundamental knowledge and is "…undertaken primarily to acquire new knowledge without any particular application or use in mind" (NSF, Higher Education Research and Development Survey, FY 2013 (**NSF 2013 Survey)**.

Applied research is the application of fundamental knowledge to a specific problem or to "gain the knowledge or understanding to meet a specific, recognized need" (NSF 2013 Survey).

Development research undertakes to provide a working prototype of the applied research and involves the "….systematic use of the knowledge or understanding gained from research directed towards the production of useful materials, devices, systems or methods, including the design and development of prototypes and processes" (NSF 2013 Survey).

Clinical research is, broadly defined, research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) in which an investigator directly interacts with human subjects, including research on mechanisms of human disease, therapeutic interventions, clinical trials and development of new technologies. It can include epidemiological and behavioral studies and outcomes and health services research. Clinical research does not include *in vitro* studies using human tissues that cannot be linked to a living individual. For a more detailed definition of Clinical Research, see **Introduction: Primary University Offices Involved in Sponsored Research – Office of Research Administration (ORA) (Chapter I, Section E(1)).**

Training

A training project involves training students in a special manner or for a specific purpose that is approved by a funding agency. Funding is provided to Columbia to support an organized course of training and Columbia selects students to participate based on the guidelines and policies of the sponsor and the University. Training grants can support trainees at all levels, including undergraduates, graduate students, postdocs and, at times, junior or mid-level faculty through "career development" awards.

Fellowship

A fellowship provides support for a named individual, usually a graduate or a professional student, who is selected by the sponsor and not by Columbia. Fellowships

may be awarded directly to the student or awarded to Columbia for support of a specific student. Fellowships are also awarded to postdocs and to faculty members.

Public Service

These are projects involving research or instructional activities that benefit a community outside Columbia.

2. By Status

New Proposal

An original request for funding from an agency for projects that have not been funded by that sponsor previously.

Competitive Renewal

A request for continued funding for existing sponsored projects, beyond the term of the current award, that require competitive peer review and sponsor action to continue beyond the current competitive segment.

Non-Competing Continuation

A request for continued support for a funded grant for a subsequent budget period based on sponsor review of progress reports, rather than peer review.

Supplement

A request for additional funds during a current project period for an existing sponsored project, typically for a particular item of equipment or subproject not anticipated in the original proposal. All additional costs must be within the scope of the approved project. Supplements rarely extend the period of performance.

Revision

A request for significant changes to a project that can be either a major change in the budget or a change in the scope of work, or both. Minor budget changes do not require separate approval. More significant changes can often be made without permission from the sponsor, under the "expanded authorities" granted to Columbia by certain federal agencies. Changes in the scope of work ordinarily require sponsor approval. See also **Programmatic Management of a Sponsored Project: Post-Award Activities That Typically Require Prior Sponsor Approval (Chapter IX, Section C)**.

No cost extension

A request to extend the period of performance of an award without additional money from the sponsor. See also **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – No Cost Extensions (Chapter VIII, Section F(8))**.

Resubmission

A grant application that was not funded, revised to reflect feedback from the initial peer review and resubmitted to the sponsor.

E. University Offices That Can Assist with Proposal Development and Submission and Other Agreements

SPA, the CTO and CTV, collectively, assist investigators in proposal preparation, contract negotiation, budget preparation and negotiation and submissions to sponsors. These Offices have been charged with ensuring that proposals, agreements and awards comply with University and sponsor policies and have been generally described in **Introduction: Primary University Offices Involved in Sponsored Projects: Office of the Executive Vice President for Research (EVPR)** (**Chapter I, Section E) and Other University Offices Involved In Sponsored Research (Chapter I, Section F)**. The following sets forth the types of proposals and other agreements that each Office processes. **Please note that all sponsored research proposals and agreements must be signed on behalf of the University by certain officers designated by the Trustees in SPA, the CTO or CTV, as applicable.**

1. SPA

SPA processes all sponsored proposals other than these specifically handled by the CTO or CTV. See **Introduction: Primary University Offices Involved in Sponsored Research: Office of the Executive Vice President for Research (EVPR) – Office of Research Administration (ORA) (Chapter I, Section E(1).**

Research proposals initiated by investigators at NYSPI are generally administered by the Research Foundation for Mental Hygiene (**RFMH**). However, the Department of Psychiatry will submit a research proposal in the University's own name when space or resources are to be used, or when other relevant considerations, make it reasonable for Columbia to have primary responsibility for conducting the research. All proposals submitted through Columbia are processed by SPA or the CTO.

2. CTO

The CTO reviews, negotiates and processes all proposals for industry sponsored clinical trials and clinical research at the University. See **Introduction: Primary University Offices That Are Involved in Sponsored Research: Office of the Executive Vice President for Research (EVPR) – Office of Research Administration (ORA) (Chapter I, Section E(1)).**

3. CTV

CTV shares responsibility with SPA for the negotiation of SRAs**.** Although all SRAs are routed to SPA for review, CTV acts as the administrative office responsible for the negotiation and execution of certain SRAs. In addition, CTV develops and negotiates the terms of subawards under SRAs that they have negotiated and executed. See **Introduction: Other University Offices Involved in Sponsored Research – Columbia Technology Ventures (CTV) (Chapter I, Section F(1))**.

In addition to the agreements for which it is primarily responsible, CTV is the responsible office for negotiating or providing guidance on intellectual property terms. SPA and the CTO collaborate with CTV regularly on intellectual property matters.

4. Summary of Processing Responsibilities

The following chart summarizes the processing responsibilities of each Office:

Processing Office	Type of Sponsored Project	Office Responsible for Proposal Review and Submission/Contract Review, Negotiation and Execution	Office Responsible for Award Receipt/ Account Setup	Office Responsible for Issuing Subawards
SPA	• All government, foundation and non-profit sponsored studies • Industry sponsored non-clinical research agreements that SPA and CTV have agreed should be processed by SPA.	SPA	SPA	SPA
CTO	• Industry sponsored clinical trials and clinical research	CTO	CTO	CTO
CTV	• Industry sponsored non-clinical research agreements that SPA and CTV have agreed should be processed by CTV.	CTV	SPA	SPA

The following chart summarizes which office is responsible for other ancillary agreements and documents:

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ALLOCATION OF RESPONSIBILITIES FOR MISCELLANEOUS RESEARCH AGREEMENTS

Type of Agreement	Responsible Unit	Comments	Contact
Assurance Identification/IRB Certification/ Declaration of Exemption	IRB review and signature	Formerly Optional Form 310	irbagreements@cumc.columbia.edu
Certificate of Confidentiality Application	IRB review and signature		irbagreements@cumc.columbia.edu
Collaboration Agreement • Clinical research	CTO review and signature		ctosubmission@columbia.edu
• Non-clinical research	SPA review and signature		CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu
Confidential Disclosure Agreement	SPA, CTO or CTV review and signature		CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu cda@columbia.edu ctosubmission.columbia.edu
Consulting Agreement - Individual	Institutional review and signature not required		
Consulting Agreement - Institutional	Procurement review Department signature		
Data Use Agreement • CUMC › Clinical data	IRB Review; CTO review and signature	Includes HIPAA limited data sets	irbagreements@cumc.columbia.edu ctosubmission@columbia.edu
› Non-clinical data	IRB review; SPA review and signature		irbagreements@cumc.columbia.edu CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu
• Non-CUMC	IRB Review; SPA review and signature		irbagreements@cumc.columbia.edu CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu
Facility Use by Non-CU Investigator	School review and signature		
Foreign Government Agreement or Award	Send to SPA; OGC review; SPA signature		CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu

Type of Agreement	Responsible Unit	Comments	Contact
Individual Investigator Agreement	IRB review and signature		irbagreements@cumc.columbia.edu
Institutional Certification for upload of data to NIH respository	IRB review and SPA signature		irbagreements@cumc.columbia.edu CUMC: grants-office@columbia.edu MS: ms-grants-office@columbia.edu
IRB Authorization Agreement	IRB review and IO signature		irbagreements@cumc.columbia.edu
Material Transfer Agreement • CUMC › Human or human-derived material › Non-human or non-human derived material	IRB review; CTO review and signature CTV review and signature		irbagreements@cumc.columbia.edu ctosubmission@columbia.edu mta@columbia.edu
• Non-CUMC › › Human or human-derived material › Non-human or non-human derived material	IRB Review; CTO review and signature CTV review and signature		irbagreements@cumc.columbia.edu ctosubmissions@columbia.edu mta@columbia.edu
Service Agreement • CUMC • Non-CUMC	CTO review and signature SPA review and signature		ctosubmission@columbia.edu ms-grants-office@columbia.edu

Clinical Research: patient oriented research, including epidemiologic and behavioral studies, outcomes research and health sciences research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials and development of new echnologies, but does not include in vitro studies using human tissues not linked to a living individual.

Studies falling under 45 CFR 46.101(b)(4) are not considered clinical research for purposes of this definition. 45 CFR 46.101(b)(4) studies are defined as "research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

F. University IT Systems Used in Proposal Development and Submission

The University has two information technology (**IT)** systems that are involved in proposal development and submission: **Rascal** and **InfoEd**.

1. Rascal

Rascal is a web-based suite of IT modules that has been developed internally at the University to simplify the University's research compliance and administration processes. You may access Rascal at: https://www.rascal.columbia.edu/

Currently Rascal serves as the electronic system for the following:

Training and Certifications

Rascal houses a number of training courses and tracks compliance with training requirements as follows:

- Human Subjects Protection
- Privacy and Security (HIPAA)
- Clinical Research Training
- Genetic Research
- FDA Sponsor-Investigator
- Responsible Conduct of Research
- Financial Conflicts of Interest and Research
- Effort Reporting
- Scientific, Budgetary and Commitment Overlap
- Contractor Business Ethics
- Safety Training
    - Laboratory Safety, Chemical Hygiene and Hazardous Waste Management
    - Radiation Safety
    - Biological Safety/Bloodborne Pathogens/Infection Control
    - Shipping Biological Materials and Genetically Modified Microorganisms
    - Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods
    - Laser Safety
    - Formaldehyde/Xylene
    - Hydrofluoric Acid
    - Recombinant DNA
    - Pyrophoric Materials
    - Viral Vectors
    - Controlled Substances
    - Cyanide Safety

    - Shop Safety
    - Biosafety Cabinet
- Laboratory Animal Regulatory Training

See **Training** (**Chapter III)** for additional information on training.

Human Subjects/IRB

Rascal is used by investigators to create IRB protocols and informed consent documents and by the IRB to administer the protocol review process. See **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Human Subjects (Chapter VI, Section E(3))**.

Rascal also links data from other modules that are needed to obtain IRB approval of a protocol:

- Financial Conflicts of Interest
- Training Certifications
- Hazardous Materials
    - Recombinant DNA
    - Infectious Agents
    - Laser
    - Hazardous Chemicals or Toxins
    - Use of Radiation in Humans
- Proposal Tracking

Animal Research / IACUC

Rascal is used by investigators to create IACUC protocols and by the IACUC to administer the protocol review process. See **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Use of Animals (Chapter VI, Section E(4)).**

Rascal also links data from other modules that are needed to obtain IACUC approval of a protocol:

- Training Certifications
- Hazardous Materials
    - Recombinant DNA
    - Infectious Agents
    - Human Materials or Other Potentially Infectious Materials
    - Laser
    - Hazardous Chemicals or Toxins
    - Use of Radiation in Animals

Proposal Tracking (PT)

Rascal routes electronic approvals of proposals or contracts required by SPA or the CTO. These include PI certifications and departmental and NYP approvals. See **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications (Chapter VI, Section E)**.

Any Columbia employee who has a Columbia UNI may use Rascal. The first time you log into Rascal, you should complete a user profile and fill out a conflict of interest disclosure form. See **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Financial Conflicts of Interest (FCOIs) (Chapter VI, Section E(1))**.

2. InfoEd

InfoEd is a web-based suite of IT modules designed to assist researchers and administrators in sponsored project development and management.

The following InfoEd modules are currently in use at the University:

- **InfoEd Proposal Tracking** (**InfoEd PT**): InfoEd PT is used by SPA as a central repository for all sponsored research proposals and awards at the University except industry sponsored clinical research or clinical trial agreements. InfoEd PT captures administrative data, records submitted budgets and maintains award information and other relevant documents during the life cycle of the grant.

- **InfoEd Proposal Development** (**InfoEd PD**): InfoEd PD electronically facilitates the preparation, review and submission of grant applications. While it is currently being used primarily for specific NIH proposals that are required to be submitted electronically through Grants.gov, other grant applications are being added over time and InfoEd PD now supports applications to 26 federal agencies, including DOE and DOD.

  There are a number of advantages to using InfoEd PD to develop applications to the participating federal agencies:

  - PD permits an investigator to prepare a proposal online and make it available for multiple users to view the proposal simultaneously, including his/her SPA Project Officer. This allows the Project Officer to assist in proposal development and review as the proposal is being generated by the PI.
  - Budgeting tools are better developed than those available through the Adobe form set and permit the application of sponsor-specific guidelines automatically.

- Standard agency forms are pre-loaded with University, sponsor, investigator and other information to eliminate repetitive data entry tasks.
- Proposals that are ready for submission are automatically reviewed for adherence to known sponsor requirements, thereby eliminating the majority of errors experienced when applications are processed by Grants.gov. Completed applications are then uploaded directly to the Grants.gov server via a direct system-to-system interface.

Support for new users is available through SPA by contacting the Help Desk at SPA-eBiz@columbia.edu.

- **InfoEd Award Tracking and Financial Tracking** (**InfoEd AT&FT**): The AT&FT modules in InfoEd are used by SPA to set up accounts in ARC after an award is granted. These modules transfer budget details from PT to ARC without re-keying award data. Accounts for all sponsored projects except for P&S industry sponsored clinical trials are set up in InfoEd.

- **InfoEd Sponsored Programs Information Network (InfoEd SPIN)**: SPIN is a funding opportunities database that contains thousands of federal, non-federal, private, non-profit and international sources in order to provide the latest information regarding research grants, fellowships and publication support. In addition to outlining specific program details (e.g., sponsor information, program names and deadline dates) and embedding links to sponsors' homepages, SPIN supplies an abstract that summarizes the program's primary objective. SPIN has an advanced search engine to permit investigators to find funding sources.

In order to get access to InfoEd, please contact the InfoEd Help Desk in SPA at (212) 305-6462 or email: SPA-eBiz@columbia.edu.

G. Developing a Proposal

1. Components of a Proposal

Most sponsors provide guidelines that specify the form and content of the proposal. Careful attention to these guidelines is essential, because lack of conformity may cause the proposal to be returned without review.

In addition to the technical description of the work to be performed, many sponsors (particularly federal agencies) require completion of specific forms. Required forms are available on the web at individual sponsor sites. Typical proposal components include:

Cover sheet

Sponsors usually request that applicants complete forms that provide basic administrative information, including project title; project period (start and end date); funds requested; PI and Co-PI name, title, address, phone, fax and email; and administrative contact

information. Basic cover sheet information also includes the University's corporate and legal name as well as the University's tax-exempt status number.

This information about the University can be found at http://spa.columbia.edu/proposals/institutional-information.

Representations and Certifications

All federal grant and contract applications require that an authorized University signatory sign a series of representations and certifications attesting to the institution's eligibility and willingness to receive and administer federal funds. The three most common types of representations and certifications are Debt and Debarment, Lobbying and Drug-Free Work Place. Other types of representations and certifications vary by agency. Most federal sponsors require that these forms be submitted with the application, but some do not require them until the time of award.

Abstract

Also referred to as a "project summary", this section provides a brief (typically no more than one page) high-level description of goals of the proposed research. If the sponsor has specific requirements for the project summary, they should be followed carefully. NSF, for example, requires that the project summary explicitly address the "intellectual merit" and the "broader impact" of the proposed research and will return without review proposals that do not include this information.

Narrative

This is the scientific/technical description of the project. Many sponsors have strict guidelines regarding page length and formatting (margins, lines per inch, font size, etc.) and may reject proposals that do not meet these guidelines, so it is essential to review the program announcement carefully and adhere to such guidelines.

Budget and Budget Justification

Most research proposals, and many fellowship proposals, ask for a detailed ("line-item") budget and explanation of the items in each budget category. Information about budget preparation can be found in **Preparing a Sponsored Project Budget (Chapter V)**.

Curriculum Vitae (CV) and Bibliography

Normally, the CV is accompanied by a bibliography, (i.e., a list of the person's publications). The CVs and bibliographies of the PI and other investigators playing a significant role in the project should be included with the proposal whether or not they are Co-PIs or Co-Investigators, and even if they are not otherwise affiliated with the University. Many sponsors have specific formatting and page length restrictions. Most federal sponsors require a shortened CV and bibliography, between two (NSF) and four (NIH) pages.

NIH applications, proposals and progress reports must include the PubMed Central reference number when citing publications that fall under the NIH Public Access Policy and are authored or co-authored by the investigator, or arose from the investigator's NIH award. For more information regarding the NIH Public Access Policy, see **Review and Submission of a Sponsored Project Proposal: Public Access Policies (Chapter VI, Section F)**.

Current and Pending Funding

Many sponsors request that applicants provide summaries of their current and anticipated grant and contract funding. Information requested usually includes sponsor, project title, period of performance, committed effort and amount funded or sought. It is import to include all projects, including pending proposals, in the list of Current and Pending Funding. The sponsor may also require an explanation of actions to be taken in the event that the proposed funding is awarded and adjustments are needed to avoid overlap.

2. Proposal Writing Tips

The following sites provide useful information and grant writing tips.

NIH Tips - Planning Your Application
http://grants.nih.gov/grants/planning_application.htm

NIH Tips - Writing Your Application
http://grants.nih.gov/grants/writing_application.htm

NIH Grant Writing Tip Sheets
http://grants.nih.gov/grants/grant_tips.htm

NSF Guide – How to Prepare Your Proposal
http://www.nsf.gov/funding/preparing/

3. Institutional Information

The Columbia Institutional Information Sheet provides very important information in order to complete your grant application. It contains institutional information, such as the University's legal name, address, contact information, DUNS numbers and taxpayer ID numbers, that is usually required when completing a proposal for sponsored project support. Often this information is needed on the Proposal Face Sheet/Cover Sheet. Please note that there is different information listed for the Morningside campus and CUMC.

Besides basic institutional information, there is pertinent information on the Sheet that you will need when preparing your budget. This includes F&A Rates, Fringe Rates, NIH Salary Cap information, Graduate Research Assistant salary cap information and other

important budgetary items. The Institutional Information Sheet can be found on the SPA website at http://spa.columbia.edu/proposals/institutional-information.

4. Sponsor Guidelines and Forms

Federal Funding

All federal funding guidelines and forms can be found on www.Grants.gov. However, you may find that it is useful to refer to some of the direct federal agency websites for more guidance:

NIH Forms and Applications:
http://grants.nih.gov/grants/forms.htm

NIH Grants Policy Statement:
http://grants.nih.gov/grants/policy/nihgps/index.htm

NIH Peer Review Process:
http://grants.nih.gov/grants/peer_review_process.htm

NSF Grant Proposal Guide:
http://www.nsf.gov/publications/pub_summ.jsp?ods_key=gpg

NSF Proposal and Award Policies and Procedures Guide:
http://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp

Department of Energy:
http://science.energy.gov/grants/

National Endowment for the Humanities:
http://www.neh.gov/grants/index.html

Other Non-Federal Funding

The Foundation Center:
http://foundationcenter.org/find-funding/fdo-quick-start

New York State Funding

Department of Health: http://www.health.state.ny.us/funding/

5. Other Resources

Additional consultation and support should be sought out for any large, complex or unusual applications, including those for institutional training grants, construction projects, limited submissions, large interdisciplinary proposals and similar applications.

Institutional Training Grants

SPA has developed a set of resources to assist with the development of institutional training grant applications and their subsequent management. These resources can be found at on the SPA home page at http://spa.columbia.edu/resources-administrators/training-grant-resources. In addition to these materials,

- a listserv has been established to enable better communication among training grant administrators;
- meetings of training grant administrators are held to address specific training needs of those preparing or managing training grants; and
- SPA can assist in the development of the NIH NRSA Table 3.

Information on these and other training grant-related matters can be found at the above website.

Limited Submissions

ORI is responsible for administering the nomination process for limited submission funding opportunities. The sponsors of such opportunities will only accept institutional nominations and/or limit the number of applications that an institution may submit. In such cases, announcements are circulated that provide the application requirements and deadlines for the internal competition and ad hoc committees are appointed to review applications and assist in the selection of the University's nominees. To allow adequate time for a review and selection of final candidates, and to enable the nominee(s) to complete the final application, internal deadlines are set well in advance of official sponsor deadlines. For more information, see http://researchinitiatives.columbia.edu/funding/limited-submission-funding-opportunities

Construction Grants

Please contact your SPA Project Officer as early in the process as possible if you are considering submitting an application for funding of a construction project.

Large Interdisciplinary or Multidisciplinary Applications

Please contact your SPA Project Officer as early in the process as possible if you are considering submitting an application for funding of a large, interdisciplinary or multidisciplinary project. Depending on the size and scope of the proposed, coordination with other University offices may be required or advantageous.

V. PREPARING A SPONSORED PROJECT BUDGET

A. Introduction

Preparation of a budget is an important part of the proposal preparation process. The budget should be accurate, realistic and reasonable in light of the work proposed. The requested amount should not be so small as to preclude successful completion of the stated goals nor so large that the sponsor will not seriously consider funding the proposal.

Research expenses can be divided into **direct costs** and **indirect** or **facilities and administrative (F&A) costs**. Direct costs can be specifically identified with a particular project, program or activity or directly assigned thereto relatively easily and with a high degree of accuracy. Direct costs include such specific line items as salaries and fringe benefits, materials, supplies and travel. F&A costs are other costs that are less readily allocable to specific individual projects, such as general administrative support and the operation and maintenance of facilities. F&A costs are paid as a fraction of direct costs, with the fraction negotiated by the University and the cognizant federal entity.

B. Direct Costs

1. Primary Concepts

The following sections set forth basic concepts relating to all direct costs: **allowability, allocability, reasonableness and consistency**. These concepts are applicable to all sponsored projects, whether government funded or not.

Consistent with federal regulations, expenditures charged to all sponsored projects must be allowable, allocable and reasonable. In addition, expenditures must be consistently treated under like circumstances in budgeting, charging and reporting expenses. These terms are covered in Subpart E (Cost Principles) of the Uniform Guidance.

Allowability

An allowable cost is a cost that meets all of the following conditions:

- It serves a University business purpose, including instruction, research and public service;
- It is permissible according to Columbia's policies and federal regulations; and
- It is permissible according to the terms and conditions of the sponsored project.

It is important to note that not all allowable costs may be charged directly to a sponsored project; many costs that meet the above definition are normally treated as F&A costs and as such, may only be charged directly to federally sponsored awards under special conditions. Unless the special conditions apply, these costs must be paid from non-federal sources;

further, many non-federal sponsors expect that the University will apply the same standard as is applied to federal projects. Accordingly, PIs and others involved in the process of assigning charges to sponsored projects must insure that charging these costs to non-federal projects is permissible in accordance with the policies of those sponsors.

Allowable costs that generally may **NOT** be directly charged to sponsored projects include the following:

Basic Administrative and Operations Costs

- Office supplies, pens, paper, basic software, etc. except in limited circumstances. See **Major Categories of Direct Costs** (**Section B(2))** below.
- Local telephone, fax, telephone line and equipment charges for general office use.
- General clerical or secretarial assistance except in limited circumstances. See **Major Categories of Direct Costs (Section B(2))** below.
- Postage and express mail
- Hazardous waste disposal
- Proposal preparation costs

For questions concerning allowable costs, contact RPIC.

Subpart E – Cost Principles of the Uniform Guidance specifically delineates certain costs as being "unallowable", meaning that they may never be directly charged to sponsored projects or included in the University's calculation of its F&A rate. Unallowable costs include the following:

Miscellaneous Expenses

- Alumnae/i activities
- Commencement and convocation costs
- Organized fundraisers
- Lobbying (federal, state or local)
- Student activities
- Bad debt costs
- Selling and marketing costs
- Fines and penalties

Entertainment/Goods or Services for Personal Use

- Sales tax
- Alcohol
- Flowers
- Catering
- Gifts
- Space rental
- Furniture
- Construction
- Housing and personal living expenses (utilities, rent, etc.)

- First or business class travel

For full details on unallowable costs, please refer to the University's Policy on Unallowable Costs.

It is important to note that the Policy does not preclude the incurrence of these costs when they are appropriate to the normal business activities of the University; however, the Policy precludes charging those costs to sponsored projects and requires that the costs themselves be segregated so that they are excluded by the University in the calculation of its F&A rate.

Allocability

An allocable cost is a cost that can be assigned to one or more sponsored projects or other activities in proportion to relative benefits received or on other equitable terms. Specifically, Section 200.405 (Allocable Costs) of the Uniform Guidance states that a cost is allocable to a sponsored project if it meets any of the following criteria:

- It is incurred specifically to advance the work under the sponsored project;
- It benefits both the sponsored project and other work of the institution, in proportions that can be approximated through use of reasonable methods; or
- It is necessary to overall operation of the institution and, in light of the principles provided in Subpart E of the Uniform Guidance, is deemed to be assignable in part to the sponsored project.

The Uniform Guidance further provides that if a cost benefits two or more projects or activities in proportions that can be determined without undue effort or cost, the cost should be allocated to the projects based on the proportional benefit. If a cost benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved, the cost may be allocated or transferred to benefited projects on any reasonable basis. It is important to note, however, that costs allocated to a sponsored project may not be shifted to another sponsored project for such purposes as eliminating a cost overrun or utilizing unexpended funds. For a discussion of Cost Transfers, see **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Cost Transfers (Chapter VIII, Section F(3))**. When a cost is allocated among projects or activities, it is important that the department be prepared to explain the basis on which the cost was so allocated, should the need to do so arise.

Reasonableness

A cost is considered reasonable if the goods or services acquired, and the amount involved, reflect actions that a prudent person would take under the circumstances prevailing when the decision to incur the cost was made. As provided in Section 200.404 (Reasonable Costs) of the Uniform Guidance, factors to consider in determining reasonableness are as follows:

- Is the cost generally recognized as ordinary and necessary for the performance of the project?
- What laws and regulations should be considered, and what are the terms and conditions of the award? Were sound business practices followed in the decision to incur the cost?
- What is the market price for comparable goods and services?
- Did all individuals act with prudence and satisfy their responsibilities to both the University and the sponsor?
- Are the actions consistent with University policies and practices?

Consistency

All costs must be afforded consistent accounting treatment. This means that a particular type of cost must always be treated similarly – as either a direct or F&A cost – under like circumstances. While this requirement is generally overseen by the Office of the Controller, the most common impact of this requirement on a PI and support staff relates to the issue of charging administrative salaries and supplies directly to sponsored projects. Except for very limited instances, these costs may not be directly charged to federally sponsored projects. For guidance on charging administrative salaries and/or costs, please refer to the University Policy: Charging Office Supplies and Other Administrative Expenses (other than Salaries) to Federal Awards

In addition to costs being consistently treated as either direct or F&A costs, there is a further requirement that the practices used in estimating costs in a proposal must be consistent with the University's normal practices for charging costs to sponsored projects, and for reporting those expenses on financial reports submitted to project sponsors.

2. Major Categories of Direct Costs

Personnel

Compensation of Faculty and Project Staff

In general, compensation costs relating to a sponsored project are allowable to the extent that total compensation of individuals:

- Is reasonable for services rendered;
- Conforms to Columbia's written policies, consistently applied;
- Follows an appointment made in accordance with Columbia's written policies; and
- Is determined and supported by appropriate documentation.

See Section 200.430(a) (Compensation-Personal Services) of the Uniform Guidance.

The PI should include in the proposal those personnel who fulfill the needs of the project with respect to experience and expertise, University position at the time of the award and available effort. Salary requests should be based on the level of payment for current or anticipated appointments and may not exceed the rate the University is then paying for such appointments. This figure should be escalated appropriately to allow for future salary increases. A working assumption is that officers' salaries increase 3% on an annual basis as of July 1 of each year and that union wages increase 4% on an annual basis as of October 1 of each year.

The PI or the individual developing the budget should consult with the appropriate DA to determine the correct salary for each individual.

For more information on charging faculty compensation to sponsored projects, please review the University's Policy on Charging and Documentation of Personnel Costs Charged to Sponsored Projects.

Personnel costs charged to sponsored projects must be based upon the researcher's "Institutional Base Salary." Institutional Base Salary (**IBS**) is defined as the annual compensation paid by Columbia for an individual's appointment, whether that individual's time is spent on research, teaching, patient care or other activities. IBS does not include bonuses, one-time payments or incentive pay. Also excluded from IBS are salary paid directly by another organization, including, but not limited to, the Howard Hughes Medical Institute and NYSPI, and income that an individual is permitted to earn outside of his/her University responsibilities, such as consulting compensation. IBS:

- may not be increased as a result of replacing University salary funds with sponsored projects funds;
- is established by the University in an annual letter regardless of the source of funds;
- includes regular salary and salary paid for an additional academic administrative appointment, such as Chair or Director; and
- excludes bonuses, incidental pay, nonguaranteed clinical compensation and extra service pay.

One of the key concepts in budgeting for personnel costs in sponsored projects is the effort devoted to the project by faculty and project staff. The applicable rule for federally sponsored projects is that salary charged to a project must be reasonable in relation to the effort expended on that project. The University policy is to maintain the same standard for all sponsored projects, whether or not federally funded.

Sponsors generally consider estimates of effort in proposal budgets to be commitments if such proposals are subsequently awarded. The effort should be listed in accordance with the sponsor's policy (percent of effort or person-months).

Total University Effort

Effort is the proportion of time spent on any activity, expressed as a percentage of an individual's Total University Effort. **Total University Effort** is not based on a set number of hours or standard work week. Rather, it depends on the specific circumstances of each individual, and the activities required to fulfill his or her obligations to the University. Accordingly, for an individual who spends 60 hours a week on University activities, those 60 hours represent 100% of that individual's Total University Effort.

Total University Effort includes not only work on sponsored projects, but also non-sponsored activities such as teaching, clinical activities, service on University committees (although the portion of proposal preparation time that relates to summarizing research results may be treated as sponsored effort). Total University Effort does not include consulting or participation in peer review study sections, professional association activities, journal peer review and similar activities, unless the University pays for travel and expenses associated with those activities. For more information about what is and is not included in Total University Effort, see http://www.effortreporting.columbia.edu/reference_guides.html.

When proposing some proportion of effort to be devoted to a particular sponsored project, individuals must ensure that they have sufficient time available to fulfill the proposed effort commitment should the project be awarded.

Some federal contract proposals request that professional time be converted to an hourly rate. For a professional, 100% effort equates to the number of hours per week the individual customarily works to complete his or her Total University Effort. If you are required to provide an hourly rate for a professional, calculate it based upon this number of hours per week.

Minimum Effort Requirements

The University's Policy on Charging and Documentation of Personnel Costs Charged to Sponsored Projects requires that key personnel participating in a sponsored project commit to some level of effort on the project greater than zero. SPA can advise as to whether an exception is available for any particular project. Committing effort "as needed" is not acceptable.

Some sponsors require certain minimum effort commitments from PIs.

Maximum Effort Commitment

The effort proposed for each project must be consistent with the level of effort expected to be devoted to that project. Any individual's Total University Effort may not exceed 100%.

The University has adopted special procedures for Faculty members whose sponsored project effort exceeds 90%:

- Following the annual effort certification, the University samples a number of Officers who certified that 100% of their effort was devoted to sponsored projects.

The sampled individuals are required to provide written confirmation to the Controller's Office that they had no non-sponsored responsibilities during the period certified.

- A Chair or Dean must acknowledge awareness of and concurrence with the reasonableness of the effort certification of any Officer of Instruction or PI who is an Officer of Research who certifies that 90% or more of his/her effort was devoted to sponsored projects.

Note: Individual Schools within the University may set minimum thresholds for non-sponsored effert.

For more information, see http://www.effortreporting.columbia.edu/reference_guides.html.

Effort Without Salary

It is the University's policy that investigators should typically request full compensation for the effort of all personnel listed in the proposal. Hence, if an individual is listed at 20% effort, 20% of his/her institutional base salary must be requested in the proposal. The policy also requires the same consistency when charging compensation to grants or contracts awarded to the University.

However, certain exceptions to this policy are allowed:

- The funding agency's specific written policy requires cost sharing.
- The individual is receiving a fellowship or career award (e.g., a NIH Research Career Development Award) that precludes requesting salary on other federal applications.

Program Directors and mentors are expected to contribute effort towards meeting the requirements of training grants. However, support for such effort is rarely allowable.

If there is no specific measureable effort commitment in the application, NIH will allow for these individuals to be named as "Other Significant Contributors (OSC)" which would permit the person to be listed in the application, but presented as 'zero effort' or 'zero person months' or 'as needed'.

Typically, NIH T or F awards do not provide funding to cover the effort of a trainee's mentor or project director. In some cases, the time devoted to these activities may be insignificant, and therefore can be ignored. If not, such effort is typically treated as a non-sponsored activity (and therefore cannot be charged to your research or other grant). In these cases, mentoring effort is usually seen as concurrent with other University teaching and administrative effort and is reported accordingly.

On the other hand, if the mentor is committed to provide effort in the grant proposal, the effort should be treated as committed cost sharing.

For information about cost sharing see **Cost Sharing (Section D)** below.

For more information on cost sharing and effort reporting, see **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Cost Sharing (Chapter VIII, Section F(4) and Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Effort Reporting (Chapter VIII, Section F(6)).** See also http://www.effortreporting.columbia.edu/downloads/Cost_Sharing-08_29_07_NS.pdf

Academic Year and Summer Salary

Officers of Instruction on the Morningside campus and at Lamont and Nevis and Research Professors at Lamont are paid a salary based on a nine-month academic year (or for the School of Business, an eight-month academic year).

Subject to sponsor and School policy, the foregoing Officers may request reimbursement from sponsored projects for academic year released time, for summer salary (if the Officer's appointment is for nine months), and/or (rarely) for academic year additional compensation. **Released time** is available time for which the Officer is formally excused from instructional duties (by his/her chair or dean) and, therefore, may be available for research.

As a general policy, NSF limits salary compensation for senior project personnel to no more than two months of their regular salary in any one year. This limit includes salary compensation received from all NSF-funded grants. This effort must be documented in accordance with the applicable cost principles. If anticipated, any compensation for such personnel in excess of two months must be disclosed in the proposal budget, justified in the budget justification and specifically approved by NSF in the award. After the award is made, SPA may internally approve an increase or decrease in person months devoted to the project, even if doing so results in salary support for senior personnel exceeding the two month salary cap. No prior approval from NSF is necessary so long as that adjustment would not cause the objectives or scope of the project to change. If that is the case, NSF prior approval is required. Your SPA Project Officer should be notified.

Summer salary may be available with nine-month appointments for work on sponsored projects during the summer months. Officers who receive summer salary must expend the effort associated with the summer salary during the summer period. Effort expended during the academic year does not satisfy a commitment relating to the receipt of summer salary. Although Officers may, in addition, also work on the project during the year, Officers who receive summer salary must provide a commensurate level of effort during the summer.

The maximum amount of summer salary permissible is three-ninths of the Officer's regular academic year salary. In other words, in any year, the Officer may receive no more than three months of summer salary. Each month of summer salary represents one month of full-time effort in the summer.

If a Faculty member has academic, administrative or non-research related responsibilities (as a journal editor, research grant reviewer, etc.), writes new funding proposals and/or intends to take more than minimal vacation time away during the summer period or attend non-project related professional meetings, he/she likely will be precluded from devoting 100% effort to sponsored projects in the summer and thus from requesting three months full summer salary from external awards.

Officers who receive sponsored summer salary and also released time for work on sponsored projects during the academic term may, with departmental approval, receive non-sponsored additional compensation during the summer for non-sponsored University activities.

For more information, see http://www.effortreporting.columbia.edu/downloads/Summer%20Salary%20Reference%20Guide%207_26_07.pdf.

Additional Compensation

All requests for additional compensation paid from an externally sponsored award require the prior authorization of the sponsor (coordinated by SPA or the CTO), the appropriate Chair, Director, Dean or Vice President and for Faculty at CUMC, the Executive Vice President for Health and Biomedical Sciences or, in other cases, the Provost.

Under certain rare circumstances, Faculty may submit a request to a sponsor for extra compensation – that is, compensation in addition to academic year base salary. Such compensation may not ordinarily be charged for intra-University consulting or collaboration, which is understood to be part of the Faculty member's University obligations. The principle also applies to a Faculty member who functions as a consultant or otherwise contributes to another University sponsored agreement.

However, in rare cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is of an unusual nature and is in addition to his or her regular University activities, it may be possible to request extra compensation.

For more information on charging compensation to sponsored projects, please review the University's Policy on Charging and Documentation of Personnel Costs Charged to Sponsored Projects.

CUMC Salary Issues

For clinical Faculty, the effort and commensurate salary reimbursement is calculated on the basis of the Faculty member's IBS plus any guaranteed additional compensation paid by the University. For sponsored project purposes, IBS thus includes the sum of these two salary components. AT P&S and the College of Dental Medicine, base for rank salary is termed the "X" salary component; the guaranteed additional compensation is termed the "Y" salary

component and IBS is the sum of X plus Y. The amount of salary that can be compensated from sponsored project accunts may never exceed an individual's IBS.

The University has a policy governing the proposing of effort for those investigators who possess an academic appointment at the University and an appointment at RFMH/NYSPI (**Joint Appointees**). Joint Appointees propose their effort on Columbia projects based on a percentage of their University effort only. However, for informational purposes, the budget justification will also indicate what the effort would be if it were calculated based on total professional effort across both institutions.

Therefore, the following statement must be included in budget justification:

"Dr. Xxx (__CM TPE, ___ CM Columbia University Effort).

The effort listed by Dr. Xxx in this submission is based upon her effort at Columbia University. If the effort were calculated based on Dr. Xxx's total professional effort at Columbia and RFMH/NYSPI, it would be yyy calendar months effort."

Salary Caps

Some agencies impose a cap on the maximum annualized salary allowed in aggregate on grants. For example, if the annual NIH salary cap is $185,100 base salary per annum and an investigator makes $200,000 per year and is requesting 10% effort on a grant from NIH, the investigator may request only $18,510 in salary support (i.e., 10% of the salary cap). The investigator's department is responsible for funding the remainder of the investigator's salary from a departmental source.

For investigators who receive summer salary that is charged to NIH grants, the rate of pay for such summer salary may not exceed the individual's IBS rate. See the University's Policy on Charging and Documentation of Personnel Costs Charged to Sponsored Projects for more information.

To view the latest salary cap information, you can go to Columbia's Institutional Information Sheet. The NIH salary cap, which changes annually, can also be found at http://grants.nih.gov/grants/policy/salcap_summary.htm.

Administrative/Clerical Salaries

Typically, administrative or clerical salaries are not an allowable charge to a federal grant. See Columbia's Policy on Charging Administration and Clerical Salaries to Federal Grants and Contracts. However, under the Uniform Guidance, these salaries may be permitted if:

- The administrative or clerical services are **integral** to a project or activity;
- The individuals involved can be specifically identified with the project or activity;
- The costs are explicitly included in the proposal budget and budget justification; and
- The costs are not recovered in the F&A charge.

Integral means essential to the project's goals and objectives, rather than necessary for the overall operation of the institution. The salaries of administrative personnel conducting such activities as financial reconciliations, general office clerical work and proposal preparation are not allowable. After award, prior written approval may be required from the sponsoring agency before these types of salaries may be charged. A SPA Project Officer can assist you in determining what administrative salaries are allowable.
See Section 200.413 (**Direct Costs)** and Section 200.430 (**Compensation – Personal Services)** of the Uniform Guidance.

Except for the circumstances listed above, the government views administrative and clerical charges as covered by the institution's indirect cost recovery, discussed in greater detail in **Facilities and Administrative (F&A) Costs** (**Section C)** below. Therefore, charges for salaries of secretaries or administrative assistants should not **typically** be included in proposals for federally sponsored projects. Administrative/clerical salaries may often be charged to foundation and other non-governmental grants.

However, direct charging of these costs may be appropriate where a project or activity explicitly budgets for administrative or clerical services. The following examples are illustrative of circumstances where direct charging may be appropriate:

- Large, complex programs (e.g., Program Projects, Center Grants) and other grants and contracts that entail assembling and managing teams of investigators from a number of institutions.
- Projects that involve extensive data accumulation, analysis and entry, surveying, tabulation, cataloging, searching literature and reporting, such as epidemiological studies, clinical trials and retrospective clinical record studies;
- Projects that require making travel and meeting arrangements for large numbers of participants, such as conferences and seminars;
- Projects whose principal focus is the preparation and production of manuals and large reports, books and manuscripts;
- Projects that are geographically inaccessible to normal departmental administrative services; and
- Individual projects requiring project-specific database management, individualized graphics or manuscript preparation; human or animal protocol and/or other project-specific regulatory protocols; and multiple project-related investigator coordination and communications. An example of this would be a project manager who is directly involved in the coordination and allocation of resources across several specific sponsored projects.

These examples are not exhaustive nor are they intended to imply that direct charging would always be appropriate for the situations described above. Where direct charges for administrative and clerical salaries are made, care must be exercised to fully justify the

charges in the proposal. Care also must be exercised to assure that costs incurred for the same purpose in like circumstances are consistently treated.

Part-time, Casual and Work Study

University employees who are paid by a sponsored project must be listed as "personnel" on the related proposal. University employees who will not be paid as part of a project may be listed as unpaid personnel or unpaid collaborators, or the extent of their participation may be indicated by submitting letters of collaboration.

Casual employees may be paid by sponsored projects so long as the amount of effort or time being requested does not exceed that allowed by Columbia Human Resources policies. If you have any questions, please contact Human Resources.

Federal funds may be used to pay all or part of the University share of the salary of a student in the College Work-Study Program.

Postdocs

Postdocs are supported by a wide variety of grants and fellowships. Often, the source of funding for a postdoc determines whether the individual is considered to be an employee of the University or a stipend recipient of the sponsor. Unless the terms of an award specifically require otherwise (e.g., NIH Training Grants or individual fellowships awards), stipends (i.e., compensation for which no service is required) may not be charged to a sponsored project.

Sometimes postdocs may be invited to serve as Teaching Assistants or to work part-time as Research Assistants on other projects. The policies of the University and of many federal agencies permit postdocs to engage in part-time University employment coincidental with their training program, provided that this employment does not interfere with, detract from or prolong their obligations as postdocs and provided that all regulatory requirements are met. Indeed, several sponsors encourage giving postdocs teaching experience as part of their training. Compensation for assistance on a research project separate from the fellowship obligations of the postdoc, if allowed by the sponsor of the full-time fellowship, may be charged to that distinct project.

For more information on postdoc compensation and benefits, see http://postdocs.columbia.edu/ or call OPA at (212) 854-0462. See also the University's Guidelines for Incidental Career Development Activities for Postdoctoral Scientists and Fellows.

Graduate Research Assistants (GRAs)

Graduate students frequently act as Research Assistants and receive compensation in the form of salary or tuition remission. Unlike fellowships and other stipend payments, GRA

salaries are an appropriate charge to a research project. These salaries are not subject to the fringe benefit charge that is normally assessed on salaries.

Sponsors vary in their allowability of compensation for graduate students. Typical expenses allowed on a research proposal for a graduate student are salary, tuition remission and other training expenses. It is important to read the sponsor's guidelines for its rules on graduate student compensation. For further information, see **Tuition Remission** below.

For example, NIH limits the compensation for graduate students. Current NRSA levels are posted at http://grants.nih.gov/training/nrsa.htm).

For more information regarding this NIH policy, please refer to: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html as well as the latest version of the NIH Grants Policy Statement.

When requesting graduate student compensation on a budget, the specific school where the student is matriculating should be consulted for current tuition rates.

Graduate student and postdoctoral fellows have unique budgetary considerations on NIH NRSA training grants. See **Special Budget Guidelines – NIH Training Grants** (**Section F(2))** below for specific instructions.

Other Professionals

Technicians, programmers and laboratory assistants may be paid for their work on sponsored projects, depending upon the sponsor's guidelines.

Severance Costs

Severance costs incurred due to the termination of a sponsored project are generally a permissible charge. However they should be discussed with your SPA or CTO Project Officer in advance of their incurrence in order to insure that any necessary agency approval is obtained.

Fringe Benefits

Fringe benefit charges are assessed to cover costs such as retirement benefits, health insurance, FICA and Medicare taxes and unemployment compensation. Fringe benefits (referred to in some contracts as "labor overhead") are calculated by multiplying the salary requested for each individual by the fringe benefit rate. Fringe benefit rates are set each year, and the rates charged are automatically updated, so that no action on the part of the PI or his/her staff is required.

The rate is a composite rate (averaged for all employees). Thus any given employee may not be entitled to all of the specific fringe benefits that make up that rate. SPA or the CTO should be contacted for information concerning the appropriate fringe benefit rates to use in each year of the proposal. The full fringe benefit rate should be included as part of the

budget request for all employees, including "casual" employees who are not Columbia, Barnard or Teachers College students. Casual employees who are Columbia, Barnard or Teachers College students are charged at a reduced fringe benefit rate. Salaries for GRAs are not charged for benefits on grants. Fellowship applications should include a charge for fringe benefits if it is an allowable cost and does not decrease the fellow's stipend.

Government grants and contracts are assessed fringe benefit charges based on a rate that is formally established with the federal government. This rate is also applied to awards received from non-government agencies that represent a pass-through of government funds (i.e., a subcontract made where the prime award is from a governmental agency). Federal rules prohibit the inclusion of certain fringe benefit costs such as dependent tuition and accordingly the fringe benefit rate applied to sponsored projects awarded by governmental agencies excludes those costs.

Sponsored projects awarded by non-governmental agencies are subject to a higher rate, which includes both the costs incorporated in the federally negotiated rate as well as other benefit costs such as dependent tuition that are excluded from the federal rate.

It is Columbia's practice to charge vacation, holiday and sick leave pay as a direct charge and not as a fringe benefit expense. The direct charge is made to the project or projects with which the employee is associated at the time that the expense is incurred. This same procedure applies to cash payouts for unused leave at the time of an employee's termination.

For current fringe rates, please refer to the Institutional Information Sheet.

Non-personnel Costs/Other Than Personnel Costs (OTPS)

OTPS costs are usually specified in a budget in the following categories: equipment, supplies, travel, consultant costs, publication costs, tuition remission and other direct costs. Training costs have additional categories such as trainee stipends, tuition and fees, and trainee travel.

Note that the University's procurement policies, including requirements for competitive bids, must be followed whenever they are applicable in acquiring goods and services. These policies can be found in the in the Administrative Policy Library at: http://policylibrary.columbia.edu/. Although the University's procurement policies will charge as a result of the adoption of the Uniform Guidance, the federal government has authorized a grace period prior to the imposition of the new regulations. As a result, the University will continue to apply the procurement standards set forth in Circular A-21 until July 1, 2017, at which time the University's implementation of the Uniform Guidance requirements will take effect.

In addition to disbursements made to outside vendors, sponsored projects may be charged by certain internal providers of services. These centers are "licensed" by the University to charge users and the costs charged and the manner in which their unit costs are determined are covered by the University's Policy on Service Centers and Recharge Centers.

Sponsored projects may not be charged for internal operations other than those licensed as centers without the approval of RPIC.

Permanent Equipment

Equipment is defined as an item having a unit value of at least $5,000 as well as a useful life of more than one year. It is important to adhere to this definition when preparing sponsored project budgets. Many agencies, including all federal government agencies, do not allow F&A costs to be charged on equipment. Items costing between $500 and $4,999 are considered "supplies" or “minor equipment” and F&A costs will be charged against them for budget purposes.

Equipment is further categorized as **special purpose** or **general purpose**. Under the Uniform Guidance, **special purpose equipment** means equipment that is used only for research, medical, scientific or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments and spectrometers. **General purpose equipment** means equipment that is not limited to research, medical, scientific or technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, IT equipment and systems, air conditioning equipment, reproduction and printing equipment and motor vehicles.

It is important that each item of equipment being requested is clearly identified and priced (including shipping and installation) in the proposal. (If possible, specific manufacturers and model numbers should be used.)

Care must be taken to include all of the cost items associated with the acquisition of equipment, such as shipping and installation costs. These latter costs may be substantial on larger, more specialized equipment items, where special power, insulation, shielding, water and/or cooling requirements must be met. Contact Facilities Management to have these costs assessed.

SPA or CTO approval is required if rebudgeting from other categories is involved in the purchasing of capital equipment. This is necessary to determine if the rebudgeting has significant programmatic impact, if prior approval from the sponsor is required, and to reallocate F&A costs.

In addition, CUMC requires approval from SPA or the CTO on requisitions on federally sponsored projects totaling more than $10,000 and for all non-governmental sponsored project capital equipment requisitions prior to submitting the requisition to Procurement.

For more information, please refer to the University’s Policy on Acquisition of Moveable Capital Equipment.

Supplies

Materials and supplies include freestanding equipment with a value up to $4,999 and consumable items such as chemicals, laboratory ware and small component parts (if not part of an equipment fabrication). For non-federal grants where indirect costs are not reimbursed at the full federal rate, office supplies clearly allocable to the project may be included as materials and supplies, if allowed by the sponsor. Office supplies are considered to be part of the F&A costs of conducting a project, so they should not be charged as a direct cost on a federal award. There are, however, two major exceptions to this policy:

- If the purchase of these and similar products relates specifically to the technical substance of the project; or
- If the nature of the work performed under a particular project requires an unusually high level of such costs.

For more information on these restrictions, please refer to the University's Policy on Charging Office Supplies and Other Administrative Expenses (Other Than Salaries) to Federal Awards.

Computing Devices

Computing devices are defined in Section 200.20 (Computing Devices**)** of the Uniform Guidance as machines used to acquire, store, analyze, process and publish data and other information electronically, including accessories (or "peripherals") for printing, transmitting and receiving or storing electronic information. Computing devices should be included under the budget category "Materials and Supplies" in proposals.

Computing devices costing less than $5,000 that are essential and allocable, but not solely dedicated to the performance of a federal award, may be charged 100% to an award or may be allocated to several awards (see Section 200.453 (Materials and Supplies Costs, including Costs of Computing Devices**)**) of the Uniform Guidance. Capitalized computer equipment (i.e., costing $5,000 or more) is still classified as general purpose equipment and is normally unallowable as a direct cost unless approved by the awarding agency.

While no prior agency approval is required, computing devise should be itemized in the proposal budget (or in the case of NIH Modular Grant applications, itemized in the budget provided to your SPA Project Officer). In addition, the project must not have reasonable access to other devices or equipment that can achieve the same purpose. Devices may not be purchased for reasons of convenience or preference.

Travel

The costs of travel related to the sponsored project, for the PI as well as project staff, are generally allowable expenses. Since travel is often one of the first budget line items to be cut by the sponsor, it is important to be as specific as possible about what travel is planned and why it will benefit the project. Domestic and foreign travel should be budgeted as separate line items.

Domestic travel includes all travel within and between any of the 50 states of the United States and its possessions and territories. Travel between the United States and Canada and within Canada is also considered domestic travel. Foreign travel is any travel not defined as domestic travel. On government sponsored projects, U.S. carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries, as required by the Fly America Act. Convenience or expense is not considered an appropriate reason for not using a U.S. carrier. Funds can be requested for travel to scientific meetings, to collaborating laboratories, and for consultation with the funding agency or with colleagues concerning project research. The federal government generally limits airfare reimbursement to the customary standard commercial airfare (i.e., coach or equivalent). Section 200.474 (Travel Costs**)** of the Uniform Guidance provides that airfare costs in excess of the basic least expensive unrestricted accommodations class offered by commercial airlines are unallowable except when such accommodations would (a) require circuitous routing, (b) require travel during unreasonable hours, (c) excessively prolong travel or (d) result in additional costs that would offset the transportation savings.

The basic policy governing travel expense reimbursement at Columbia is that an individual traveling on University business should be reimbursed for the actual cost of such travel. Unless specifically stated otherwise by the agency, University policy prevails. (For example, some government contracts only allow reimbursement at government rates.)

It is suggested that each trip requested in the budget should be specifically identified as to location and length of stay. All travel expenses (transportation, hotels, registration fees, etc.) should be itemized based on expected costs. Trips approved as part of the awarded budget normally do not require further approval from the sponsor or the University. For sponsors that require additional approvals (e.g., for foreign travel), please contact your SPA Project Officer.

For further information, see the University's Travel Expense Policy and the Fly America Act.

Consultants

It is University policy to contract for consultant services when factors such as timing, costs, qualifications or the nature of the service to be rendered make it beneficial for such services to be acquired outside of the University than performed by employees. A **consultant** is defined as a firm or individual with whom the University enters into a Service Provider Agreement for a specialized type of service. The Agreement contains a scope of work that clearly defines the goods or services being procured and addresses the needs of the user. This can be done either through performance specifications or through a description of the tasks to be performed. Honoraria (for example, for Advisory Board participation) and human subject reimbursement are exempt and not considered consultant costs.

The PI must complete a Subrecipient/Contractor Classification Form for each consultant proposed in a sponsored project application. This Form is used to classify the consultant as

a contractor versus a subrecipient and outlines the relationship and characteristics used in making the determination. This Form can be found on the SPA website under Internal Forms.

In addition to classifying the individual as a consultant versus subrecipient, the circumstances under which services are to be rendered determine an individual's classification as either an independent contractor or employee. However, there is no precise definition for either of these terms in the federal tax code or IRS guidelines. A set of questions has been developed and is available from Procurement to help determine whether an individual should be considered an employee or consultant. When it is not clear into which category an individual falls, assistance will be provided by Procurement. See http://finance.columbia.edu/procurement/purchasing.

It is important to determine whether an individual is to be considered an employee or a consultant prior to listing him/her on a proposal. Compensation for employees must include fringe benefits. Consultants, not being employees of the University, do not receive fringe benefits from the institution. In order to prepare a budget correctly, the contract cost of the consultant should be included.

The University does not have a standard consultant or honoraria rate. An individual may be paid according to the customary scale for a particular field and level of expertise, unless there are sponsor-specific requirements. In some cases, notably the NSF, consultants may not be paid more than the daily rate for a GS-18 federal employee. If an individual is paid an honoraria and is exempt from the consultant policy, the budget should contain, if appropriate, the itemized daily fee, per diem allowance and travel expenses. The number of trips and the length of stay should also be discussed.

All consulting arrangements must conform to established University requirements, which may be seen at:
http://www.columbia.edu/cu/administration/policylibrary/policies/acpy/48.html?base=responsible_office

Additional guidance on the use of consultants can be found at:
http://finance.columbia.edu/procurement/lifecycle/purchasing/consultants

Tuition Remission

In addition to salary, GRAs are also provided with tuition remission, which is an allowable charge to federal and most other research grants as a direct cost. Unless further limited by specific agency policy, the University has set the maximum tuition chargeable to sponsored projects at 50% of the University's full resident tuition rate for graduate students as published for the Graduate School of Arts and Sciences. The current tuition remission rate is available from SPA. See http://spa.columbia.edu/proposals/institutional-information#GRAinfo.

Tuition charges are assigned to research grants and other funding sources in proportion to the GRA's salary allocation during the nine-month academic year. For example, if during the period September through May, a GRA's salary is funded 25% by grant A and 75% by grant B, the GRA's tuition remission is assigned to those funding sources in the same percentage as the GRA's salary.

With respect to GRAs funded in whole or in part by NIH, that agency has established a funding cap that limits the amount it awards for a combination of GRA salary and tuition remission. The cap varies from year to year, and the cap in effect at the time the proposal is submitted applies to the entire life of the competitive segment of the project (i.e., there is no escalation factor in the proposal budget for increases in this cost category over the life of the competitive segment). Similarly, the tuition amounts charged to NIH grants are based on the cap in effect at the time the award is made.

While most agencies permit tuition remission charges, some agencies or particular awards may have restrictions that limit or preclude charging their grants for these costs. For example, the American Cancer Society does not permit charging any tuition remission to its awards.

Subawards

Proposals may include work to be done at one or more other institutions. In these cases, the other participating institutions may be considered to be subrecipients under the University's (prime) award. The PI must make case-by-case classifications to determine if the work conducted by the other participating institution is to carry out a portion of the prime award (subrecipient), or if the participating entity is providing goods or services to Columbia in a procurement relationship (contractor).

If the Columbia PI plans for the participating entity to carry out a portion of the work, and it is determined that the entity will be a subrecipient, to apportion the work in this way, appropriate documentation is needed at the time the proposal is submitted to confirm the proposed subrecipient's eligibility and willingness to participate. When a subaward has been prepared as part of a larger proposal, the total yearly cost for the subaward is included as a line item in the Columbia budget. The subrecipient must include his/her institution's F&A costs in the subaward, but the University does not currently assess any of its own F&A costs on the amount of the subaward in excess of the first $25,000 during the competing project period.

Please note that the administration of some subawards may entail additional costs that must be included as part of Columbia's direct cost project budget. Such costs could include audit-related expenses, especially if subawards are proposed to institutions that are deemed to have a higher than normal risk associated with them as a result of the University's subaward risk assessment process. Allowability of such costs should be discussed with your SPA or CTO Project Officer.

For additional information, see **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Subawards** (**Chapter VI, Section E(10))** and the University's Policy on Sponsored Project Subawards.

Participant Support Costs

Participant support costs are direct costs, such as stipends or subsistence allowances, travel allowances and registration fees paid to (or on behalf of) participants or trainees (but not employees) in connection with meetings, conferences, symposia and workshops, where there is a category for participant support costs in the award budget. These costs should not be confused with general travel costs that may be incurred by PIs and others as those costs relate to individual research and other projects.

Participant support costs are generally awarded on specific projects sponsored by NSF and are subject to special sponsor regulations. For example, NSF does not permit participant support funds to be used by grantees for other categories of expense without the specific prior written approval of the cognizant NSF project office. Any additional categories of participant support costs other than those described in Section 200.75 (**Participant Support Costs)** of the Uniform Guidance (such as incentives, gifts, souvenirs, t-shirts and memorabilia), must be explained in the proposal budget justification, and such costs will be closely scrutinized by the NSF. Therefore, participant support costs must be accounted for separately. In addition, participant support allowances may not be paid to trainees who are receiving direct or indirect compensation from other federal sources. F&A charges are not applied to participant support costs.

When a sponsored project includes participant support costs, the PI and his/her administrative support personnel are required to be familiar with the specific requirements as set forth by the sponsor, and to insure that those requirements are complied with.

For further information, see the University's Participant Support Costs Policy.

Patient Care Costs

See **Special Budget Guidelines – Clinical Research** (**Section F(4))** below for a reference to a chapter in the Clinical Research Handbook that describes research and standard of care costs relating to patients.

Other Direct Costs

This category is used to delineate costs not specified in any other category. Examples would include animal care costs, specialized tests, central computer charges, shop charges, core facility charges, publication costs, copying and telephone charges (if not for general office activity), maintenance contracts, service agreements, payments to volunteers or patients, patient travel, student tuition charges, student health and computer fees, seminar costs and typing services. In certain circumstances, space rental, the rental of equipment and the purchase of insurance are also allowable. Costs associated with radioactive waste, chemical

and biohazardous materials disposal are currently not treated as direct costs. These costs are recovered as part of the University's F&A costs.

In determining other direct costs, it is best to itemize each cost. However, the degree of detail is set by the sponsor requirements and individual investigator. Since many of these costs are incurred in the general operation of a laboratory, it should be kept in mind that only that proportion of the total cost that is related to the specific proposal should be included.

C. Facilities and Administrative (F&A) Costs

Facilities and administrative (F&A) costs (which are commonly referred to at the University as **IC** or **ICR)** are real costs that are associated with carrying out sponsored projects, but are difficult to quantify with respect to any given project. For example, electricity, heat, maintenance, building depreciation, administrative expenses and library use are all F&A costs. Funds received as F&A costs are reimbursement for funds expended for central and departmental administration, buildings and grounds and library costs.

F&A costs are recovered on sponsored project proposals by multiplying the appropriate direct cost base by the sponsor's F&A cost rate and including that figure in the total cost of the budget. Depending upon the sponsor, the direct cost base may be either the simple total of all direct costs in the budget (**Total Direct Costs** or **TDC**), or the "modified" total direct costs (**MTDC**), i.e., TDC minus the total of certain items in the budget. Federal sponsors use MTDC. Some federal agencies, such as DOD, have specific F&A cost restrictions. For more information, contact your SPA or CTO Project Officer.

On budgets for federal sponsors, the following line items are subtracted from the direct cost base to arrive at MTDC:

- Equipment
- Capital expenditures
- Charges for patient care
- Subcontract costs in excess of the first $25,000 during the competing project period
- Tuition remission
- Rental costs of off-site facilities
- Scholarships and fellowships
- Participant costs

In addition, MTDC on training grants and fellowships exclude tuition, fees and health insurance. Non-federal sponsors may require F&A costs to be computed on a different base.

The University has a policy of recovering full F&A costs on all sponsored projects where specific written agency policy does not preclude it. The University will agree to an agency's F&A cost policy that is less than the federal negotiated rate provided that it is part of the

agency's written policy and is applied uniformly to all institutions funded in that particular program area.

Federal F&A cost rates are negotiated with the federal government and vary by campus and whether research or other sponsored projects are conducted on or off campus. The University's Rate Agreement with the government provides that if a project is partially on-campus and partially off-campus, the F&A rate for that project is based upon the location(s) where 50% or more of the program or budget is located. Exceptions to this rule would only occur in rare circumstances where there are very significant costs incurred both on and off campus. Examples of the latter include the International Center for AIDS Care and Treatment Programs (ICAP) and the Multi-country Columbia Antiviral Program (MCAP) where a large component of the study is conducted on campus with a significant part also being in the field outside the United States. A complete list of rates is available at http://spa.columbia.edu/proposals/institutional-information.

For public service agreements and non-government sponsored clinical trials, the F&A rate can be less than the federal rate. If you have any questions concerning the appropriate rate to use for any government or non-government sponsored projects or are unsure how to correctly calculate these costs, contact your SPA or CTO Project Officer.

The University will grant a waiver of its F&A cost policy due to either extenuating circumstances or in cases of extreme hardship. To request a waiver, the investigator must first obtain the approval of his/her chair or director and, in the case of P&S investigators, the Vice Dean for Administration at P&S. The investigator should provide his/her SPA or CTO Project Officer with an explanation of the reason for the waiver request, stating what rate reduction is being requested for what budget period and confirming the school/ department/institute/center's approval and, if applicable, contribution.

A special policy exists for sponsored projects being transferred from another institution whose F&A cost rate is lower than the University's. If the sponsor is unwilling to provide additional funds to compensate for the higher F&A rate during the first budget period or all remaining non-competitive period(s), the University will accept the lower rate until the next competing continuation or renewal phase of the project is awarded.

To locate the appropriate F&A rate for your proposal, please refer to the Institutional Information Sheet**.**

D. Cost Sharing

When the University bears a portion of the costs of a sponsored project (e.g., by purchasing equipment or supplies for the project from University resources, by committing faculty or staff effort to project at no cost to the sponsor or by waiving all or a portion of F&A costs), it is considered to be cost sharing. Cost sharing can be classified in the following ways:

- **Mandatory Cost Sharing**: Cost sharing that is required by the sponsor as a condition of the award. Such requirements are typically noted in the sponsor's program announcement, request for proposals, etc.
- **Voluntary Cost Sharing**: Cost sharing that is not required by the sponsor, but is included in the proposal.

Any type of cost sharing that is included in a proposal is considered a commitment on the part of the University and must be honored should the proposal be awarded. Cost sharing has programmatic, administrative and financial consequences for the University and, as a general rule, is strongly discouraged unless it is required by the sponsor. Cost sharing commitments

- Are auditable, requiring that additional attention be paid to these expenses throughout the life of the award. For example, if cost sharing includes effort, the individual's effort certification must document that the effort that was committed was in fact provided; and
- Have an adverse effect on the University's recovery of F&A costs as these costs are included with other direct charges in the **research base** (the denominator of the fraction used to calculate the University's federal F&A rate).

As a result, beyond the actual funds committed, cost sharing both increases the administrative cost to the University for these awards and reduces the potential amount of F&A costs that can be recovered from other sponsored projects.

For proposals that require cost sharing, please note:

- Mandatory cost sharing requirements are often specified as a fraction of the total project costs. Should such an award be funded at less than the amount requested in the proposal budget, the cost sharing commitment should be reduced proportionately. Such reductions should be evaluated throughout the life of the project whenever the sponsor reduces the amount of the anticipated award.
- Should a sponsor require cost sharing and cap F&A costs at a rate below the full federal rate, the proposal should include the difference between maximum F&A costs allowed by the sponsor and the full federal rate in satisfying the cost sharing requirement.
- On any federal award including cost sharing, federal funds from a different source may not be used to meet the cost sharing requirement unless approved by the sponsor.

For more information, see the University's Policy on Cost Sharing and **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Cost Sharing** (**Chapter VIII, Section F(4))**.

E. Budget Justification

The Budget Justification is the narrative in a proposal that provides additional detail on line items in the budget. Sections should be included for Personnel, Equipment, Travel and any other budget categories that may require explanation. If the budget includes costs of normally unallowable items, these must be justified, although a justification (or the award itself) does not, in and of itself, make the costs allowable without explicit sponsor approval. Equipment expenses also require careful delineation, since the sponsor approves individual line items in this category.

F. Special Budget Guidelines

1. NIH Modular Grants

To help streamline the proposal review and award process, NIH requires that proposals requesting $250,000 or less in direct costs per year be submitted as **modular grants**. Funds are requested in $25,000 increments, or **modules**, based on a locally-generated detailed budget that is not sent to the funding agency. Ordinarily the same number of modules should be requested in each year of the award period. Additional restrictions and guidelines are outlined at http://grants.nih.gov/grants/funding/modular/modular_features.htm. Key points include:

- The budget narrative must include all personnel by position, role and level of effort. This include consultants, personnel on any consortium/contractual arrangements and any "to be appointed" positions.

- Any variation in the number of modules requested must be explained in the budget justification. Equipment costs should not be explained unless they result in a variation in the number of modules being requested.

- The inclusion of a subaward does not preclude using the modular submission format. In such cases the proposal should include a statement of intent to establish a consortium between the participating institutions. The subawardee should provide the PI sufficiently detailed (non-modular) budget information so that the cost of the consortium agreement (which includes the subawardee's associated F&A costs) can be estimated to the nearest $1,000.

Please note that SPA and the CTO require a detailed budget to be prepared for modular grants, even though a detailed budget is not required by NIH, in order to confirm that F&A cost calculations are correct.

For a full description of which grants are eligible for the modular format, with instructions on how to complete a modular application, please refer to:
http://grants.nih.gov/grants/funding/modular/modular.htm

2. NIH Training Grants

NIH Institutional Training Grants have unique budget instructions and considerations. When preparing a training grant, you must consider the number of predoctoral students and postdocs, their level of experience (in relation to the dollar amount NIH sets forth for stipends), tuition and fees, travel and training related expenses. Applicants should pay special attention to the specific instructions for Institutional Training Grant Applications using the SF424 (R+R) Application.

For a full description of NIH Training Grants, with instructions, please refer to: https://researchtraining.nih.gov/programs/training-grants.

3. Unsolicited NIH Grant Applications with Direct Costs Exceeding $500,000

For unsolicited (i.e., not responding to a specific RFA or other announcement) NIH grant applications requesting $500,000 or more in direct costs (excluding consortium and F&A costs) in any individual grant year, prior approval to submit the application from NIH is required to be included as part of the application submission. This approval must be obtained six weeks before submission of the application. Your SPA Project Officer can assist you with the details on how to request this approval. Additional information can be found in the latest version of the NIH Grants Policy Statement.

4. Clinical Research

Clinical research requires special budgetary considerations. A full discussion of budgeting for clinical research can be found in **Preparing for a Study: Project Feasibility and Study Documents: Budgets** (**Chapter IV, Section E)** in the **Clinical Research Handbook**.

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VI. REVIEW AND SUBMISSION OF A SPONSORED PROJECT PROPOSAL

A. Introduction

Once a proposal is completed, it is required to be reviewed by the appropriate University administrative office to ensure that all of the sponsor's requirements have been met and that the proposal complies with all governmental laws and regulations and University policies. In addition, the budget is thoroughly reviewed for accuracy, allowability and completeness.

For a description of which proposals are reviewed by SPA, the CTO or CTV, see **Preparing a Sponsored Project Proposal: University Offices That Can Assist with Proposal Development and Submission and Other Agreements** (**Chapter IV, Section E)**.

B. Review Process

1. Non-Industry Sponsored Research

Rascal PT

The review process for non-industry sponsored research studies is initiated by entering information about the research proposal into Rascal PT. To enter such information:

- Go to the Rascal website at www.rascal.columbia.edu
- Select "Grants and Contracts"
- Log in with your UNI and password
- Select "Create a Proposal"
- Complete, at a minimum, the following fields:
    - Primary responsible department number
    - Submitting to (which campus office)
    - Deadline date
    - Deadline type
    - Title
    - Abbreviated title
    - Answers to questions about involvement of Select Agents, Hazardous Materials, Recombinant DNA and Human Gene Transfer
    - PI's Name (on Personnel Page)
    - Agency/Sponsor name (on Sponsor page)
- Obtain a Rascal "Proposal Tracking ID Number"

Receipt of a Rascal Proposal Tracking ID Number means that the proposal has been registered in Rascal.

Note that a proposal will not be reviewed by SPA or the CTO unless the proposal has been registered in Rascal.

Proposal and Budget Review

At least five business days prior to the sponsor's submission deadline, the following documents should be submitted to your Project Officer in SPA or the CTO in final form:

- Grant application, proposal or contract
- Budget and budget justification
- FCOI disclosure forms. Annual, up-to-date FCOI disclosure forms must be completed in Rascal by all individuals who will conduct the proposed research, including the PI and each other person identified in the proposal. For more information on FCOIs, see **Additional Approvals and Certifications – Financial Conflicts of Interest (FCOIs)** (**Section E(1))** below.
- Finalized **Rascal PT Record** that includes:
  - All of the fields required to register a proposal in Rascal (see **Rascal PT** above)
  - Subdepartment number (if none, use default of 000000)
  - Agency/Sponsor address
  - Line 1 Budget
  - Begin and end date of budget
  - Building and space information (building, floor, room)
  - Evidence that all approvals and certifications required prior to submission have been obtained.
- Subawards. If the proposal includes subawards, the following forms and documents are required for each proposed subaward:
  - Subrecipient/Contractor Classification Form
  - A statement of work
  - Detailed budget
  - Budget justification
  - Biosketch for each key personnel listed by the subrecipient
  - FCOI certifications
  - Subaward Face Page signed by the subrecipient's institutional official
  - An International Research Questionnaire (IRQ) if the proposed subrecipient is a non-U.S. entity or individual. See the University's International Research and Service Projects: Risk Management Procedures
  - A Pre-award Assessment of the Proposed Subawards Form if the aggregate amount of all proposed subrecipients in the grant or contract proposal exceeds 50% of the total prime award.

For more information on subawards, see **Additional Approvals and Certifications - Subawards** (**Section E(10))** below.

Note that a proposal will not be submitted to a sponsor unless a fully completed Rascal PT Record has been entered and signed in Rascal.

2. Industry Sponsored Clinical Research

For a description of the review process for industry sponsored clinical research, see **Preparing for a Study: Review and Finalization of Proposals and Contracts – Review Process: Industry Sponsored Clinical Research (Chapter VI, Section B(2))** of the **Clinical Research Handbook**.

3. Industry Sponsored Non-Clinical Research

As with non-industry sponsored research and industry sponsored clinical research, the review process for industry sponsored non-clinical research is initiated by entering the research proposed into Rascal PT. See **Review Process: Non-Industry Sponsored Research (Section B(1))** above.

Industry sponsors vary in their requirements for SRAs. In general, the SRA takes the place of a proposal and only in rare cases is a formal proposal required by the sponsor. SPA should be contacted as soon as an investigator thinks that he/she may receive funding from an industry sponsor. The following items are required by SPA in order to review, negotiate and sign an SRA:

- Budget
- Written research plan
- Description of who is working on the project with their roles and responsibilities
- Proposed agreement from the sponsor, if available (if the sponsor has not provided a form of agreement, SPA can provide a sample agreement from which to begin negotiations)
- Finalized Rascal PT Record (see **Review Process: Non-Industry Sponsored Research (Section B(1))** above)

C. Deadlines for Non-Industry Sponsored Research

In order to ensure adequate time for review, notification of corrections that need to be made and institutional sign-offs, all proposals for non-industry sponsored research projects should be submitted to SPA or the CTO in final form with a finalized Rascal PT Record at least **five business days** prior to a sponsor's designated deadline. To be in final form, a proposal must have the scientific and technical portions completed, the budget finalized and departmental approvals obtained. This deadline applies to all proposals, but it is particularly important for those proposals that are being submitted electronically.

Proposals will be processed in order of receipt. It is the responsibility of the PI to ensure that a proposal reaches the sponsor in time to meet the established deadline.

D. PI Certification and Departmental and School Approvals

PI certifications and departmental approvals are obtained through Rascal.

1. PI Certification

The University must secure and retain a written assurance from the PI prior to submitting any new or continuing application (whether or not competing), which is completed using Rascal. This assurance includes the certifications set forth in **Annex C**.

When multiple PIs are proposed in an application, this assurance must be obtained for all named PIs.

2. Departmental and School Approvals

In addition to SPA or CTV, the PI must obtain the approval of the relevant department Chair, Dean or other authorized official of the school before submitting any proposal to a sponsor. In addition, appropriate Chair, Dean or other authorized official approval from a Department or School with whom you are collaborating must also be obtained and be evidenced in Rascal. Such review involves the following considerations:

- commitments of Faculty and staff time and the possible effects on the teaching and other obligations of the personnel involved;
- salary arrangements (e.g., reimbursement of appropriate academic year salaries and provision for summer support);
- requirements for space and facilities;
- the budget, especially a verification that all costs, including F&A costs, are provided for, that all needs are realistically estimated and stated, that items included are not contrary to the policies of the University or the sponsor, and that the funds are available when a University cost sharing commitment is included in the application; and
- the identification of special conditions requiring further review, such as use of human subjects, animals, biohazards, radioactive materials, radioactive drugs or intellectual property concerns.

Approval by the Chair, Dean or other authorized official of the School constitutes an endorsement attesting to the academic purposes of the proposed research or other sponsored activity, its departmental compatibility, its appropriateness in the context of

budget, the time available to the Faculty member to carry out the project and the availability of space and research equipment and any cost sharing commitments.

E. Additional Approvals and Certifications

In addition to the approvals described above, investigators must obtain other approvals or make other certifications for their research to proceed. Some of these requirements apply to all research projects. Others apply only to particular types of research. These steps are described below and are summarized in a table in **Additional Approvals and Certifications: Special Approval Summary Chart (Section E(13))** below that also provides links to websites where more detailed information can be obtained.

1. Financial Conflicts of Interest (FCOIs)

The PI and all personnel who conduct University research must disclose any potential FCOIs that may relate to the proposed research prior to a proposal being submitted to a sponsor. As defined in the University's Policy on Financial Conflicts of Interest and Research, **conducting research** includes, but is not limited to, the design, performance and/or reporting of research. Disclosure forms must be completed in Rascal on an annual basis and must be updated throughout the year as appropriate. A complete disclosure form must be filed annually; updates may be filed on "amendment" forms during the year. Unless current annual financial interest reports are on file in Rascal, new proposals for funding may not be submitted to a sponsor.

In addition, if the proposed project involves human subjects, an additional "protocol specific" financial interest report must be completed in Rascal and a proposal may not be approved by the IRB unless all financial interest reports have been completed in Rascal.

All disclosures concerning significant financial interests relating to research are reviewed by RCT, which refers potential research FCOI to the Committee on Financial Conflicts of Interest and Research for review. The Committee has two subcommittees, one for CUMC research and one for non-CUMC research. Cross-campus collaborative research conflicts may be reviewed by the full Committee. The Committee will determine whether a conflict exists and if so, whether it can be reduced, managed or eliminated. If the research involves human subjects, and the Committee finds that a FCOI exists, the protocol may not be approved by the IRB until the Committee has resolved how to reduce, manage or eliminate the FCOI.

Additional disclosure and training requirements apply to investigators involved in research funded by the U.S. Public Health Service (**PHS**). The current PHS regulation on FCOI (*Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*) governs research sponsored by NIH, CDC, AHRQ and other PHS agencies. The regulation took effect on August 24, 2012, and applies to all investigators on new awards, new proposals, non-competing renewals and no cost extensions received or submitted on or after that date. The

regulation requires that PHS researchers complete training in Financial Conflicts of Interest and Research. See also **Training: Mandatory Training: Financial Conflicts of Interest and Research for PHS Researchers (Chapter III, Section C(3)).** For complete text of the regulation, visit http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.

One additional requirement of the PHS regulation is that covered investigators must disclose all sponsored or reimbursed travel that relates to their institutional responsibilities. Such information may be disclosed in the annual disclosure form or by emailing TravelUpdate@columbia.edu. More information about travel disclosures is available at http://www.columbia.edu/cu/compliance/docs/conflict_interest/PHS_COI/PHS_Travel.html.

Additional information about PHS FCOI requirements is available at http://www.columbia.edu/cu/compliance/docs/conflict_interest/PHS_COI/index.html

Additional information about Columbia's Policy can be found at Policy on Financial Conflict of Interest and Research.

The University recently adopted a companion policy to the above Policy on Financial Conflicts of Interest and Research. The new policy, entitled the Columbia University Policy on Institutional Conflict of Interest in Research (the **ICOI Policy**), protects the objectivity of University research from potential conflicts that may result from financial interests held by the University itself or by it officials who have responsibility for research oversight. Such financial interests could include, for example, royalties paid to the University by research sponsors; ownership interests in start-up companies whose products are the subject of University research; or certain large corporate gifts. More information about the ICOI Policy is available on the RCT website.

2. Effort Reporting

Each Faculty member who receives any of his/her salary from a sponsored project, or otherwise provides committed effort on a sponsored project, must (a) complete the effort reporting training described in **Training: Mandatory Training – Effort Reporting** (**Chapter III, Section C(7))** and (b) monitor his/her effort at least quarterly, self-certify his/her effort annually and, if a PI, monitor quarterly and certify annually the effort of his/her researchers. All quarterly monitoring and annual certifications are done through ECRT, the University's online effort reporting tool. For any proposal to be submitted to a sponsor, the PI of the project and each other self-certifier who is listed on the application must complete the training and the most recent annual certification. For additional information, see **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Effort Reporting** (**Chapter VIII, Section F(6))**.

3. Human Subjects

The term **human subjects** includes not only individuals who participate in research studies, but also other living persons about whom information is collected and whom the

investigator can identify individually. Research involving the use of human subjects requires prospective review and approval by one of the six IRBs or the Administrative Review Committee at CUMC or the IRB at the Morningside campus.

Most sponsors allow proposals to be submitted with IRB review "pending", but some will not make a funding decision until IRB approval is granted, and neither the sponsor nor the University will allow research involving human subjects to proceed without IRB approval or certification of exemption.

The Columbia IRB also acts as the Privacy Board under the HIPAA Privacy Rules that governs the use of data involving protected health information in research studies.

Training requirements for personnel conducting human subjects research are summarized in **Training: Mandatory Training – Human Subjects (Chapter III, Section C(1))**.

The IRB approval process and informed consent, as well as HIPAA, are discussed more fully in **Preparing for a Study: IRB Approval** (**Chapter V)** and **Working with Study Subjects: Informed Consent** (**Chapter IX)** in the **Clinical Research Handbook**.

4. Use of Animals

The responsible care and use of animals in research is a matter of considerable interest to the public, and is of the utmost importance to Columbia. The University's animal facilities are managed by veterinarians who are Board certified specialists in laboratory animal medicine. The policies and procedures for animal care are reviewed regularly by internal committees, by state and federal regulators (the Office of Laboratory Animal Welfare and the U.S. Department of Agriculture) and by an independent outside accrediting agency. If a project requires the use of vertebrate animals, approval must be obtained from the IACUC. IACUC approval is given only when (a) the information to be gained from the research is important for medical purposes; (b) such information cannot be gained in any other way and (c) the research is performed humanely and in accord with all applicable laws and regulations. Most funding agencies will accept evidence that IACUC review is pending. However, research that involves animals may not proceed (and animals may not be ordered from a supplier) until the IACUC has approved the protocol.

Training requirements for personnel conducting animal research are summarized in **Training: Mandatory Training – Research with Animals** (**Chapter III, Section C(2)).**

For further information on IACUC review and approval of protocols, see **Preparing for a Study: IACUC Approval (Chapter IV)** in the **Animal Research Handbook**.

5. Environmental Health and Safety

Training

Columbia has a number of EH&S training courses that must be completed in order to work on research projects using hazardous materials. These training requirements are summarized in **Training: Mandatory Training – Environmental Health and Safety** (**Chapter III, Section C(4))**.

Biosafety

All research involving the use of hazardous biological materials in research, such as potentially infectious tissues or bodily samples and research involving recombinant RNA or gene therapy requires approval of the University's Institutional Biosafety Committee (**IBC**). The NIH also provides oversight for Human Gene Transfer (**HGT**) activities. In addition to IBC approval, HGT activities also require IRB approval. See **Preparing for a Study: Review and Finalization of Proposals and Contracts: Approval Process – Additional Approvals and Certifications** (**Chapter VI, Section D(2))** in the **Clinical Research Handbook**.

The IBC reviews Rascal hazardous material appendices for recombinant DNA (Appendix A), infectious agents (Appendix B) and human materials or other potentially infectious materials (OPIM) (Appendix C). Protocol review typically occurs after a grant has been awarded. Some grant proposals require a statement of Biohazard and Recombinant DNA Assurance. Please contact biosafety@columbia.edu concerning such requests.

Select agents are pathogens and toxins that have been declared by HHS or by the U.S. Department of Agriculture (USDA) to have a "potential to pose a severe threat to public health and safety" (http://www.selectagents.gov/). Any intention to use select agents in research must be reported by answering the select agent question in the Rascal proposal tracking module. Research with some select agents such as tetrodotoxin is permitted without registering with the select agent program, provided that the inventory of the toxin is maintained below prescribed thresholds. Please contact biosafety@columbia.edu for guidance.

Dual Use Research of Concern (**DURC**) is life sciences research that can be reasonably anticipated to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals the environment, material or national security. PIs must review the of Columbia University Policy For Institutional Oversight of Life Sciences Dual Use Research of Concern and self-screen their research. Review of potential DURC is performed by the IBC and an ad hoc committee convened by the EVPR.

Controlled Substances

The use of controlled substances in research activities is regulated by both federal and state law. In addition, the University has adopted the Columbia University Policy for the Acquisition, Use and Disposal of Controlled Substances in Research (the **Controlled Substance Policy**), which covers *in vitro* and animal studies. A **controlled substance** is

a drug or other substance, or immediate precursor, listed in any of the Schedules I-IV of the federal Controlled Substances Act (21 USC 801-971) or the New York State Controlled Substances Act (NY Public Health Law, Article 33).

The University does not hold an institutional license for the use of controlled substances in research. Instead, any person who uses controlled substances must (a) be licensed with the New York State Department of Health **(DOH)** and registered with the federal Drug Enforcement Administration (**DEA**) in the Department of Justice or (b) authorized under the license of licensed individual. Typically the PI is the individual who is licensed and he/she can authorize members of his/her research staff as needed.

All purchase requisitions for controlled substances must be processed through the University's Procurement Department. Purchase orders for controlled substances must be accompanied by the purchaser's DOH license, DEA registration and a copy of his/her Rascal training certificate evidencing completion of *TC0502: Controlled Substance Use and Management in Research*. See **Training: Mandatory Training – Environmental Health and Safety (Chapter III, Section C(5))** for further information on this course.

PIs working with controlled substances in research involving animal models must complete Appendix I in Rascal to describe the use and management of such materials. The Appendix will be attached to the applicable IACUC protocol.

Certificate of Environmental Compliance

A number of granting agencies require specific documentation of compliance with federal, state and local environmental and occupational health and safety regulations. EH&S will approve compliance statements (e.g., Certificates of Environmental Compliance) after confirming that a PI's laboratory is operating in accordance with such regulations and University policies. See http://www.ehs.columbia.edu/grantsredux.html for additional information on submitting a Certificate of Environmental Compliance for approval.

6. Radiation Safety

All research involving the use of radioactive material (**RAM**) or sources of ionizing radiation (such as x rays, CT scans, etc.) for research purposes must be approved by a Radiation Safety Officer and, if the research involves human subjects at CUMC, NYP or NYSPI, the Human Use Subcommittee of the Joint Radiation Safety Committee or in certain cases, the Radioactive Drug Research Committee. Application forms for the non-human, non-animal use of RAM or radiation sources can be accessed at www.ehs.columbia.edu/RadiationFormsMC.html. Application forms for the use of radiation in animal studies and for the use of radiation in humans can be accessed in Rascal at https://www.rascal.columbia.edu/. The attachment of an Application to the IRB Protocol initiates the JRSC or RDRC review process. A description of the application and the application review process can be found in **Preparation of Applications (Chapter V)** in the **Research Radiation Safety Handbook**

Radiation safety training requirements are outlined in **Training: Mandatory Training – Radiation Safety (Chapter III, Section C(6))**. See also **Preparing for a Study: Review and Finalization of Proposals and Contracts: Approval Process – Additional Approvals and Certifications** (**Chapter VI, Section D(2))** in the **Clinical Research Handbook**.

7. Human Embryos and Embryonic Stem Cells

There are limitations on the use of federal funds for research involving human embryos or human embryonic stem cells (**hESC**). Since 1996, the so-called Dickey Amendment has prohibited the use of federal funds for (a) the creation of a human embryo for research purposes or (b) research in which a human embryo is destroyed, discarded or knowingly subject to greater than minimal risk.

In 1991, President Bush restricted the use of federal funds for all research involving hESC other than hESC belonging to a small number of approved cell lines. This prohibition was somewhat relaxed by President Obama in Executive Order 13505 (March 9, 2009), which was implemented in 2009 through new NIH Guidelines for Human Stem Cell Research. Under these Guidelines, research involving hESC may be conducted with federal support if such cells are derived from cell lines that are listed on a NIH Registry or approved by the NIH pursuant to the Guidelines. Lines that are registered can only be obtained from discarded embryos that have been donated for research following strict disclosure requirements.

The following research may not be conducted with federal support, but may be conducted with non-federal funding:

- Research in which hESCs (even if derived from embryos donated in accordance with the Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts
- Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with the Guidelines) or human induced pluripotent stem cells may contribute to the germ line
- Research involving the derivation of hESC from human embryos
- Research using hESCs derived from other sources, including somatic cell nuclear transfer, pathenogenesis and/or IVF embryos created for research purposes.

In addition to any requirement for IRB review, the University requires that all proposals that involve the derivation or use of human embryos or hESC be approved by the University's Human Embryo and Human Embryonic Stem Cell Research Committee (the **Stem Cell Committee**) prior to the commencement of such research. The Committee reviews both ethical and regulatory considerations and requires submission of an abstract describing the research.

For further information, see the University's Policy on Research Involving Human Embryos and Human Embryonic Stem Cells.

8. International Research and Export Controls

The University supports and encourages international research and service and is committed to helping investigators address and manage the special requirements and risks involved in international projects. These projects are governed by the laws of both the United States and the country in which the activities will take place, and may be regulated by a variety of U.S. and internationally-based government agencies, such as the Departments of State, Commerce and Treasury. Managing these requirements may add unexpected costs to the project and may take specialized knowledge.

To help researchers plan for risks and requirements that may be associated with international projects, the University has established International Research and Service Projects: Risk Management Procedures. In addition to enabling the project team and the University to identify and manage risks, the Procedures assist the University in developing databases and other resources for the University community, including a central repository of information relating to international projects.

International projects often involve additional costs, including the cost of retaining local counsel, fees associated with obtaining necessary permissions, filing local reports, and fulfilling other requirements. SPA, SPF and the Office of the General Counsel (**OGC**) may be able to help with anticipating and estimating such costs for budget preparation.

The following sections summarize certain key laws and regulations that may apply to the conduct of international research or collaborations with non-U.S. researchers. Penalties for violation of these regulations are severe, and can include civil and criminal penalties for both the University and individuals. Additional information is available on the RCT website, http://www.columbia.edu/cu/compliance/docs/international_research/index.html.

The Finance Gateway Global Support website provides a central point of access for information, guidance and resources to help facilitate international activities, travel or program administration: http://finance.columbia.edu/departments/global-support.

U.S. Sanctioned Countries and Specially Designated Nationals

The Treasury Department's Office of Foreign Assets Control (**OFAC**) administers and enforces economic sanctions imposed by the United States against foreign countries. These sanctions may require obtaining OFAC approval before conducting research or other activities in or involving the sanctioned country. Some sanctioned regimes are more restrictive than others, and apply to the whole country, while other regimes are more targeted against certain individuals or entities in a country. Currently, sanctioned countries include the following (most restrictive sanctions regimes are in bold):

- Balkans

- Belarus
- Burundi
- Central African Republic
- **Crimea Region of Ukraine**
- **Cuba**
- Democratic Republic of the Congo
- **Iran**
- Iraq
- Lebanon
- Libya
- **North Korea**
- Somalia
- **Sudan** (**North**)
- South Sudan
- **Syria**
- Ukraine/Russia
- Venezuela
- Yemen
- Zimbabwe

The list of sanctioned countries is updated periodically and is available at http://www.treasury.gov/resource-center/sanctions/programs/pages/programs.aspx. Any project involving activities in an OFAC-sanctioned country must be reviewed by the University's International Research Committee.

OFAC can designate persons and entities (including persons and entities in the United States) as **Specially Designated Nationals** or **SDN**s. OFAC designates persons and entities as SDNs for narcotics trafficking, weapons proliferation and other reasons. The University, its personnel and U.S. persons are prohibited from engaging in transactions with SDNs, and property of SDNs must be "blocked." In addition to the SDN List, OFAC maintains other sanctions lists (**Non-SDN Lists**). As with SDNs, the University, its personnel and U.S. persons are prohibited from engaging in transactions with persons and entities listed on OFAC's Non-SDN Lists.

OFAC's SDN and Non-SDN Lists appear on OFAC's website, available at http://www.treas.gov/about/organizational-structure/offices/pages/Office-of-Foreign-Assets-Control.aspx. When entering into discussions with a proposed collaborator, it is critical to check OFAC's lists for the name of the person or entity with whom or which you are dealing. OGC and RCT can provide guidance on how to complete such checks.

U.S. Export Controls on Transferring Information, Items and Software

The Departments of State and Commerce each administer its own export control regulations. Export control regulations determine the conditions under which certain information, items and software can be transmitted overseas to individuals, including

U.S. citizens, or to a foreign national on U.S. soil. The Department of State regulations are entitled the International Traffic in Arms Regulations (**ITAR**); Department of Commerce regulations are entitled the Export Administration Regulations (**EAR**). The ITAR applies to transfers of military or defense related items, software and information, while the EAR apply to transfers of commercial or "dual use" items, software and information.

Under the ITAR and/or EAR, if research involves export-restricted information, items or software, the University may be required to obtain prior federal approval before allowing foreign nationals to participate in the research, partnering with a foreign entity or sharing export-restricted information in any manner (including by publication or presentation at conferences) with persons who are not U.S. citizens or legal permanent residents. Export controls may also limit the ability to transport equipment needed for experiments or research conducted abroad. If anyone at Columbia receives information identified by a third party as "export controlled," the information should not be disclosed to any non-U.S. persons, including international students, without prior review by RCT. If Columbia personnel receive ITAR controlled items or software, contact RCT to determine how to proceed.

Export regulations apply whether or not the research is funded by a federal or non-federal grant, contract or other agreement, and apply whether or not the ITAR or EAR are cited in the award document. If a researcher accepts export-controlled technology or information, items or software from a government agency or from industry, the researcher is subject to ITAR or EAR regulations.

The research results generated by University research activities may be excluded from export controls because of a general exemption for "fundamental research" under the export control regulations. By not accepting any restrictions on publication or participation of foreign nationals in its research grants, Columbia protects the fundamental research exemption. Consequently, faculty members who wish to make their research available worldwide should decline public and private sector funding conditioned on prepublication approval by the sponsor, restrictions on the citizenship of those who work on the research project and/or nondisclosure restrictions/agreements.

RCT, SPA and OGC will assist you in complying with export control laws, but the primary responsibility rests with the PI.

International Boycotts not Supported by the United States Government

U.S. federal regulations also prohibit the University or its personnel from agreeing to participate in any international boycott not supported by the U.S. government, such as the Arab League boycott of Israel. Violation of these regulations could result in fines being imposed by the U.S. government.

These regulations are broad and complex and encompass, for example: (a) agreements not to do business with a distributor with Jewish employees; (b) agreements to stamp an

invoice with the statement "We certify that goods are not of Israeli origin;" (c) agreements to comply with the boycott laws of a boycotting country and (d) letters of credit with the notation that "the goods cannot be shipped on a vessel that calls at Israeli ports."

Under certain circumstances even the receipt of a request to cooperate in a boycott must be reported to the U.S. government. Boycott-related requests involving any of these activities may be oral or written, and may appear as provisions in a proposed bid invitation, contract, purchase order, letter of credit, research or other agreement that calls for boycott-related information or action. The Commerce Department's Office of Antiboycott Compliance (https://www.bis.doc.gov/index.php/enforcement/oac) posts examples of boycott requests as well as other useful information regarding antiboycott regulations.

If Columbia personnel receive a boycott related request, immediately contact OGC before responding further to the request. OGC will advise you on how to proceed, and assist in filing any required reports with the Department of Commerce.

In addition, the Internal Revenue Service (**IRS**) maintains a separate set of boycott rules and regulations that require annual reporting of operations in or related to boycotting countries, as well as receipt of, and action in response to, boycott requests. These laws deny some foreign tax benefits to persons who cooperate with certain boycott requests. It also requires annual reporting by Columbia (not the individual Columbia employee) of business activities in boycotting countries. The Treasury Department publishes a list of boycotting countries in the Federal Register each quarter. This list currently includes:

- Iraq
- Kuwait
- Lebanon
- Libya
- Qatar
- Saudi Arabia
- Syria
- United Arab Emirates
- Yemen

If Columbia personnel are engaging in any operations in or related to boycotting countries, report such operations to the Tax Director of the Controller's Office. The IRS defines "operations" broadly to include purchasing, leasing, financing, extracting, constructing, transporting, contract negotiating, site selecting and other activities. Operations must be reported even if no boycott requests are received.

The Foreign Corrupt Practices Act (FCPA)

U.S. law also contains provisions related to anti-corruption, including rules for handling transactions and rules related to keeping of accounts and records. For example, the FCPA makes it unlawful to offer something of value to foreign government officials in order to obtain or retain business, direct business to a particular party or otherwise obtain an unfair advantage. The business to be obtained or retained need not be with a foreign government or foreign government instrumentality, but may be private.

Columbia personnel may not offer or make payments to a foreign official with the intent of:

- influencing the individual's acts or decisions;
- inducing the individual to violate his or her lawful duty;
- obtaining any improper advantage; or
- inducing the foreign official to use his or her influence improperly.

The prohibited payments need not only be monetary, but may consist of *anything of value* (including, for example, meals or other gifts).

The University's Anti-Corruption Policy is available at http://policylibrary.columbia.edu/columbia-university-anticorruption-policy. For more information about the FCPA, a "Resource Guide to the FCPA" is available on the Department of Justice website at https://www.justice.gov/criminal/fraud/fcpa/guidance/guide.pdf. If you have questions about the FCPA, you should consult with OGC.

Other Laws and Regulations

In addition to the laws and regulations outlined above, a number of other laws could also apply, including U.S. laws, host country laws and international treaties. RCT, SPA and OGC can help with navigating these complex areas.

9. NewYork-Presbyterian Hospital

In additional to any other approvals required by the University, any sponsored project proposal that involves hospital resources must be approved by an authorized signatory at NYP through Rascal PT.

10. Subawards

As the recipient of an award for a sponsored research project, the University may award financial assistance to a subrecipient to facilitate performance of, and payment for, specific work to be conducted for the sponsored project. A subaward may be made by the University as the recipient of a primary award or as the subrecipient of another institution's primary award. Subawards are governed by the University's Policy on Sponsored Project Subawards (the **Subaward Policy**).

Subawards are awards of financial assistance only and do not include the following:

- technical assistance that provides services rather than money;
- loans, loan guarantees, interest subsidies or insurance;
- direct payments of any kind to individuals; or
- contracts that are required to be entered and administered under procurement laws or regulations.

It is University policy that subawards are funded for a maximum of one year, renewable for additional periods as appropriate. All modifications to existing subawards must be negotiated with the subrecipient and are dependent on the continuation of the primary award to Columbia.

In accordance with federal regulations, it is University policy that the University awardee must perform a substantive role in carrying out the activities of a project and not merely serve as a conduit for an award to another party. It is expected that the aggregate amount payable under all subawards issued under a prime award to the University should not exceed 50% of the total award amount.

As a condition of its acceptance of funding from a sponsor, the University is obligated in its role as primary recipient to undertake certain stewardship activities and to ensure compliance with the restrictions placed upon the primary award by the sponsor. In addition, the University remains responsible to the sponsor for managing funds and meeting performance goals.

The University's stewardship activities include the following:

- Prior to granting a subaward, the University will assess the potential subrecipient's organizational and financial status and internal controls as well as the terms of the proposed subaward agreement and will establish conditions for the subaward consistent with the level of risk perceived.

- The University will advise the subrecipient of all appropriate flow-down provisions from the primary award, all relevant University policies and, if such subrecipient is a non-U.S. entity, all applicable U.S. laws and regulations.

- The University will, on an ongoing basis throughout the life of the award, monitor the activities of a subrecipient under the subaward in accordance with the subaward agreement to ensure that awarded funds are used for authorized purposes and that performance goals are achieved.

SPA is responsible for processing all subawards resulting from sponsored projects other than industry sponsored clinical research or clinical trial subawards, which are processed by the CTO, and subawards under SRAs negotiated and executed by CTV, which are processed by CTV. SPA and the CTO, in collaboration with RPIC, will assess a potential

subrecipient's risk to manage sponsored project funding, in accordance with the Subaward Policy.

In general, a subrecipient must have its own policy on FCOI and research. For projects funded by PHS, the subrecipient's policy must comply with the PHS regulations. More information about FCOI requirements for PHS subrecipients is available at: http://www.columbia.edu/cu/compliance/pdfs/FCOI_FAQs.pdf.

Requirements Prior to or At Time of Proposal Submission

Prior to the submission of a proposal for a sponsored project that has subawards (or, if the subaward is not known at the time of the submission, prior to the execution of the subaward agreement), the PI is required to provide his/her SPA or CTO Project Officer with certain information and/or documentation about the proposed award. See **Review Process: Non-Industry Sponsored Research** (**Section B(1))** above.

In accordance with the University's Subaward Policy, SPA will determine if the University has entered into prior subawards with the proposed subrecipient. If the University (a) has never entered into a subaward with the proposed subrecipient or (b) has entered into a subaward with such subrecipient, but such subaward ended more than three years ago, SPA will collaborate with RPIC to conduct a risk assessment of the proposed entity. Details of the risk assessment are included in the Subaward Policy.

If the proposed subrecipient has not negotiated an indirect cost rate with the federal government, the parties will agree that the de minimis indirect cost rate (as defined in Section 200.414 (Indirect (F&A) Costs**)** of the Uniform Guidance)) or a rate set under specific sponsor guidelines will be applicable to the subaward during proposal submission, and if the proposal is awarded.

Establishment of Subaward

Following the receipt of a notice of award and prior to the execution of the subaward, SPA will ensure that all applicable laws and regulations and terms and conditions of the primary award are included in the subaward agreement. Additional requirements may be imposed on a subrecipient that is deemed to be high-risk as a result of the risk assessment. If the award is funded by PHS, the PI must submit to SPA a Follow Up Subrecipient FCOI Policy Confirmation Form or an Exception Form, as applicable. For more details on the issuance of subawards, see the Subaward Policy.

11. NSF Postdoc Mentoring Requirements

All NSF grant applications that include funding support for postdocs are required to include a mentoring plan for postdocs. Examples of mentoring activities include: career counseling; training in preparation of grant proposals publications and presentations; guidance on how to effectively collaborate with researchers from diverse backgrounds and disciplines; and training in responsible professional practices. Proposals that do not

include a separate section on mentoring activities within the grant proposal will not be reviewed by the NSF.

For further information, including web links, on how to prepare a mentoring plan, see the Memorandum, dated December 2008, on NSF Postdoc Mentoring Requirement that is available on the OPA website (http://postdocs.columbia.edu).

12. Model Organisms

All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a concise plan addressing the timely distribution of organisms and resources or an explanation as to why sharing is not possible. The term **model organism** includes mammalian models, such as mice and rats, and non-mammalian models, such as budding yeast, social amoebae, roundworms, Arabidopsis, fruit flies, zebrafish and frogs. Genetically modified organisms are those in which mutations have been induced by chemicals, irradiation, transposons or transgenesis (e.g., knockouts), those in which spontaneous mutations have occurred and congenic or consomic strains.

See NIH Model Organism for Biomedical Research website http://modelorganisms.nih.gov/ and the NIH Model Organism Sharing Policy at http://grants.nih.gov/grants/policy/model_organism/.

13. Special Approval Summary Chart

The following chart summarizes the special approvals and provides links to websites where more detailed information can be obtained.

Type of Research	Requirement	Timing	Mechanism	More Information
All Research	FCOI report filed by all individuals who are in a position to influence the design, conduct or reporting of the research.	Up-to-date report must be filed before a proposal is submitted.	File Annual FCOI Reports in Rascal. https://www.rascal.columbia.edu/coi	Office of Research Compliance and Training – Conflict of Interest http://www.columbia.edu/cu/compliance/docs/conflict_interest/index.html
All Research	FCOI resolution	Before research begins; before any award money is spent.	Conflict of Interest Committee review of potential conflicts; compliance with Committee determinations.	Office of Research Compliance and Training – Conflict of Interest http://www.columbia.edu/cu/compliance/docs/conflict_interest/index.html
Research with Human Subjects	Approval by the IRB	Before research begins. For NIH, around "just in time" notification.	Submit protocol to the IRB through Rascal. https://www.rascal.columbia.edu/irb	Institutional Review Board http://www.cumc.columbia.edu/dept/irb http://www.columbia.edu/cu/irb/
Research with Human Subjects	Protocol-specific FCOI report filed by all "key personnel" involved in the proposed research.	Up-to-date report must be filed before a proposal is submitted.	File protocol-specific FCOI report in Rascal when prompted.	Office of Research Compliance and Training – Conflict of Interest http://www.columbia.edu/cu/compliance/docs/conflict_interest/index.html
Research with Animals	Approval by the IACUC	Before research begins. For NIH, around "just in time" notification.	Submit protocol to the IACUC through Rascal. https://www.rascal.columbia.edu/iacuc	IACUC http://www.cumc.columbia.edu/dept/iacuc/

Type of Research	Requirement	Timing	Mechanism	More Information
Research Involving rDNA, rRNA, potentially infectious tissues, gene transfer	Approval by the IBC	Before research begins. Some research permits IBC notice simultaneous with the initiation of a study.	Contact Biological Safety Officer in EH&S at (212) 305-6780	Office of Environmental Health & Safety http://ehs.columbia.edu/recombdna.html
Dual Use Research of Concern (DURC)	Review by the IBC and ad hoc committee and the EVPR	Before research begins	PI reviews DURC Policy, self-screens research and notifies biosafety@columbia.edu of any suspected DURC activities	DURC Policy http://evpr.columbia.edu/files/evpr/pdf/DURC%20Policy%20February%202015%20Final.pdf
Research Involving Radioactive Materials	Approval by the RSC (Morningside) or the JRSC or RDRC (CUMC)	Before research begins	At CUMC: Contact Radiation Safety Office at (212) 305-0303 At other campuses: Contact Radiation Safety Office at (212) 854-8749	At CUMC: Radiation Safety Office http://www.ehs.columbia.edu/rs.html At other campuses: Radiation Safety Office http://www.ehs.columbia.edu/rs.html
Research with Human Embryos and Human Embryonic Stem Cells	Approval by the Stem Cell Committee	Before research begins.	Submit abstract and protocol to the Office of the EVPR.	Policy on the Conduct of Research with Human Embryos and Human Embryonic Stem Cells http://evpr.columbia.edu/files/evpr/pdf/Stem_Cell_Policy_07-07-14.pdf

Type of Research	Requirement	Timing	Mechanism	More Information
International Research	For research meeting certain criteria, approval by International Research Committee	Before proposal is submitted; further analysis post-award.	Provide information to SPA to CTO project officers.	Office of Research Compliance and Training – International Research http://www.columbia.edu/cu/compliance/docs/international_research/index.html
Research Using NYP Resources	Approval by NYP.	Before proposal is submitted.	Route protocol through Rascal PT.	
All Research	Key personnel must complete effort reporting requirements, including annual effort certification.	Before proposal is submitted.	Complete annual effort certification at https://ecrt.columbia.edu	Office of Research Compliance and Training-Effort Reporting www.effortreporting.columbia.edu
NSF Research Using Postdocs	Mentoring plan	Before proposal is submitted	Include in proposal	Office of Postdoctoral Affairs http://postdocs.columbia.edu

F. Public Access Policies

In the Increasing Access to the Results of Federally Funded Research policy memorandum released in February 2013, the White House's Office of Science and Technology Policy (**OSTP**) directed federal agencies to develop plans to make the publications resulting from federally funded research freely available to the public within one year of publication, and required researchers to better account for and manage the digital data resulting from federally funded scientific research with the goal of making these data publicly accessible as well.

As of the date of this Handbook, the federal agencies continue to roll out their public access implementation plans. A summary table provided by the Scholarly Communication Program of the Columbia University Libraries outlines the federal agencies that have made their implementation plans public. See http://scholcomm.columbia.edu/open-access/public-access-mandates-for-federally-funded-research/.

Note that each agency has a different date as of which its public access mandate is effective, in addition to varying requirements for complying with their policies. Public access of publications and digital data will be stated in the funding announcement and the terms and conditions of the Notice of Grant Award issued by the federal agency.

NIH Public Access Policy

The NIH Public Access Policy, which became effective on April 7, 2008, ensures that the public has access to the published results of NIH funded research. This Policy applies to the final manuscript of any peer-reviewed publications, such as journal articles, research reports and reviews that result from NIH funding, regardless of the amount. To determine manuscript applicability, go to http://publicaccess.nih.gov/determine_applicability.htm.

Under the Policy, any investigator publishing a peer-reviewed article that results from NIH funding must:

- Upon submission of the article, notify the publisher that it is subject to the NIH Public Access Policy
- Upon acceptance of the article, ensure that the publication agreement reserves the right to send the manuscript to PubMed Central
- Upon publication of the article, submit the final manuscript to PubMed Central
- Upon the investigator's next proposal submission to NIH, include the PubMed Central identification number (called a **PMCID**) for previous NIH-funded articles, demonstrating compliance with the Policy
- Applicants citing articles in NIH applications, proposals and progress reports that fall under the Policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIH Manuscript Submission

System Identification Number (**NIHMSID**). The NIHMSID may be used to indicate compliance with the Policy in applications and progress reports for up to three months after a paper is published. After that period, the PMCID must be provided to demonstrate compliance.

- Investigators must use My NCBI (National Center for Biotechnology Information) to manage all citations to be included in progress reports. See http://www.ncbi.nlm.nih.gov/sites/myncbi/

The investigator submitting the article and signing the publication agreement will need to ensure compliance with the Public Access Policy, but the PI has overall responsibility for this and all other requirements of sponsored projects, whether or not the PI is an author on the publication in question.

The University Libraries Scholarly Communications Program and SPA have developed the expertise to address questions relating to Public Access (http://scholcomm.columbia.edu/open-access/nih-public-access-policy and http://spa.columbia.edu/nih-public-access-policy).

In addition, NIH has developed significant resources on the topic. See http://publicaccess.nih.gov and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-160.html.

NIH will delay processing of a Notice of Grant Award if publications arising from the award are not in compliance with the Public Access Policy. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-042.html. To avoid delays, it is important to communicate with the publisher the need to comply with the policy **at the time of manuscript submission**. Refer to the NIH Public Access Policy Tips Sheet at http://spa.columbia.edu/nih-public-access-policy to avoid award delays.

G. Submitting a Proposal

Proposals are submitted to the sponsor either in paper format or electronically. Each sponsor has its own requirements for how proposals should be submitted; SPA Project Officers can assist PIs and DAs in making sure the correct procedures are followed. All proposals, whether to be submitted in paper format or electronically, should be submitted to SPA five business days before the sponsor's deadline. See **Deadlines for Non-Industry Sponsored Research** (**Section C)** above.

See **Review Process** (**Section B)** above for the items that are required to be submitted to SPA prior to the submission of a proposal to the sponsor.

1. Paper Submissions

SPA Project Officers review proposals against the sponsor's guidelines. In addition to a thorough review of the budget for accuracy and allowability of costs, the reviewer checks

for page limitations, font size and margins, and ensures that all required forms are included in the application.

Once a proposal has been reviewed and signed by the appropriate Authorized Signatory in SPA, the Project Officer notifies the PI or DA that the proposal is ready for mailing; it is the responsibility of the PI or DA to mail the proposal. Note that some sponsors have specific requirements with respect to the number of copies sent and how attachments are included.

A copy of the signed proposal is maintained in SPA until the proposal is no longer pending (generally, two years after the submission date).

2. Electronic Submissions

A number of sponsors, both governmental and non-governmental, require electronic submission of proposals. These electronic proposal submission processes can be demanding, particularly the first time a PI uses them. Prior to the first submission of a proposal using any form of electronic proposal submission, the PI is strongly encouraged to contact his/her SPA Project Officer for assistance. In addition, the PI may need to have Adobe Acrobat and pdf capability on his or her computer or a first time investigator may need to register with the site prior to submission. SPA Project Officers can assist with this.

Note that, for every electronic submission of a non-industry sponsored proposal, SPA needs a finalized approved Rascal PT Record, just as would be needed for a paper proposal.

There can be major problems getting access to an agency's server on the day of a deadline. SPA must approve the proposal before it can be submitted, so allow time for its review and approval. SPA reviews a very large volume of applications at deadline dates. Therefore it is strongly suggested that applications be submitted well, and no later than five business days, before the deadline to allow for sufficient review. Failure to do so may jeopardize the timely submission of the application.

Grants.gov

Grants.gov is a web-portal used to submit applications for opportunities offered by 25 federal grant-making agencies. To prepare a grant, there are several electronic options as described in later sections (i.e., InfoEd, Adobe Forms, etc.). Applications submitted by your SPA Project Officer through the Grants.gov portal are validated and then forwarded on to the respective funding agency (i.e., NIH, DOD, etc.). Currently, most NIH, AHRQ and HRSA applications are required to be submitted through Grants.gov. New opportunities and mechanisms are added frequently, so it is important to read the sponsor’s RFA or RFP very carefully for application submission instructions.

Note that Columbia is considered the applicant and is the registered entity with Grants.gov. There is no need for an individual PI to register with Grants.gov. Contact your SPA Project Officer with any questions. For more information on Grants.gov, go to www.Grants.gov

InfoEd Proposal Development (PD)

InfoEd PD electronically facilitates the preparation, review and submission of grant applications. While it is currently being used primarily for specific NIH proposals that are required to be submitted electronically through Grants.gov, other grant applications are being added over time and InfoEd PD now supports applications to a variety of federal agencies including DOE, DOD, AHRQ and HRSA. Please check with the InfoEd Help Desk (212-851-4368 or SPA-eBiz@columbia.edu) if you have any questions about using InfoEd PD.

Adobe Forms

If you are not using InfoEd PD to submit your application for federal funding via Grants.gov, you will need to use Adobe software to prepare your application. You are encouraged to check the requirements of your specific funding announcement to ensure that you are using the format and most recently revised forms required for your specific application.

Information on supported software and download instructions can be found at http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html.

Additional instructions on how to download and use the Adobe forms can be found at http://www.grants.gov/web/grants/applicants/apply-for-grants.html .

If you have any questions, please contact your SPA Project Officer for assistance.

NIH ASSIST

Another option for proposal development and submission is the Application Submission System & Interface for Submission Tracking (**ASSIST**) used to prepare and submit grant applications electronically to NIH and other PHS agencies. Active Grants.gov and eRA Commons credentials are required to prepare and submit applications using ASSIST. For more information, see http://spa.columbia.edu/electronic-systems/assist.

NSF FastLane

FastLane is web-based system used for information exchange and business transactions between NSF and its client community of investigators and administrators. Through FastLane, the NSF community can apply for grants, review proposals and perform some administrative functions related to awards and proposals. For the vast majority of its opportunities, NSF offers applicants the choice of Grants.gov or FastLane for submitting

applications. In addition, any proposal involving more than one organization must use FastLane. Read your program announcement carefully to ensure you are using the correct submission mechanism.

PIs and co-PIs must be registered through Columbia and have a password to access FastLane. To request an account, visit the SPA website, http://spa.columbia.edu/electronic-systems/nsf-fastlane and register for an account.

For more information on NSF FastLane, go to https://www.fastlane.nsf.gov/. If you are unsure how to proceed, contact your SPA Project Officer.

proposalCENTRAL

There are a number of sponsors who require the use of proposalCENTRAL for grant submissions, such as the American Cancer Society and the Burroughs Wellcome Fund. It is an e-grant making website shared by many government, non-profit and private grant-making organizations.

If you are working on an application that requires the use of proposalCENTRAL, contact your SPA Project Officer to ensure that you are registered.

For more information on proposalCENTRAL, go to: https://proposalcentral.altum.com/

H. Just in Time/Additional Information Requested

Many sponsors, including NIH, DOD and Centers for Disease Control, no longer require that all approved compliance materials be submitted with the proposal. These materials, along with revised budgets and/or other items, are now requested just prior to the anticipated awarding of the funding, or "Just in Time" (**JIT**) for funding. Applicants may not submit JIT materials directly to the sponsor, nor can they submit the JIT items until such time as they are requested by the sponsor. Typically, items requested include:

- Updated information on other support. Note that "other support" includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research, including grants, cooperative agreements, contracts and institutional awards, but excluding training awards, prizes or gifts.
- If human subjects are involved, IRB approval date and assurance number.
- If vertebrate animals are involved, IACUC approval date and assurance number.
- If human subjects are involved, a certification that all individuals listed as Key Personnel in the grant application have completed an educational program on the protection of human subjects.
- If requested, a revised budget.

NIH JIT materials are uploaded to the eRA Commons by the PI and, once they have been reviewed by the SPA or CTO Project Officer, he/she will provide the institutional endorsement required by the sponsor.

Note that JIT notification is not a guarantee that an award will be made and only indicates that your application is being considered for funding.

Keep in mind when submitting other support information that the sponsor will review such information before an award is made to ensure the following:

- Sufficient and appropriate levels of effort are committed to the project.
- There is no scientific, budgetary or commitment overlap.
    - Scientific overlap occurs when (a) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (b) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
    - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application, but are already provided by another source.
    - Commitment overlap occurs when an individual's time commitment exceeds 100%, whether or not salary support is requested in the application.
- Overlap, whether scientific or budgetary, or commitment of an individual's effort greater than 100%, is not permitted. Any overlap will be resolved by the sponsor with the applicant and the PI at the time of award.
- Only funds necessary to the approved project are included in the award.

For more information about JIT procedures using eRA Commons, see: http://era.nih.gov/services_for_applicants/application_tracking_and_award/just_in_time.cfm.

Please note that a PI remains responsible for notifying the sponsor of any substantive changes to previously submitted JIT information up to the time of award. This includes items such as other support changes that could lead to budgetary overlap, scientific overlap or commitment of effort greater than 12 person-months for the PI or any changes in the use or approval of vertebrate animal or human subjects.

VII. INITIATING A SPONSORED PROJECT AWARD

A. Introduction

Upon receipt of an award by SPA, a sponsored project is created in the University's financial system, Accounting and Reporting at Columbia (**ARC**). Establishing a sponsored project in ARC is necessary to make purchases to carry out the terms and conditions of an award, to segregate expenses, create a mechanism for billing sponsors and to generate reports to monitor financial activity. This chapter will review the policies for setting up a sponsored project in ARC, describe the considerations in accepting a sponsored award and provide resources for more detailed information on ARC.

B. Award Notification

A Notice of Grant Award (**NGA**) is a generic name for any of the various documents (including contracts) that sponsors send to notify the University formally of the terms and conditions of an award. NGAs are issued for both new grants and continuations. The NGA is typically received by SPA, although on occasion a PI may be notified directly. The NGA often requires the signature of an authorized University official. In the case of most federal awards, acceptance of the award is indicated when SPF draws down funds from the respective federal payment management system.

Should you receive a NGA directly, it should be immediately forwarded to one of the following central email boxes: CUMC – grants-office@columbia.edu
Morningside campus – ms-grants-office@columbia.edu

A typical NGA includes:

- Application/grant identification number
- Name of the grantee organization
- Name of the PI(s)
- Name(s) of the senior/key personnel who are subject to prior approval requirements if a significant change in level of effort occurs
- Approved project period and budget period start and end dates
- Amount of funds authorized for obligation by the grantee
- Amount of anticipated future-year commitments (if applicable)
- Names of the sponsor's contacts, which typically includes a Program Official for scientific concerns and a Grants Management Officer or Specialist for policy and administrative concerns.
- Applicable terms and conditions of award, either by reference or inclusion.
- Any restriction on the use of funds

For more information about federal NGAs, see Section 200.210 (**Information Contained in a Federal Award**) of the Uniform Guidance.

C. Can You Accept This Award?

1. Terms and Conditions

Before accepting an award on behalf of the University, the SPA Project Officer reviews all of its terms and conditions, regardless of the sponsor, and is responsible for negotiating appropriate remedies if an award fits into one of the following categories:

- It contains provisions that are incompatible with the University's policies on sponsored research;
- It is inconsistent with government-wide regulations for universities;
- It fails to include all elements agreed upon prior to the award; or
- It requires modification to conform to the PI's needs.

The award may have additional terms and conditions that may specify such things as key personnel, limitations on availability or use of funds, need for prior approvals and similar additional oversight by the awarding agency. It is critical to understand these restrictions before incurring costs. The PI and SPA must take note of these requirements in addition to reading all referenced documents within the award notice.

The basic objective of almost all award negotiations is to ensure that the University and the PI do not relinquish the right to make the ultimate decisions on the manner in which the research is to be conducted or the results disseminated. Guiding principles are both academic and financial. On behalf of the PI, the University seeks to guarantee that the sponsor cannot unilaterally amend, suspend or terminate the project; that there be no prohibition on the publication of results; and that the ownership or control of intellectual property resulting from the research not be relinquished.

Other matters that may require negotiation concern the handling of confidential information, and/or conditions on the disclosure of some or all research findings. Publication delays to allow the sponsor to determine whether its confidential information has been disclosed or to determine whether intellectual property requires protection (i.e, filing patent applications) are permissible, but should not exceed 60 days.

These same provisions apply to clinical trial agreements in industry sponsored clinical trials and SRAs in industry sponsored non-clinical studies.

PIs or DAs are not authorized to sign award documents on behalf of the University.

2. Reductions in Budget and Rebudgeting

Very often, sponsors do not award the same total dollar amount as was originally requested in the grant application. However, the sponsor will still expect that the objectives of the originally proposed project will be met, regardless of a reduction of funds, including the originally proposed effort commitments. In such cases, the PI should

carefully consider how he/she will be able to meet the objectives on a reduced budget. Additional time and resources devoted to the project without additional funds from the sponsor is considered cost sharing. The PI should talk with his/her Chair or Dean to discuss resource options before accepting the award. He/She can also coordinate with his/her Project Officer to go back to the sponsor and propose a reduced scope of work which reflects the revised budget. Should you have questions about this, contact your SPA Project Officer.

It is not recommended that a cut of more than 25% from the proposed budget be accepted without going back to the sponsor and requesting a reduced scope of work or a reduction in the specific aims. Please contact your SPA Project Officer to discuss budget reductions that need to be discussed further with the sponsor.

After an account is established, approval of rebudgeting of funds on a sponsored project is the prerogative of the sponsor. Since policies differ from sponsor to sponsor, it is important that the rebudgeting policy of the awarding sponsor be reviewed.

For more information regarding rebudgeting during the life cycle of a grant, see **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Rebudgeting** (**Chapter VIII, Section F(2))**.

3. Effort Commitments

Prior to accepting an award, the PI should consider his/her overall time commitments. At the time a new project is awarded, the PI should confirm that the new award fits with other previous commitments, including teaching, clinical activities and other sponsored research. The PI should also confirm that the effort estimates included in the proposal still reasonably approximate the effort expected for the project. If any adjustments are needed, they should be made at this time.

During the JIT process for NIH grants (see **Review and Submission of a Sponsored Project Proposal: Just in Time Notification** (**Chapter VI, Section H**)), the PI must send the NIH documentation on other support, which includes all financial resources, whether federal, non-federal, commercial or organizational, available in direct support of his/her research endeavors, including, but not limited to, research grants, cooperative agreements, contracts or organizational awards. NIH will be reviewing other support documentation for commitment overlap. Commitment overlap occurs when an individual's time commitment exceeds 100%, whether or not salary support is requested in the application.

In order to not exceed 100% effort, effort on one project may need to be reduced in order to support the new project. This may require prior approval from the sponsor. Or, alternatively, time toward other University activities may need to decrease. If you have any concerns regarding commitment overlap, please contact your SPA Project Officer for guidance.

4. Scientific Overlap

Scientific overlap occurs when (a) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (b) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Prior to accepting the terms of a NGA, PIs should consider if there is any scientific overlap with other sponsored projects. NIH and certain other federal agencies review scientific overlap prior to issuing an NGA during the JIT process (see **Review and Submission of a Sponsored Project Proposal – Just in Time Notification** (**Chapter VI, Section H**)). PIs are responsible for reporting and resolving any overlap prior to accepting a new award. Should you need guidance, please contact your SPA Project Officer.

D. Account Setup and Modifications

The following definitions will help familiarize you with ARC terminology:

Project: A project is created by SPA when a sponsored project is awarded and all conditions to ensure compliance with University and sponsor regulations have been met. A project is set up in ARC to capture transactions associated with a specific funding source for the purposes of billing and reporting. A project must have a start and end date and is owned by a specific department. All projects are set up with **activities** to further define a budget period or scope of work. A project number will remain the same for the life of a competitive segment of an award.

Activity: At least one activity is required for each sponsored project in ARC. The activity further defines a budget period or scope of work and helps researchers and administrators manage their funding over the life of a project. For example, a complex project may include separate activities to easily identify separate budget periods and scopes of work or to separate the work of multiple departments contributing to one project. Unlike projects, multiple activities may be created throughout the life of a project, depending on its complexity and any restrictions and carryover funds from year to year.

Account: This term is used in ARC to refer to:

- **Budget account** – a category used for budgeting within activities (for example, "supplies")
- **Natural account** – the codes used to define detailed expenses or transactions within budget accounts (for example, "laboratory glass ware")

For more ARC terminology, you can refer to the Finance Glossary at http://finance.columbia.edu/glossary.

1. Non-Industry Sponsored Research

Requirements for Account Setup

SPA sets up all projects for newly awarded or continuing non-industry sponsored awards in InfoEd, which sends the information to ARC on a nightly basis. Your SPA Project Officer or Financial Analyst may contact you during account set up if there are questions concerning your budget, assurances, special terms and conditions or missing documentation.

New project numbers are issued for new awards or competitive renewals. Non-competing renewals, however, may or may not require the creation of new activity numbers from one budget period to the next. If (a) the award requires an annual financial report or (b) the use of any carry forwards requires the prior approval of the sponsor, a new activity will be opened for each non-competing year. This will ensure that the Controller's Office completes an accurate financial report, and that the department does not inappropriately spend carry forward without sponsor approval.

Setting Up Accounts

The following documents are necessary for account setup. Your Financial Analyst will contact you if any of the following items are missing:

New Awards, Competing Awards and Contracts

- NGA or fully executed contract
- Copy of original application (if applicable)
- Finalized Rascal PT Record – electronically signed by relevant parties, with up-to-date FCOI disclosure and certification and approval information
- FCOI certification from subcontractors or consultants (if applicable)
- Notice of IRB approval (if applicable)
- Budget - See **Can You Accept This Award? – Reductions in Budgets and Rebudgeting** (**Section C(2))** above regarding reductions in budget and rebudgeting
- Review of scientific overlap

Non-competing Multi-year Awards and Contract Amendments

- NGA or Contract Amendment
- Updated list of personnel on the study
- Updated Rascal PT Record –electronically signed by relevant parties, with up-to-date FCOI disclosure and certification and approval information
- FCOI certification from subcontractors or consultants (if applicable)
- Copy of Progress Report
- Notice of IRB approval (if applicable)

- Review of scientific overlap

Note that for non-federal government sponsors and for awards under Subaward Agreements, a guarantee letter, a foundation check or an award letter will be required in place of the contract in noncompeting years.

Modifications

Modifications of all non-industry sponsored accounts (including clinical trials) are handled by SPA. Modifications are the result of an amendment or revision to an agreement or NGA and can be driven by the investigator's needs (i.e., a request for additional time or funding) or can originate from the sponsor (change in amount awarded, terms of award, etc.). Account modifications are handled by SPA in the same manner as outlined above for new projects.

2. Industry Sponsored Research

For information on setting up accounts for industry sponsored clinical research, see **Initiating a Study: Account Set Up – Industry Sponsored Clinical Research** (**Chapter VII, Section B(2))** in the **Clinical Research Handbook**.

SPA sets up accounts for all industry sponsored non-clinical SRAs regardless of whether SPA or CTV negotiated and executed the SRA. Prior to setting up an account, the following documents are required to be provided to SPA:

- Fully executed SRA
- Finalized Rascal PT Record – electronically signed by relevant parties, with up-to-date FCOI disclosure and certification and approval information

3. Advance Accounts

Advance accounts provide PIs with an opportunity to initiate an activity and begin incurring associated expenses prior to institutional acceptance of an award. Advance accounts allow PIs and departments to record and track expenditures and eliminate the need to charge other unrelated accounts.

If an investigator is expecting an award or subcontract to start on a given date, but the award document has been delayed, and so long as the sponsor allows pre-award costs to be covered by the award or subcontract, a project can be established in ARC prior to its receipt by submitting a "guarantee letter" to SPA. A budget will be established in ARC for the amount of the guarantee. If the PI wants to spend funds up to 90 days before a new competing award starts, an Institutional Approval/Prior Approval Form (**IPASS**) signed by the PI and his/her Dean/Chair/Director should be submitted to his/her SPA Project Officer. The request should clearly show the need to start spending early and should be limited to only those expenses that are essential. The SPA Project Officer may request that the PI complete a budget demonstrating how the grant funds will be spent

over the initial period of time, and may also request a complete budget demonstrating how funds will be spent over the period of time, and may also request a complete budget demonstrating how the funds will be spent over the extended period of time without causing a deficit by the end of the budget period. If prior approval of pre-award cost coverage by the sponsor is required, the Project Officer will coordinate the request with the PI and/or DA.

The IPASS should request that a project be established in ARC and indicate that the School/Department/Center/Institute will guarantee the funds if the award is not made. An unrestricted project/activity number, which will be charged in the event an award is not made, must also be included. All advance projects will be set up for a 60-day period only. If the NGA is not received during the 60-day period, SPA will review the project, contact the sponsor as appropriate and determine if an extension of 60 days should be given.

An advance/guarantee account for a non-competing award may be set up without a guarantee letter if: The award is covered under NIH's Streamlined Non-Competing Award Process (**SNAP**) policies (for more information on SNAP see: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4_monitoring.htm).

For NIH non-competing awards, the advance account is set up after the PI submits his/her progress report.

4. Project Information Notifications (PINs)

Once a project is set up, SPA sends a PIN alert by email to the applicable PI and/or DA. The alert explains how to generate a PIN report in ARC. Notification is also sent to SPF and other central administrative offices, such as the Office of Alumni and Development and Procurement, when appropriate. Supporting documents such as the NGA, contract and guarantee letter are also sent by SPA upon initial receipt. It is the PI's responsibility to become familiar with the requirements and restrictions of the project by referring to the NGA or contract.

The PIN translates the budget provided by the sponsor into the appropriate budget accounts recognized by ARC (e.g., travel, professional salaries, fringe benefits, etc.). For the vast majority of projects, the University financial system works on an obligation rather than cash received basis. This means that accounts are set up based upon the receipt of award letters and contracts and not on the basis of cash or checks actually being received. That is not the case for SRAs and clinical trial studies where funding is based on deliverables. Once the PIN is issued, the project is officially established and funds can be utilized. The budget and natural accounts are utilized by SPF for budget monitoring and expenditure reporting. If any problems exist with the PIN, your SPA Financial Analyst should be notified.

The account information appears in ARC the day after SPA enters or updates the data in InfoEd. The PI or DA can review the budgets and project activity attributes in ARC. For more information regarding ARC, please refer to the ARC portal by logging into:

https://my.columbia.edu/. See also **Financial Management of a Sponsored Project: University Systems and Reports Available to Assist in Monitoring Expenditures - ARC** (**Chapter VIII, Section C(1))**.

5. Project and Activity Numbering

As a supplement to the award number that is assigned by the sponsor, the University assigns each award a project number for internal monitoring purposes. This eight digit project number has components from which characteristics of the account can be derived.

An example is as follows:

Project Number: GG012345

The format of the project number includes two characters followed by 6 digits. The first characters in the project number in this example are "GG", referring to government grants (and other government funding), a construct of internal accounting from which the funds are drawn. The project number is used to locate financial and demographic award details on the University's financial accounting systems and its various interfaces. Sponsored projects all fall within 2 ledgers:

GG: government funding
PG: private grants and other non-government funding

Projects and Activities

Each award is assigned a project and activity number. In some cases, at the request of the PI and by mutual agreement among the investigators involved in the research, an award will be split up into more than one activity if funds are to be shared among multiple departments. Additionally, when a proposal is awarded with a component to be performed at a different campus, separate activities are required to ensure that each campus can adhere to their respective F&A recovery policies. The activity will be created based on a mutually agreed upon budget.

An example of an award with multiple activities is as follows:

Award Number: 5 P01 DK012345-05

Prime: GG654321-01, GG654321-02, GG654321-03, GG654321-04, GG654321-05

Each portion of the award shares the same project number, while the activities allow budgeting and expenditure to be tracked at a lower level. The projects and activities can be reported in the aggregate or individually. The department/center/institute that owns each activity is responsible for ensuring that all expenses are accurate and for any resulting cost overruns. Responsibility for final accounting reconciliation with SPF will reside with the department owning the project.

E. Subawards

Once a subaward has been issued, SPA will establish a Subaward Purchase Order (SAPO) in ARC.

F. E-Verify

Certain federal contracts include a requirement that all employees (existing and new) working on such contracts undergo additional employment authorization validation through a federal system called E-Verify. This requirement applies to academic personnel (Officers of Instruction, Officers of Research, Officers of the Libraries and student officers) and administrative staff (including casual employees).

E-Verify is a web-based system operated by U.S. Citizenship and Immigrations Services (**USCIS**), part of the Department of Homeland Security, in partnership with the Social Security Administration. Columbia utilizes its current electronic I-9 system, which will interface with the Federal system, to fulfill the E-Verify requirement.

SPA will identify contracts that contain the E-Verify clause. Human Resources, in collaboration with SPA, SPF and Columbia University Information Technology (**CUIT**), will notify the DA and PI for all E-Verify contracts. This notification will identify all individuals who are paid through the contract and must complete the E-Verify process. Instructions on how to complete the E-Verify process will be provided at the time of notification. The PI and DA will be required to forward the notification to those individuals within their department or working on their contract.

All current employees who become subject to the E-Verify requirement will be required to complete a new Form I-9 electronically as part of the E-Verify process.

More information is available at http://hr.columbia.edu/links-especially/new-hires/getting-started/i-9-and-e-verify/e-verify-faqs

VIII. FINANCIAL MANAGEMENT OF A SPONSORED PROJECT

A. Introduction

While central administrative offices such as SPA, the CTO and SPF perform tasks such as creating projects, billing sponsors, preparing financial reports and serving as the central focus of audit and other financial inquiries, the obligation for the day-to-day management of sponsored projects and ensuring compliance with the myriad of federal and other sponsor regulations is the responsibility of the PI, supported as necessary by his/her DA and other administrative staff.

See **Introduction: Overview of Principal Investigator and Departmental Administrator Roles and Responsibilities** (**Chapter I, Section G)** for an overview of PI and DA roles and responsibilities.

The following sections describe the obligations of PIs and administrative support staff in the financial monitoring of sponsored projects, as well as key elements that are necessary in order to ensure compliance with both University and sponsor requirements.

As it is highly regulated by OMB and individual funding sponsors such as the NIH and NSF, the management of sponsored projects is complex and requires Columbia to be responsible and accountable for both the regulatory and fiduciary caretaking of funds.

It is critical that sound financial management of sponsored funds be practiced and adhered to in order to maintain the public trust in how these funds are spent. Proper stewardship of these funds is a responsibility that must be shared among many individuals and departments within the University. Our primary sponsors are becoming increasingly involved in ensuring that systems and controls are in place to oversee and monitor the funding they provide to the University.

Proper stewardship will result in the effective management of funds to maximize research outcomes and higher standards of research integrity. Managing these funds properly is essential to eliminate cases of fraud, institutional mismanagement and poor individual management of awards.

The University policy Principal Investigator Responsibilities for Financial Oversight of Grants and Contracts describes a PI's responsibility for the stewardship of the financial management of grants and contracts awarded to the University on his/her behalf.

See **Introduction: Regulatory Oversight** (**Chapter I, Section I)** for a brief description of regulatory oversight of sponsored projects.

B. Charging Expenditures to Sponsored Projects

The concepts of allowability, allocability, reasonableness and consistency that were discussed in **Preparing a Sponsored Project Budget: Direct Costs: Primary Concepts** (**Chapter V, Section B(1))** with respect to the preparation of a sponsored project budget are equally applicable to expenditures actually charged to such project, regardless of whether they were specifically budgeted for. See **Preparing a Sponsored Project Budget: Direct Costs: Primary Concepts** (**Chapter V, Section B(1))** for further information.

C. University Systems and Reports Available to Assist in Monitoring Expenditures

The following University tools are available to assist in monitoring project expenditures:

1. ARC

ARC is the primary system for online tracking of all expenditure activity at the individual project level. Within the Reporting Quick Links on the ARC homepage, the Reports Module of the Financial Data Stores (**FDS**) provides online access to several useful reports, including:

Sponsored Project Financial Report - Detail

This report displays individual non-salary transactions for the month by expenditure category. This report assists in ensuring that only authorized transactions have been charged to the project, and for reconciling source documents (e.g., invoices) to the charges applied to the project. The report also displays total salary expenditures by category (e.g., Faculty, administrator, GRA); however, the report does not display this information by individual.

Sponsored Project Financial Report – Summary By Budget Category

This report summarizes the cumulative fiscal year-to-date and fiscal year expenditures of the project, as well as project budget information, displayed as totals by expenditure category. This report is useful in monitoring the current financial status of the project, for controlling the level of expenditures and for anticipating any potential financial concerns (e.g., cost overruns) for the project. The Sponsored Project Financial Report – Summary by Budget Category aggregates financial information by project, but can be run to reflect a defined Activity Type or Activity.

Payroll Detail Report

This report shows each individual salary transaction charged to the project for a particular user-defined period, and is useful in monitoring the appropriateness of salary charges when individuals receive salary payments more frequently than monthly. It is also useful in identifying the source document authorizing the salary charge, where corrective action is necessary.

Payroll Summary Report

This report displays summary salary information for each employee, as defined in the report parameters. It also provides a snapshot of all of the individuals whose salaries are, or have in the

past, been charged to the project. Used in conjunction with the ECRT tool, the reviewer can monitor cumulative effort allocations in order to identify any necessary revisions to salary allocations.

SAPO vs Encumbrance Report

This report is used to monitor a subaward budget, expenses and remaining balance.

All of these reports and others are viewable through FDS Reports on the ARC homepage, (https://my.columbia.edu/content/finance-erp), and the information contained in the reports may be downloaded into spreadsheets and other formats that users may find helpful.

2. ECRT

ECRT is a web-based University system used to satisfy the federal requirements related to effort reporting. In addition to serving as the tool used by Faculty and staff to monitor and certify their effort, ECRT captures and accumulates salary charges by funding source for each individual, displaying both the absolute dollars and the relative percentage of salary by funding source. This information is useful in assessing whether the year-to-date salary charges are reasonable in relation to the effort devoted to a particular project.

3. StudyManager™

Study payments in industry sponsored clinical trials are generally triggered by certain milestones such as specific activities (screening and enrollment), visits completed or Case Report Forms completed. Because invoicing and reconciliation of industry sponsored research are so different from non-industry sponsored research, the financial management of industry sponsored clinical trials is centralized in the CTO. The CTO utilizes the StudyManager™ system to invoice industry sponsors for clinical trial activity. When the CTO executes a contract for an industry sponsored clinical trial, the CTO Budget Analyst builds the study in StudyManager™, based on the Schedule of Events in the protocol and the budget. When the study activity occurs (such as a patient being screened or enrolled), the clinical research coordinator on the study logs it in StudyManager™. The CTO Finance group invoices the sponsor for the activity according to the terms of the contract. StudyManager™ produces real time reports on invoicing, accounts receivable and payments.

D. Why Does the University Require Regular Review of Project Activity?

While every effort is made to assure that the charges to each sponsored project are correct, errors do occur. In addition, the nature of sponsored projects is such that activities overlap, and it is sometimes necessary to reallocate charges after they were initially assigned to a specific project by processing a cost transfer. For further guidance, please refer to the discussion of cost transfers in **Monitoring a Sponsored Project – Cost Transfers** (**Section F(3))** below.

University financial policies recommend monthly project financial reconciliation as a best practice and require quarterly PI attestation of expenses over the life of the project. Administrator validation is required by SPF annually, at the anniversary date of the commencement of the project, and at project closeout, additional validation procedure are required. See **Closing Out a Sponsored Award (Chapter X).** Reviewing project activity on a regular basis will help ensure that expenditures are within appropriate limits and guidelines. Further, regular monitoring of sponsored projects helps to:

- Confirm the availability of project funds as needed;
- Ensure that costs are consistent with the project schedule and incurred between the start and stop dates of the project;
- Uncover errors in either the project budget or expenditures, whether those errors are caused by an end-user, a service department or any other system-generated source;
- Avoid cost overruns, which will ultimately need to be funded from non-sponsored sources;
- Provide comfort that the expenditures are in compliance with the sponsor's spending terms and conditions;
- Ensure that any necessary cost transfers and corrections are made in a timely manner;
- Maintain a clear audit trail for the future; and
- Allow for problems to be timely noted and dealt with.

E. Monitoring and Reviewing Charges

As charges are recorded on individual sponsored projects, SPF seeks reimbursement for those costs from project sponsors. For most federal agencies, the University has established letters of credit that allow for the immediate transfer of funds from the government. It is important that the charges themselves are promptly reviewed to verify their accuracy, allowability and allocability to the sponsored projects to which they are assigned. Accordingly, the following monitoring and reviewing procedures should be followed:

1. Salary and Fringe Benefit Charges

The Uniform Guidance allows for initially assigning salary distributions based on the estimated workload of the individuals who are working on a particular project, provided that: (a) the anticipated workload reasonably approximates the work performed; (b) significant changes in work activity (i.e., material changes in effort that last more than 2 months) are identified and timely reflected in the individual's salary distribution; and (c) salary charges are reviewed after-the-fact, in accordance with the University's effort reporting policies described in **Preparing a Sponsored Project Budget: Direct Costs – Major Categories of Direct Costs (Chapter V, Section B(2)).** All necessary adjustments must be made such that the final amount charged to the award reasonably reflects the work performed and thus is accurate, allowable, and properly

allocated. Accordingly, ongoing monitoring of effort distributions is needed so that timely modifications of salary allocation can be made where necessary. Using the payroll information available in both ARC-FDS Reports and ECRT, the reviewer should assess whether the salary charges to the project are reasonable in relation to the effort that has been provided.

Fringe benefit charges are applied through the application of a fringe benefit rate. All sponsored projects are assessed at a rate negotiated by the University with the federal government. In addition, non-governmental projects are charged an additional fringe benefit rate to cover certain benefits such as dependent tuition costs which federal regulations do not permit.

For further information, see **Preparing a Sponsored Project Budget: Direct Costs – Major Categories of Direct Costs** (**Chapter V, Section B(2))**.

2. Vendor Invoices

When a vendor's invoice is received, in addition to reviewing the accuracy of the charges themselves, the reviewer is obliged to ascertain the appropriate project or projects to which the charge relates. In some cases, it may be that the PI reviews the invoice and makes that judgment. In other cases, the PI may have given instructions to the DA on how such charges are to be assigned. In any case, it is necessary to review the monthly accounting statements on a regular basis to ensure that these charges do in fact appear, and that there are no inappropriate or incorrect charges. Any necessary cost transfers must be done promptly. Further details on cost transfers are provided in **Monitoring a Sponsored Project – Cost Transfers** (**Section F(3))** below.

3. Subrecipient Charges

Sponsored projects that include subawards require special attention, as the PI must ensure that subrecipient charges are reflective of the work that has been performed and are proper expenditures before any payments are authorized. See the University's Subaward Policy for more details.

4. Charges Initiated by Service Centers and Recharge Centers

In addition to disbursements made to outside vendors, sponsored projects may be charged by certain internal providers of services. These centers are "licensed" by the University to charge users, and the costs charged and the manner in which their unit costs are determined are covered by the University's Policy on Service Centers and Recharge Centers.

Sponsored projects may not be charged for internal operations other than those licensed as centers without the approval of SPF.

Unlike vendor invoices, these charges are applied to sponsored projects without the necessity for a sign-off. Nevertheless, the goods or services for which the charge is assessed must have been authorized by the PI or his/her delegate. As in the case of vendor invoices, it is important that all

such charges be reviewed on a regular basis, and the provider of the service should be immediately contacted if there are any questions about either the charge itself or the project(s) to which the expense is applied.

5. F&A Charges

F&A charges are applied nightly by an ARC automated process and are based on the F&A rate and F&A base assigned to a project. It is important to monitor F&A charges to ensure that the rate charged is correct, and that the rate has been applied to the appropriate expenditure base (which excludes all types of expenditures that cannot generate F&A costs as indicated either the terms and conditions of the project award or the awarding agency's policy). F&A rates and the base to which they apply vary based on sponsor and type of grant (e.g., research vs. training vs. public service). In accordance with the requirements of Section 200.68 (Modified Total Direct Cost (MTDL)) of the Uniform Guidance, the F&A rate on federal research projects is applied to a direct expenditure base called **Modified Total Direct Costs** or **MTDC**. For further information, see **Preparing a Sponsored Project Budget: Facilities and Administrative (F&A) Costs** (**Chapter V, Section C)**.

The rates applicable to other sponsors are varied, and should be verified for accuracy by referring to the sponsor's guidelines.

6. Compensation and Reimbursement for Human Subjects

Human research relies on volunteers to participate in studies. It is not uncommon for subjects to be reimbursed for travel or other expenses or to be compensated for their willingness to participate in a study. All plans to compensate subjects in research studies must receive prior approval of the IRB, which ensures that the payments are not coercive and that confidentiality of the subjects is protected.

Instructions on how to set up and manage a petty cash fund and request reimbursement from the fund are described in **Working With Study Subjects: Managing the Study – Subject Reimbursement/Compensation** (**Chapter X, Section D**) of the **Clinical Research Handbook**.

F. Monitoring a Sponsored Project

1. General

Just as the PI is responsible for ensuring that the project itself is carried out properly, he/she is also responsible for monitoring project finances throughout the life of the project. This process is vital to ensuring that:

- Funds awarded by the sponsor are used only for permissible purposes and in accordance with University policies;
- In expending funds, appropriate attention is given to the availability of project resources;

- Cost overruns are avoided to the maximum extent possible, and that where incurred, are promptly resolved;
- Budget variances are monitored so that (a) where sponsor regulations require agency approval for variances over a defined threshold, the PI is aware of the need to obtain that approval, and (b) any necessary rebudgeting between direct and indirect costs is noted and completed; and
- Cost sharing commitments have been satisfied.

Monitoring the financial status of each project can be performed by using the Sponsored Project Financial Report – Summary by Budget Category as a reference, as it provides cumulative fiscal year-to-date and fiscal year period expenditure vs. budget information, as well as displaying outstanding funding commitments that have been made (e.g., purchase orders assigned to the project for which vendor invoices have not as yet been processed, future salary and fringe benefit commitments, etc.). Regular review of the Sponsored Project Financial Report – Summary by Budget Category allows for the timely correction of errors and any necessary cost transfers, as described under **Cost Transfers** (**Section F(3))** below.

2. Rebudgeting

Rebudgeting is necessary if the utilization of funds is planned in a way that differs from the original or most recent budget approved by the sponsor. Approval of rebudgeting of funds on a sponsored project is the prerogative of the sponsor. In some instances, specified rebudgeting authorizations have been granted to the institution or to the investigators by the sponsor. Since policies differ from sponsor to sponsor, it is important that the PI obtain a copy of the rebudgeting policy of the awarding sponsor. It can be obtained either from the agency or your SPA Project Officer. DAs should also be aware of the applicable policy and confirm adherence to it to the PI quarterly.

Most sponsors permit some variances within budget categories without sponsor approval. As a rule of thumb, rebudgeting involving, in the aggregate, less than 25% of the direct costs of the project or a reduction of key personnel time devoted to the project of less than 25% of the time promised in the application will not require sponsor approval. However, certain budget categories and/or agencies have more or less stringent requirements (e.g., NSF requires that any rebudgeting of Participant Support Costs be approved; prior approval to rebudget is not required on NIH modular grants if the scope remains unchanged); accordingly, it is important that the PI and/or administrative support staff be familiar with the particular limitations of project sponsors. PIs and administrative support personnel should consult with their SPA Project Officers with respect to any questions on rebudgeting, as the Project Officer is responsible for countersigning any correspondence with the sponsoring agency.

For significant rebudgeting, the PI should submit an IPASS Form signed by the PI and his/her dean/chair/director, prior to any rebudgeting, indicating:

- Which category to withdraw funds from;

- Which category to add funds to;
- Why the transfer of funds is needed;
- Why funds can be taken from that particular category; and
- How the need relates to the project.

If sponsor approval is required for any proposed rebudgeting, a letter to the sponsor should be prepared and countersigned by your SPA Project Officer and forwarded to the sponsor for approval. In general, all requests for rebudgeting in a contract have to be made to the sponsor. For consortium or subaward agreements with respect to which the University is the secondary recipient, the authority may either be delegated to the University or remain with the primary institution.

For non-federal government sponsors, be sure to check that sponsor's rules regarding rebudgeting.

One area of rebudgeting that is frequently overlooked is the rebudgeting of funds between direct and F&A costs. Any cost overrun resulting from the rebudgeting of direct costs from certain expenditure categories not subject to F&A costs to other expenditure categories that are subject to F&A costs will ultimately be the responsibility of the department. For example, if a federal research grant includes a budget line for equipment (which by definition is excluded from the application of the F&A rate) and the equipment is not purchased, but the funds are ultimately used to cover the cost of additional staff, the project will ultimately be charged for more F&A costs than were budgeted. In order to cover the additional F&A costs, the F&A cost funding available to the PI will be reduced.

Once the necessary rebudgeting approvals are authorized, the budget must be updated and forwarded to your SPA Financial Analyst to revise the budget in InfoEd. The revised budget information entered into InfoEd will be fed to ARC and a revised PIN will be distributed. Updated budget information is essential for comparing expenditures with amounts budgeted.

3. Cost Transfers

While faculty and staff must make every effort to allocate sponsored project costs to the appropriate project(s) at the time the costs are incurred, it is recognized that under certain conditions, it may be permissible, or in the case of an error, necessary to transfer costs from one project to another. Cost transfers to sponsored projects are allowable only when:

- There is a direct benefit to the project activity being charged;
- The cost being transferred was incurred during an allowable time period;
- The terms and conditions of the project do not explicitly prohibit the charge; and
- The cost transfer is accompanied by required documentation.

Further, University policy requires that all cost transfers to sponsored projects must be prepared and submitted within 90 days following the end of the month in which the original charge was posted to a University project; thereafter, cost transfers to sponsored projects will not be

permitted except in extenuating circumstances. If SPF disapproves a cost transfer request, the costs in question must be moved to a non-sponsored project. Cost transfers that remove expenditures from a sponsored project are not subject to the 90-day time limit, and must be processed at the time that it is determined that an expenditure charged to a sponsored project is not appropriate to that project. For further information, see the University's Policy on Cost Transfers.

4. Cost Sharing

Cost sharing represents that portion of the total project costs of a sponsored project borne by some entity or funding source other than the project sponsor. Typically, cost sharing relates to the commitment of personnel (i.e., effort devoted to the sponsored project), but may also include non-personnel commitments, such as equipment costs.

It is generally the case that all of the costs incurred in carrying out a sponsored project are normally funded by the sponsor of that project. There are occasions, however, when some of the costs of carrying out a sponsored project are to be funded from other sources, whether required by the sponsor as a condition of the award (***Mandatory Cost Sharing***), not required by the sponsor but nevertheless promised by the PI to the sponsor (***Voluntary Committed Cost Sharing***), or not required by the sponsor and not promised by the PI, but nevertheless charged to a funding source other than the sponsored project (***Voluntary Uncommitted Cost Sharing***).

The University's Policy on Cost Sharing requires that when cost sharing commitments are made to sponsors (i.e., mandatory or voluntary committed cost sharing), the source of funds to be used to cover that cost sharing must be identified and approved at the time the commitment is made to the sponsor. In addition, those costs must be readily identifiable in the University's financial records to auditors and others in order to document that cost sharing commitments have been met and are properly accounted for. Because of the documentation requirements imposed on cost sharing, the University strongly discourages voluntary committed cost sharing.

It is important that during the life of the project, the PI ensures that any and all commitments made to sponsors are either met, or if not, that the sponsor is timely apprised of any changes in the commitment.

It is not necessary to either identify or account for voluntary uncommitted cost sharing nor should such costs be reported to the sponsor.

Mandatory cost sharing will be identified by SPA at the time of submission of a proposal. At the time of award setup, the DA must establish non-sponsored cost share projects within which mandatory cost share expenses can be segregated. The DA must provide the unrestricted cost share project number to SPA. If the DA fails to provide this information for awards with mandatory cost sharing, SPA will proceed with award setup. However, when mandatory cost share information is missing, the SPA Financial Analyst will send an email to the applicable DA stating that the cost share information must be provided to SPA within 60 days or SPA will ask SPF to change the project status to "Hold" and all financial transactions on the award will be stopped until the requisite cost share information is provided.

Cost sharing associated with individuals receiving NIH funding whose salaries exceed the NIH salary cap will automatically be reflected in ECRT. In addition, the ECRT system should reflect any other cost sharing. DAs should determine if there are other cost sharing commitments besides those associated with "salary over the cap," and communicate these commitments to RPIC. In order for an individual to certify his/her effort card, cost sharing information should be entered into ECRT prior to certifying the effort card. RPIC is responsible for entering the cost share information.

The University's Policy on Cost Sharing contains more specific requirements when cost sharing commitments are made.

5. Cost Overruns

A **cost overrun** in a sponsored project occurs when total expenditures charged to the sponsored project exceed the total project budget. Overrun spending can place the University at risk because overrun costs are not covered by sponsored agreements and cannot be billed or reported to the sponsor.

The University expects that the PI will monitor each sponsored project as outlined in this chapter in order to ensure that the funds awarded by the sponsor over the life of the project will be sufficient to cover all of the expenses incurred in carrying out the project, or alternatively, to identify and utilize other resources in order to avoid incurring an anticipated cost overrun. It should be noted that it is University policy that the Controller may require an explanation of any cost overrun.

Following the end of the competitive segment of a sponsored project, any residual cost overrun for which alternative funding has not been identified will be removed from the sponsored project and charged to a non-sponsored source.

SPF distributes monthly email notifications of sponsored projects in overrun status to both DAs and PIs. Administrators must either clear or justify all overruns to their SPF Project Manager. If the DA does not provide documentation of forthcoming sponsor funding commitments, documentation of a request to SPA to increase the project budget, documentation of another exception deemed acceptable by SPF or the number of a department-initiated GL Internal Transfer that clears the overrun, SPF may clear the overrun to the responsible unit's unrestricted funding source.

Further guidance on resolving residual cost overruns may be found in the University's Policy on Financial Reporting and Closeout of Sponsored Projects and Policy on Cost Overruns on Sponsored Projects.

6. Effort Reporting

Effort reporting is the federally-mandated process by which the salary charged to a sponsored project is documented as being reasonable in relation to the effort expended on that project. During the course of the year, the University charges salaries to sponsored projects and other

non-sponsored projects based on allocation instructions (i.e., the percentage of salary to be charged to one or more sponsored projects or other non-sponsored projects based on committed effort) provided by academic department personnel who are acting upon instructions from PIs and others who oversee those sponsored projects. These allocations must reasonably approximate the work performed. Throughout the course of the year, these charges must be monitored to ensure that any significant change in effort or workload results in a change in salary distribution. At the close of the fiscal year, a certification is required. The University's Policy on Charging and Documentation of Personnel Costs Charged to Sponsored Projects provides comprehensive guidance on the various requirements inherent when salaries are funded by sponsored projects. See also **Preparing a Sponsored Project Budget: Direct Costs – Major Categories of Direct Costs** (**Chapter V, Section B(2))**.

Unlike vendor payments and other non-salary transactions that are documented on a transactional basis (i.e., there is supporting documentation for each charge that is subject to review and approval), the federal regulations governing the allocation of salaries among sponsored projects and other University activities are more flexible. They recognize that in a university setting, it is often impossible to precisely allocate an individual's effort among the various sponsored and non-sponsored activities. Ultimately, the charges must reflect a reasonable estimate of the work performed, such that the final charge is accurate, allowable and properly allocated.

As briefly described in **Preparing a Sponsored Project Budget: Direct Costs – Major Categories of Direct Costs** (**Chapter V, Section B(2))**, salaries and fringe benefit costs may be assigned to a sponsored project based on a planned workload. However, there is an ongoing obligation to monitor those charges and to modify them as necessary to reflect any significant change in effort or variance from the planned workload; in doing so, short term fluctuations may be ignored as long as over the long term the salary and fringe benefit charges are reasonable in relation to the effort devoted to each project or activity. A final requirement of the regulations is an annual effort certification.

The University uses ECRT, an on-line tool, to facilitate the annual effort certification process, as well as to provide information during the course of the year to assist faculty and others in monitoring effort, so that appropriate adjustments to salary distributions are made on a timely basis. Faculty (i.e., Officers of Instruction and Officers of Research (other than Postdoctoral Fellows)) who devote effort to one or more sponsored projects are required to monitor and certify their own effort. In addition, PIs are required to monitor and certify the effort of graduate students and others whose efforts are devoted to sponsored projects. All Faculty engaged in sponsored activity are required to complete on-line training on effort reporting concepts, and administrative staff who are Effort Coordinators are required to complete classroom training. See **Training: Mandatory Training – Effort Reporting** (**Chapter III, Section C(7)**) for further information on training. Certification takes place each Fall.

While these are federal requirements, the University follows the same procedures for all sponsored projects, irrespective of the sponsor.

The University maintains and regularly updates a website that contains comprehensive information on all aspects of effort reporting, including reference guides, FAQ's, links to federal regulations and to the training itself. The website also serves as the pathway to the ECRT tool. All University personnel engaged in conducting or administering sponsored projects should regularly review the Effort Reporting Website.

7. Subawards

Federal funding agencies require that institutions working on subawards under Columbia prime awards follow all of the rules and regulations that would apply to prime awards at their own institutions. Further, the responsibility for monitoring compliance with those regulations devolves to Columbia as holder of the prime award. As indicated in **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Subawards** (**Chapter VI, Section E(10))**, the University has a Subaward Policy that includes requirements that apply both prior to and after a subaward is granted. The pre-subaward requirements are discussed in **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Subawards** (**Chapter VI, Section E(10))** and the following describes certain post-subaward requirements:

General

The Subaward Policy mandates that the PI:

- Routinely gather and review technical performance reports;
- Routinely review invoices and expenses relative to budget;
- Conduct periodic on-site visits, when necessary; and
- Initiate audits, when necessary.

Following the execution of a subaward agreement, the PI and his/her DA should jointly determine the frequency and scope of departmental monitoring procedures based on the risk mitigation strategy, if any. The PI and the DA should report any material problems with respect to any subaward to SPA, the CTO or CTV, as appropriate.

Performance

The PI will monitor the progress of the subrecipient work scope by reviewing formal progress reports on a timely basis. He/She may also receive informal progress reports by phone or email. Review by the PI of progress reports from the subrecipient must occur regularly. Progress reports must be solicited, reviewed and filed with the prime award documents.

Site visits are generally conducted in connection with ongoing collaborations to manage the research and administrative aspects of the subaward. Site visits are a discretionary monitoring procedure, but are recommended to evaluate the subrecipient's compliance with the scientific objectives of the subaward, the level of complexity of activity and the scope and duration of the project. Site visits should be documented by meeting notes, trip reports or correspondence and such documentation retained in the files.

Invoices

Invoices from subrecipients must be reviewed by the PI and the DA for allowability, reasonableness and compatibility with the subaward budget. The specific requirements for reviewing invoices are described in the Subaward Policy and, in particular, Appendix D to the Policy that sets out the requirements for reviewing subrecipient invoices.

RPIC Monitoring

On an annual basis, RPIC is required to take certain actions with respect to each subrecipient listed in the subaward database maintained by RPIC that is party to an active subaward agreement. Such actions are described in the Subaward Policy.

Federal Funding Accountability and Transparency Act (FFATA)

As part of FFATA, all recipients of federal funds, including grants, contracts, loans and other assistance and payments, are responsible for reporting certain information related to subaward agreements under federal direct awards (i.e., name, location and indentifying number of subrecipient, amount of award and type of funding). As part of its responsibilities relating to subaward agreements, SPA is responsible for providing the required information to the federal government for all Columbia federal subawards. PIs and DAs will not be required to report this information directly. The information will ultimately be reported via USAspending.gov and more information about FFATA can be found at https://www.fsrs.gov.

8. No Cost Extensions

As a general rule, upon expiration of a sponsored project, in addition to providing the sponsor with a final progress report and other non-financial deliverables, a number of actions are necessary to close out the financial aspects of the project. However, if the work under the project is not yet complete and the project is not being competitively renewed, it may be possible for the PI to obtain a no cost extension in order to fulfill the obligations of the award.

Extension requests are the responsibility of the PI and must follow the sponsor's policies. Requests should be addressed to the awarding agency. The letter should state the reason for the request, the amount of additional time needed and the use to which the funds will be put during the extension period, and should be sent before the expiration of the budget period in question. Before the letter can be sent to the sponsor, an IPASS signed by the PI and his/her Chair, Director or Dean must be reviewed and countersigned by a SPA Project Officer.

Agency policies differ with respect to the method of submission, timing of the letter and the length of the allowable extension. Note that in order to request an extension, the resources available to cover the cost of the work itself must be identified. Typically, those resources are in the form of an unexpended balance on the project itself.

9. Supplemental Funding Requests

If, during the course of the project, the PI feels that supplemental funds are required, he/she must submit a request to the agency in the form of a short proposal outlining the work to be done and the need for additional funds. A budget and budget justification must be attached showing how the additional funds will be used. The supplemental request is submitted in the same manner as any other proposal and must follow the sponsor's specific requirements.

Note: During a no cost extension, effort expended on the project may need to be documented in the effort report and the salary cost shared with the department.

10. Property Management

Property purchased under sponsored agreements must be used exclusively or primarily for the sponsored project. Many sponsored agreements provide special terms and conditions regarding the vesting of title as well as reporting requirements for capital equipment purchased by the PI or by a subrecipient. Care should be exercised to ensure property is managed with strict controls. The PI should discuss any special terms and conditions regarding property management and see guidance regarding compliance with Capital Asset Accounting within the Controller's Office. Columbia University's policies for property management are provided in the "Property and Equipment Manual" dated June 2014.
http://finance.columbia.edu/files/gateway/content/controller/property_equipment_manual.pdf

PIs should familiarize themselves with the contents of this Manual and the policies to the extent that they apply to the management of their awards.

G. Global Support

The Global Support website is the product of a collaboration of multiple University central administration offices, including Treasury, Controller, Procurement and OGC. Accessible via the Finance Gateway, the site aims to provide University faculty, researchers, administrators and students with the tools needed to adhere to the highest standards of fiscal responsibility, in light of the growing demands of globalization.

The Global Support website is structured with three major categories of content: Getting Started includes topics meant as a general overview for faculty and staff new to international work; Managing Financial Needs includes guidance and options for enabling program related expenses across international borders; and Working Globally focuses on topics that are more pertinent for projects with actual operations outside the United States. Additionally, Global Support includes a comprehensive International Travel section with pertinent advice and helpful topics that are relevant to all members of the Columbia community who travel internationally.

You can visit the main page of the Global Support website at
http://finance.columbia.edu/departments/global-support or email them at
globalsupport@columbia.edu.

IX. PROGRAMMATIC MANAGEMENT OF A SPONSORED PROJECT

A. Introduction

In addition to the financial monitoring of a sponsored project as described in **Financial Management of a Sponsored Project** (**Chapter VIII)**, the PI, supported as necessary by his/her DA and other administrative staff, has full responsibility for the conduct of a sponsored project and the results achieved. As a result, the PI should monitor the performance of a project to assume adherence to performance goals, time schedules and other requirements as appropriate to the project. In addition, the PI has the obligation to provide the reports required by the sponsor and to otherwise comply with the terms and conditions of the award.

The following description of certain particular responsibilities is based on federal regulations and in particular those of NSF and NIH. Non-federal government sponsors may have additional or other requirements and the relevant grant application, NGA or agreement should be reviewed carefully to understand post-award responsibilities.

B. Reporting

1. Progress Reports

Most sponsors require periodic progress reports during the life of an award. The PI uses this report to document his/her progress with the originally proposed project plan. It is an opportunity for the investigator to explain the highlights, the set-backs, any changes to what was originally planned and the accomplishments of the project.

The requirements for completing progress reports differ from sponsor to sponsor. Some sponsors require annual reports, while others may request them as often as on a monthly basis. It is the PI's responsibility to read the NGA or project agreement and comply with the progress reporting requirements. Sponsors may require additional forms to be completed (for example, if the study contains human subjects). This will usually be outlined in the NGA or the instructions accompanying progress reporting forms.

2. Timeliness of Reports

It is extremely important for PIs to keep track of progress report due dates. It is the PI's responsibility to file reports on time. Failure to do so could jeopardize future funding with that sponsor both to the PI and to other University investigations. In some cases, continued funding for subsequent budget years is contingent upon receipt of timely progress reports.

A NGA or project agreement generally contains a project timetable, milestone chart and a list of specific deliverables. If these timetables, milestones and deliverables are not met, the sponsor may determine that only partial project payment is due the University. It is therefore critical that all elements of the work plan be completed and reported on in the allotted timeframe. Unexpected changes can occur during the funded time period. It is extremely important to communicate delays in research to SPA, the CTO or CTV as appropriate. The appropriate University office will be able to guide the investigator on next steps.

The information in periodic reports must be completely accurate. Please contact SPA, the CTO or CTV for guidance.

C. Post-Award Activities That Typically Require Prior Sponsor Approval

Most sponsors expect that the work performed on a sponsored project will follow the scientific plan as set forth in the application or agreement, but ordinarily permit some latitude in the methodology, approach or other aspects of the project. However, significant charges typically require prior sponsor approval.

Section 200.308 (**Revision of Budget and Program Plans**) of the Uniform Guidance outlines the circumstances under which federal sponsors require prior approval. However, federal agencies are authorized to waive prior written approvals for any one or more of the following:

- The incurrence of project costs within 90 calendar days before the awarding agency makes the award;
- The initiation of a one-time extension of the period of performance for up to 12 months; and
- A carry forward of unobligated balances to subsequent periods of performance.

It is important to review the terms and conditions of the NGA carefully as prior approval requirements for the three above circumstances may or may not be required depending on the federal agency or the specific project.

The following circumstances are examples of when prior approval of the sponsor is typically required:

1. Substantive Changes to Proposed Research

Significant changes to the research from what was proposed and approved by the sponsor require notification and/or approval. PIs are therefore advised to contact their SPA Project Officers as soon as possible in the following situations:

Changes in Objectives or Scope

Neither the phenomena under study nor the objectives of the project stated in the proposal should be changed without first obtaining sponsor approval. Such changes should be proposed to the sponsor in writing and countersigned by a SPA Project Officer.

Changes in Methodology

The PI may wish to pursue interesting and important leads that arise during the conduct of a research project, or to adopt an alternative approach that appears to be a more promising means of achieving the objectives of the project. A PI should contact his/her SPA Project Officer in these situations to ascertain whether formal approval is necessary.

Significant Changes, Delays or Events of Unusual Interest

It is appropriate for the PI to contact his/her SPA Project Officer when he/she becomes aware of any delays or adverse conditions that will affect the ability to attain the objectives of the project or to meet any time schedules outlined in the original proposal. The Project Officer should also be informed when any events of unusual interest occur during the course of the project.

2. Change of PI

The sponsor's decision to support or not to support a proposal is based, to a considerable extent, upon its evaluation of the PI's knowledge of the field of study and ability to conduct the project. Therefore, sponsors expect to be notified formally if the PI:

- Devotes substantially less effort to the work than anticipated in the approved proposal (for NIH, a decrease of 25% or more from the level that was approved at the time of the award),
- Is disengaged from the project for more than three months or reduces his/her time devoted to the project by 25%,
- Leaves the University, or
- Otherwise relinquishes active direction of the project.

In such instances the PI must request formal agency approval for the change via his/her SPA Project Officer. Approval may also be needed for changes in key personnel on the project other than the PI.

3. Absence of PI

Short-Term Absence of the PI

If a PI will be absent from the research for a period of time less than three months, the sponsor should be notified and formal agency approval should be sought. The agency can decide whether a temporary PI should be appointed. It is advisable for the PI to discuss these situations directly with his/her SPA Project Officer before contacting the sponsor.

Long-Term Absence of the PI

If the PI will be away from the project for a period longer than three months, arrangements for interim oversight of the project should be made and a request for approval sent to the agency. This information should be provided to the SPA Project Officer as far in advance as possible, who will provide written approval of such arrangements. If the arrangements are not satisfactory to the sponsor, the award may be terminated.

4. Transfer of Grant To or From Columbia

Grants and contracts are always made to the institution rather than to the PI. Therefore, when a PI wishes to transfer a grant to or from Columbia, appropriate institutional approvals must be sought. Sponsors require that the award be properly closed out at the PI's prior institution before granting approval to transfer the award to the new institution. The prior institution must provide a final financial accounting with which the sponsor concurs. The award balance will be returned to the funding agency and will then be transferred to the new institution. It is the PI's responsibility to notify his/her SPA Project Officer as soon as possible to alert them to any changes of this nature. No transfers will be made until the PI is up-to-date on all reporting requirements.

In many cases, grants to be transferred to Columbia from other institutions will have a lower F&A rate than Columbia's negotiated federal rate. In some circumstances Columbia may choose to accept the F&A rate approved at the former institution, rather than requiring rebudgeting of the award, with the understanding that this lower rate will be allowed only until the next competing continuation or renewal phase.

Note that pending proposals require formal transfer of ownership when the PI moves from one institution to another before a funding decision has been made. In this situation, the PI's previous institution relinquishes ownership of the proposal to the sponsor. The new institution then submits a revised budget (using its F&A rate), budget justification, and other pertinent forms as requested by the sponsor. In some cases the agency may require the PI to resubmit the proposal in its entirety.

See **Transfer of Sponsored Projects** (**Section E)** below for more information.

5. Equipment Not in the Original Budget

Approval is generally necessary when the PI of a federal award wishes to purchase an equipment item (defined as costing more than $5,000 with a useful life of more than one year) not originally identified in the budget. These requests require a scientific/ programmatic rationale for the purchase, a cost breakdown, and, if possible, vendor quotes. Such requests must be vetted and signed by your SPA Project Officer. Prior approval is usually not required for a change of vendor or model for research and technical equipment included in the approved budget, or for a change of 25% or less in

the acquisition price of approved equipment. Specific sponsor policies vary and should be reviewed prior to purchasing any equipment not previously approved.

6. Subawards Not in the Original Budget

In general, sponsors must approve subawards not identified in the original budget. Appropriate paperwork from the potential subrecipient must be included as described in **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Subawards (Chapter VI, Section E(10))**. The Columbia PI should supply a cover letter explaining the need for the subaward.

7. Other

Other examples of post-award activities that may require sponsor prior approval are:

- Significant rebudgeting. See **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – Rebudgeting** (**Chapter VIII, Section F(2))**.
- Substitution of one animal model for another.
- Change from the approved use of animals or human subjects.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract or any other means. If the third party is a non-U.S. contractor, this type of action always requires NIH prior approval.
- Incurrence of research patient care costs if costs in that category were not previously approved by the sponsor or if a grantee desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.
- Carryover of unobligated balances from one budget period to the next unless specifically allowed by the sponsor. Most training grants, cooperative agreements, center grants and clinical trials do not permit automatic carryover of unobligated balances.
- Transfer of funds between construction and non-construction work.
- No cost extensions. See **Financial Management of a Sponsored Project: Monitoring a Sponsored Project – No Cost Extensions** (**Chapter VIII, Section F(8))**.

D. Retention and Access to Research Data

The PI is responsible for the collection, management, maintenance and retention of research data accumulated during a research project. The University must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, privacy and compliance with laws and regulations governing the conduct of the research. It is the PI's responsibility to determine what records need to be retained to comply with sponsor requirements. PIs should adopt an orderly system of data organization and should communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, PIs should establish and maintain procedures for protection of essential records in the event of a natural disaster or other emergency.

Research data must be archived for a minimum of three years after the final project close-out, with original data retained wherever possible. Some sponsors require a longer period of retention. Some circumstances may require a longer period of retention such as:

- Data that must be kept for as long as necessary to protect intellectual property and complete patenting and licensing procedures for inventions resulting from the work;
- If any charges regarding the research arise, such as allegations of scientific misconduct, conflict of interest or improper charging of costs, data must be retained at least until such charges are fully resolved; and
- If a student is involved in the research, data must be retained at least until the student's degree is awarded or it is clear that the student has abandoned work on the project.

See **Study Closure: Data Retention** (**Chapter XV, Section D)** in the **Clinical Research Handbook** for additional holding periods for clinical research studies.

E. Research Integrity

1. Research and Data Integrity (ReaDI) Program

Robust data and research integrity is vital to ensuring that research results are reproducible and verifiable. The Research and Data Integrity (ReaDI) Program was created to enhance data management and research integrity at Columbia. Based in RCT, the ReaDI Program provides resources, outreach and consultation services to research at all stages in their careers. Resources and information are available on the ReaDI Program website, http://www.columbia.edu/cu/compliance/docs/ReaDI_Program/index.html.

2. Misconduct in Research

Occasionally, questions may arise concerning the integrity of research. The University's Institutional Policy on Misconduct in Research governs concerns regarding falsification, fabrication or plagiarism in research, including research proposals, regardless of whether such research is federally funded. RCT administers the research misconduct process and is a resource for anyone with concerns in this area. More information about the research misconduct policy and procedures is available at http://www.columbia.edu/cu/compliance/docs/research_misconduct/index.html. Contact RCT with any research integrity concerns.

F. Transfer of Sponsored Projects

1. Transferring Sponsored Funding to Another Institution

Investigators who resign from the University have several options to consider if they have sponsored funding. The two main considerations when transferring to another institution are whether the investigator's funded projects remain at the University under the direction of a new investigator, or whether the funding is transferred to the new institution where the project is then continued. As all sponsored funding is formally awarded to the University and not to the PI, the University must be involved in any decision to transfer funding to another institution.

When resigning from the University, faculty must follow the termination guidelines set forth by the Provost's Office in the Faculty Handbook:

Officers of Instruction:
http://www.columbia.edu/cu/vpaa/handbook/instruction.html

Officers of Research:
http://www.columbia.edu/cu/vpaa/handbook/research.html

All administrative requirements must be completed, including completion of an effort certification for the period up to departure from the University.

When leaving the University, a PI must contact his/her SPA Project Officer to initiate the process of moving his/her sponsored projects to the new institution. This will normally involve initial discussions with the sponsor. The sponsor has the overall authority over whether a grant or contract may be transferred to a new institution. If you have institutional grants, such as training grants or program project or center grants, the applicable Dean's office or the Office of the EVPR should be contacted prior to contacting your SPA Project Officer.

Some factors to consider:

- Is the departmental chair at the new institution aware of the PI's current funding?
- Does the department of the new institution have the resources and staffing available to assist on a project currently in progress?
- Can the materials, supplies and equipment be transferred to the new institution?
- When using human subjects, can new subjects be recruited at the new institution? Will that be necessary at the point of transfer?

The above questions will, in all likelihood, be asked by the sponsor. Sponsors differ in their requirements for transferring out a grant. The following items are typical for a sponsor to request when the funding is being transferred to a new institution:

- Formal letter, signed by the PI and his/her SPA Project Officer.
- New grant application, signed by a Signing Official of the new institution, requesting the remaining funds and describing how the project will continue. The application should contain all relevant information as outlined in the questions above.
- Final Progress Report.

All administrative requirements must be completed, including effort certification for the period up to departure from the University.

Relinquishing Statements

Most sponsors require that a formal statement be completed to release an award from one institution before it can be awarded to another institution. Many sponsors have specific forms (**Relinquishing Statements**) that must be used for this purpose. A Relinquishing Statement is required when a PI leaves the University, relocates to another institution and takes a sponsored project to that institution. In such cases, the school or department must prepare a Relinquishing Statement and send it to the appropriate SPA Project Officer with the PI's signature for review and transmittal to the sponsor. Prior to transmitting it to the sponsor, SPA will forward the statement to SPF for a review of the reasonableness of the unexpended balance projected by the PI as reflected on the Relinquishing Statement. Upon approval of the project transfer by the sponsor, SPF will request a final reconciliation from the school or department, prepare the final Financial Status Report and begin the award closeout.

In addition to transferring the sponsored project to another institution, the relocation of a PI to another institution sometimes involves the transfer of equipment to that institution. The Equipment Inventory Adjustment Form is used to request the transfer of equipment to another institution. No equipment may be moved from Columbia until approval has been obtained. Once approved, the Controller's Office will provide the receiving institution with a listing of the equipment, requiring that organization to acknowledge receipt and to accept responsibility for the equipment. The Controller's Office will

obtain any necessary approvals of the transfer from the sponsor. Before shipment, any University or government identification must be removed from the equipment. The transferee institution is responsible for all transportation costs.

If there is any inconsistency between University policies and the terms of the grant or contract under which equipment was funded, the terms of the grant or contract govern.

When using animals and human subjects, discussions need to take place with the IACUC and the Institute of Comparative Medicine or the IRB, to discuss the procedures for transferring a funded project. See **Animal Care and Use During a Study: Animal Transfers** (**Chapter VII, Section F)** in the **Animal Research Handbook** for further information.

You should work with your assigned SPA Project Officer to gather all materials necessary. They will be communicating with the sponsor on the investigator's behalf to ensure all administrative documents are filed.

2. Transferring Sponsored Funding to the University

When coming to Columbia, the same questions apply as mentioned above. SPA will require:

- New grant application to the sponsor, containing all requested sponsor forms and detailed budget
- A signed Relinquishing Statement from the other institution
- A copy of the final Financial Status Report from the other institution
- Finalized Rascal PT Record
- Completed FCOI reports
- Completed IRB or IACUC protocols in Rascal (if applicable).

X. CLOSING OUT A SPONSORED PROJECT AWARD

A. Introduction

The closeout of a sponsored project has both programmatic and financial components and the PI has responsibilities in both areas. In the programmatic and operational close-out of a sponsored project, the PI is responsible for the submission of all technical reports required by the sponsor, closure of bank accounts and petty cash funds, termination of services and contracts and close-out of subawards. For the financial closeout, the PI is responsible for the review and validation of project expenditures prior to SPF's submission of final financial reports required by the sponsor providing financial reconciliations on which SPF will base the financial reports required for close-out. PIs must ensure that any charges and/or adjustments necessary are made in a timely and accurate manner to ensure that the expenditures reflected on financial reports agree with those recorded in the University's accounting records.

B. How to Close Out an Award

1. Expenditure Finalization and Validation and Final Financial Report

Following the expiration of a project, the University is required to submit a final financial report or statement of costs incurred to the sponsor. The final financial report is prepared by SPF and sent to the sponsor prior to the due date specified in the terms and conditions of the award, which may vary from sponsor to sponsor. Generally the due date of the final financial report is between 90 and 120 calendar days after the last day of the final budget period of the project, although a sponsor may set an earlier date.

SPF prepares final financial reports (or statements of expenditures) utilizing expenditure data for the project recorded in ARC. In advance of preparing and submitting the final financial report, SPF requires that expenditures be finalized in ARC and that the PI and DA both review the expenditures attributed to the project pending closeout and provide an email validation that they have done so to their SPF Project Manager.

The due date of the required expenditure validation is predicated on the due date of the sponsor's final financial report, although SPF generally requires validation 30 days before the final financial report is due. The expenditure validation due date is detailed in notifications that are sent by SPF to the PI and DA 90 days before the project termination date and on the project termination date. These closeout notifications also specify that on the date that the expenditure validations are due, the ARC activity or activities attributed to the project will be inactivated, preventing further expenditure changes from being posted.

In advance of expenditure finalization and expenditure validation deadlines, PIs and DAs should conduct a thorough review of expenses and execute any transactions needed to bring expenditures to finality. A thorough review includes:

- Review of budget and all direct and indirect costs
- Analysis of outbound subawards to ensure that all invoices have been received, reviewed and paid
- Submission of pending cost transfer requests and review and cancellation of anticipated integrating systems and distributions
- Reconciliation of petty cash and travel advances, liquidation of open encumbrances and purchase orders
- Removal of a cost overrun or determination of the disposition of an unexpended balance, as applicable

If an expenditure validation is not provided to SPF by the deadline specified in the notifications, SPF will prepare and submit the final financial report to the sponsor using the charges applied to the project as of the date of preparation of the report. Any outstanding encumbrances will be removed, and any cost overruns must be cleared by the department. Further, any additional costs incurred on the project, but not reported in the final financial report will be the obligation of the department. Only expenditure credits deemed necessary after the expenditure validation deadline will be allowed.

The following table summarizes the responsibilities of the PI, the DA and SPF in the financial closing out of an award:

PI and/or DA	***SPF***
Review projects on an ongoing basis to ensure that all expenses are appropriate and allowable; correct errors promptly	
	Send closeout notification to DA and PI approximately 90 days prior to ARC project termination date.
Process any outstanding vouchers that are allowable on the project; begin to finalize expenditures; perform through expense review	
	Send follow-up closeout notification to DA and PI at ARC termination date
Finalize expenditures; perform thorough review of expenditures; provide separate email validations of	

project expenditures to SPF Project Manager	
	Review final project expenditures; adjust F&A charges when necessary; prepare and submit final FFR to the sponsor
	Provide copies of final FFR to the DA and SPA and archive documentation for auditors
	Close ARC Project

For further information, see the University's Policies on Financial Closeout Reference Guide.

2. Final Technical Report, Progress Report and Other Deliverables

The PI is responsible for submission of all technical and/or progress reports required under the terms of an award, as well as other agreed upon deliverables such as data, graphs or software. Failure on the part of the PI to deliver any required reports to the sponsor in a timely matter may have a negative impact on the collection of funds for the project and future funding from that sponsor to the University. In addition, the terms of many contracts provide that final payments will not be made until the required final reports have been submitted.

As the failure to submit final reports can result in severe negative consequences to the University, the Chair of the PI's department may be called upon to coordinate the completion of reports if the PI is unable to do so.

3. Final Invention Statement

Many sponsors require an invention report as part of the closeout process. PIs are responsible for completing a Final Invention Statement in whatever format the sponsor requests, whether or not the funded project resulted in any subject inventions and whether or not inventions were previously reported. Final Invention Statements must be submitted to SPA or the CTO, which will work with CTV to verify inventions and sign the Statement. If any inventions are reported, the PI should clearly indicate the name of invention, title of the invention and date it was reported to the sponsor.

4. Treatment of Open Commitments and Encumbrances

Open commitments, also known as “encumbrances”, are expenses that the award is expected to incur, but for which payment has not yet been made.

Subaward Commitments

Departments must reconcile amounts paid by the University for a subaward against the services rendered by the subrecipient. All open commitments related to the subaward must either be liquidated or cancelled.

Petty Cash

Departments must maintain documentation of all petty cash funds used, and must regularly reconcile those funds, as required by the University’s Petty Cash Policy.

Petty cash encumbrances are liquidated via either payment vouchers and/or a departmental check totaling the amount of the encumbrance. These supporting documents must be presented to SPF.

Travel Advances

Departments must maintain documentation of all travel advances and must perform a travel advance reconciliation by completing a Travel and Business Expense Form as required by the University’s Travel Expense Policy. Any unallowable travel expenses (as defined by sponsor regulations, University policy or grant/contract terms) must be segregated from allowable travel expenses, and may not be charged to the sponsored project. All travel advances must be cleared before project closeout.

5. Release Forms

Although not generally required for grants, release forms are often required for contracts in order to formally release the University from any legal liability. If a release form is required, it will be prepared and signed by SPF and sent to the sponsor with the final invoice.

6. Subawards

Upon termination of a subaward, the PI must ensure that all narrative and progress report obligations, as well as financial deliverable obligations, are satisfied by the subrecipient prior to the release of final payment to the subrecipient.

7. Project Termination Issues

By the expenditure finalization date in the project closeout notification, all appropriate expenditures should have already been recorded on the project. Any necessary subsequent charges or adjustments must be approved by SPF.

Residual Balances Remaining at the End of a Sponsored Project

Upon the termination of a project, any unexpended funds will be automatically returned to the sponsor unless there is a competitive renewal of the project that has been awarded and sponsor regulations permit the carryover of that unexpended balance into the new project period or the terms and conditions of the award permit the University to retain the unexpended balance. Typically, any such carryover requires a formal request from the PI.

If the award is in the form of a fixed price contract and the terms and conditions explicitly state that the University may keep unexpended funds, SPF will transfer the residual balance to a project specified by the PI or DA upon receipt of a written statement:

- From the PI substantiating that all project requirements have been satisfied and that all costs related to the sponsored project have been charged to the sponsored project
- From the DA substantiating that all costs relating to the sponsored project have been charged to the sponsored project.

In the case of industry sponsored clinical trials, approval by the CTO is also required. For SRA projects, residual balances will be reviewed by SPA and CTV and a determination made on a case by case basis.

Cost Overruns Remaining at the End of a Sponsored Project

As noted in **Financial Management of a Sponsored Project (Chapter VIII)**, an overrun on a sponsored project occurs when total expenditures charged to the sponsored project exceed the total project budget. Overrun spending can place the University at risk because overrun costs are not covered by sponsored agreements and may not be billed or reported to the sponsor.

SPF distributes monthly email notifications detailing sponsored projects in overrun to both DAs and PIs; these notifications clarify that overruns are expected to be justified or resolved as they emerge over the life of the project. Any cost overrun remaining at the termination of a sponsored project must be promptly cleared. The funding source of the cost overrun is at the discretion of the PI or the department, except that it may not be another sponsored project. The PI or department will be responsible for providing alternate funding for the direct cost portion of the cost overrun.

Major Equipment Disposition and Excess Supplies at Closeout

For federal sponsored projects, major equipment disposition activity and excess supply disposition activity may occur at project closeout.

Major equipment disposition activity will occur when the federal project's terms and conditions require it. If required, the Controller's Office will contact the PI and DA when a piece of equipment purchased on a grant has a Fair Market Value (**FMV**) of more

than $5,000 at award termination. When this is the case, the piece of equipment must have one of the following dispositions:

- Continue to be used by the PI on the original project or program, whether or not the project or program continues to be supported by the federal award;
- Be used by the PI or another Columbia PI on another federal award;
- Be used by the PI or another Columbia PI on another non-federal award;
- Be retained with the FMV credited back to the sponsor; or
- Be resold and proceeds returned to the sponsor.

Excess supply disposition activity will occur during federal project closeout if the estimated FMV of total reusable supplies purchased on an award exceeds $5,000 and the PI does not have another active federal or non-federal award. SPF will estimate the value of residual supplies at project closeout using an algorithm that considers the date of purchase, amount, depreciation of computer equipment, and supply type (i.e., non-reusable supplies such as reagents and gases). If this amount exceeds $5,000, SPF will contact the DA to confirm disposition.

For both federal and non-federal projects, unless the award or agreement provides otherwise, title (ownership) to equipment acquired with sponsored funds vests with the University upon acquisition. Prior to asset disposition, the Controller's Office must be contacted so that it can verify if there are any sponsor restrictions. Equipment purchased by a sponsored project must be used for the work of that project so long as it is needed, whether or not the project or program continues to be supported by federal funds. It may also be used for other purposes, to the extent that such use does not affect its availability to carry out the work of the project that funded it.

ANNEX A

GLOSSARY OF HANDBOOK ACRONYMS

AHRQ	U.S. Agency for Healthcare Research and Quality
ARC	Accounting and Reporting at Columbia
CDC	Centers for Disease Control
CITI	Collaborative Institutional Training Center
CRC	Clinical Research Coordinator
CTAC	Clinical Trials Advisory Committee
CTO	Clinical Trials Office
CTSA	Clinical and Translational Science Award
CTV	Columbia Technology Ventures
CUMC	Columbia University Medical Center
DA	Departmental Administrator (or any other departmental staff member who manages the administration of sponsored projects)
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
ECRT	Effort Certification and Reporting Technology
EH&S	Office of Environmental Health and Safety
EVPR	Executive Vice President for Research
F&A	Facilities and Administrative
FCOI	Financial Conflict of Interest
FDS	Financial Data Store
FFR	Federal Financial Report
GRA	Graduate Research Assistant
hESC	Human Embryonic Stem Cells
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protection Office
HRSA	U.S. Health Resources and Services Administration
IACUC	Institutional Animal Care and Use Committee
IPASS	Institutional Approval/Prior Approval Form
IRB	Institutional Review Board
JIT	Just in Time
NGA	Notice of Grant Award
NIH	U.S. National Institutes of Health
NSF	U.S. National Science Foundation
NYP	NewYork-Presbyterian Hospital
NYSPI	New York State Psychiatric Institute
OGC	Office of the General Counsel
OMB	U.S. Office of Management and Budget
OPA	Office of Postdoctoral Affairs
ORI	Office of Research Initiatives
OTPS	Other Than Personnel Services

PA	Program Announcement
P&S	College of Physicians and Surgeons
PHS	Public Health Service
PI	Principal Investigator
PIN	Project Information Notification
Rascal	Research Compliance and Administration System
RCR	Responsible Conduct of Research
RCT	Office of Research Compliance and Training
rDNA	Recombinant DNA
RA	Research Administration
RFA	Request for Applications
RFMH	Research Foundation for Mental Hygiene
RFP	Request for Proposals
RPIC	Research Policy and Indirect Cost Department of the Office of the Controller
SPA	Sponsored Projects Administration
SPF	Sponsored Projects Finance Department of the Office of the Controller
SRA	Industry Non-Clinical Sponsored Research Agreement

Determining Your Safety Training Requirements @ Columbia University

Columbia-specific training is mandatory for numerous positions and job functions at the University. Please consult the following guide to determine which safety courses are required based on your job function, and the requirements for maintaining your training currency.
Please contact EH&S to arrange a specialized in-lab training session.

Job Function or Activity	Required Safety Training	Initial Training Method	Refresher Training Method	Training Frequency
General Research Safety Courses				
Working in a "laboratory" or with chemicals (*Examples: PIs, research staff, post-docs, students*)	**Laboratory Safety, Chemical Hygiene and Hazardous Waste Management Training** *Course#: TC0950*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; refresher every 2 years or sooner if determined by EH&S
Working in a laboratory or with chemicals at CUMC or Morningside campus *(Examples: PIs, research staff, post-docs, students who qualify)*	**Certificate of Fitness for Supervision of Chemical Laboratories (C-14)**	"Live" (see http://www.ehs.columbia.edu/cof.html for schedule & information)	Self-review of FDNY C14 examination study material upon renewal of certification	Per FDNY certification Renewal requirements
Radiation Safety Courses				
Working in a lab that uses Radioactive Material (RAM) or X-ray producing machinery *(Examples: all users of RAM)* or X-ray producing machinery *(Examples: all users of RAM)*	**Radiation Safety and Radioactive Waste Training** *Course #: TC1750*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; Annual refresher
Using an irradiator (*Example: irradiating cell lines, etc)*	**Increased Control of Radioactive Materials and Unescorted Access** *Course #: TC2500* **NOTE: requires prior approval by Human Resources**	RASCAL	RASCAL	Annual at intervals not to exceed 12 months

Human Use of Radioactive Materials (ex. F-18) or X-ray emitting devices (ex. CT, DEXA, Radiographs)	**Radiation Safety Training**	"Live" initial	"Live" or RASCAL/NYP COLE	Live initial training at the time of hire or before involvement in such activities; Annual refresher via RASCAL or NYP COLE
Biological Safety and Shipping Courses				
Working with: human blood, body fluids, cell lines or unfixed tissue, infectious microorganisms (capable of causing disease in healthy adults), or viral vectors (*Examples: PIs research staff, post-docs, students, all "active" staff listed on Appendix A, B, or C forms*)	**Biological Safety/ Bloodborne Pathogen Training** *Course #: TC0509*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities incl. approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix A, B or C); annual refresher
Working with viral vectors in research (Note: replication-deficient vectors are NOT exempt)	**Viral Vector Research – Handling and Biosafety** *Course #: TC1150*	RASCAL	RASCAL	Initial training before approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix B); refresher every 2 years
Working with recombinant DNA in research (Note: replication-deficient vectors are NOT exempt)	**Recombinant DNA Training** *Course #: TC0508*	RASCAL	RASCAL	Initial training before approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix A); refresher every 2 years
Shipping specimens/viable microorganisms known to or reasonably expected to contain material that may cause disease in humans or animals with Dry Ice (*Examples: anyone involved in any shipping function, including labeling, packaging, or paperwork completion*)	**Shipping Biological (infectious and potentially infectious) Materials, Genetically Modified Microorganisms (GMMOs)** *Course #: TC0507*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training before involvement in such activities; refresher every 2 years

Shipping non-hazardous materials with Dry Ice (*Examples: anyone involved in any shipping function, including labeling, packaging, or paperwork completion*)	**Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods** *Course #: TC0076*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training before involvement in such activities; refresher every 2 years
Activity- or Hazard-Specific Research Safety Courses				
Working with Formaldehyde (*Examples: PIs, research staff, post-docs, technicians, students*)	**Formaldehyde Safety Training** *Course #: TC0016*	"Live" or RASCAL (individual's preference)	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; Annual refresher as per OSHA
Working with Hydrofluoric Acid (*Examples: PIs research staff, post-docs, students, all Clean Room users*)	**Hydrofluoric Acid Safety Training** *Course #: TC1650*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; refresher every 2 years or sooner if determined by EH&S
Working in a lab that uses cyanide or cyanide-containing substances (*Examples: PIs, research staff, post-docs, technicians, students*)	**Cyanide Safety Training** *Course #: TC0085*	RASCAL; "live" session available upon request by department or group	RASCAL; "live" session available upon request by department or group	Initial training at the time of hire or before to involvement in such activities
Working in a lab that stores, handles or uses pyrophoric materials (Examples: PIs, research staff, post-docs, technicians, students)	**Pyrophoric Materials Training** *Course #: TC1850*	"Live" as determined by EH&S or available upon request by department or group	"Live" as determined by EH&S or available upon request by department or group	Initial training at the time of hire or before to involvement in such activities
Working with Controlled Substances *in vitro* or *in vivo*, under IACUC-approved protocols (*Examples: License/permit applicants, all users of controlled substances in research*)	**Controlled Substances Use and Management in Research** *Course #: TC0502*	RASCAL; "live" session available upon request by department or group	RASCAL; "live" session available upon request by department or group	Initial training before procurements and/or use of Controlled Substances; refresher every 2 years or sooner per EH&S determination

Working with Class 3b or 4a Lasers. Personnel working with other lasers are encouraged, but not required, to attend. (*Examples: all users of lasers*)	**Laser Safety Training** *Course #: TC1600*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; refresher every 2 years
Working in a machine shop or other area with machinery. Personnel working with a specific machine must also receive machine specific training provided by their department before use. (*Example: all users of machinery*)	**Shop Safety Training** *Course #: TC0600*	RASCAL; "live" session available upon request by department or group	RASCAL; "live" session available upon request by department or group	Initial training before working in a shop or with machinery and annual refresher thereafter

In addition to these safety training courses, you may be required to complete other Columbia University training courses. Please utilize the Research Compliance Training Finder tool to identify all of your training requirements.

PI CERTIFICATIONS

- To the best of my knowledge and belief I and all other individuals who will be responsible for the design, conduct or reporting of the research or educational activities included in this project completed an up to date Conflict of Interest Disclosure.
- I/we have not, to the best of my/our knowledge, been excluded from federal financial and nonfinancial benefits under federal programs or activities.
- I/we have not, to the best of my/our knowledge, utilized federal appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government.
- I/we and all scientific/technical officers to be employed on this project have executed and filed the Columbia University "Agreement to Assign to the University Inventions or Discoveries Conceived or Reduced to Practice in the Performance of Sponsored Projects".
- The human and/or animal subjects protocol(s) that have been/will be reviewed and approved by the Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) faithfully reflects the work proposed in this proposal.
- All activities in this project will be carried out in compliance with the Environmental Health and Safety policies and procedures of Columbia University.
- If the sponsored project is awarded, I/we will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity within the sponsored project.
- The information presented in this proposal is complete, accurate and developed according to practices commonly accepted within the scientific community.
- To the best of my/our knowledge, all of my/our pending proposals and current awards have been identified as Other Support in this proposal or progress report to the extent required to be disclosed to the sponsor. Assuming that all of the pending proposals are funded, my/our effort to be expended on the projects to which such proposals and awards relate has been accurately stated or will be adjusted as required (with prior sponsor approval having been requested through SPA where applicable).
- To the best of my/our knowledge, any scientific budgetary or effort overlap between this application and any other proposal or award has been appropriately disclosed on this application and if the sponsored project to which this application relates is awarded, any such overlap that exists at the time of award will be identified, reported to and approved by the requisite sponsors prior to acceptance of such award.
- I/we hereby assign to Columbia all my/our right, title and interest in any discovery, invention or algorithm that is or may be patentable, together with any supporting technology resulting primarily from the use of Columbia's facilities or from my/our activities while engaged in Columbia's service.