

SECTION 5. SPONSORED PROJECTS ADMINISTRATION

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5.1 OVERVIEW

Columbia University, including the College of Dental Medicine (CDM), receives support from funding agencies and other organizations for clinical research, bench research, and direct implementation of projects or programs. The research and programs are called *sponsored projects* and the mechanisms for awarding the financial support are most often *grants*, but may alternatively be *cooperative agreements* or *contracts*. For descriptions of the different types of awards, see “Types of Sponsored Projects” in the [Sponsored Projects Handbook](#).

Key Links

[Sponsored Projects Handbook](#)
[Administrative Policy Library](#)
[Sponsored Projects Administration](#) (SPA)
[Sponsored Projects Finance](#) (SPF)
[RASCAL](#)
[IRB Policies and Guidance](#)
[Institutional Information Sheet](#)
[Effort Reporting](#)
[Institutional Animal Care and Use Committee](#) (IACUC)
[Clinical Trials Office](#) (CTO)
[Institute of Comparative Medicine](#) (ICM)
[Research Compliance and Training](#)
[Science and Technology Ventures](#) (STV)
[International Risk Management Procedures](#)

The CDM Office of Research Administration (ORA) is the first point of contact for questions related to sponsored projects. Sponsored projects are heavily regulated, particularly by the U.S. government, which provides most of the sponsored research funding in the United States. Many of the University’s policies and procedures have been established to conform to federal regulations overseen by various government agencies and, as applicable, have been extended to non-federally funded sponsored projects.

Section Administrators (SAs) are heavily involved in sponsored project administration: one of their key responsibilities is to interact closely and frequently with principal investigators (PIs) to oversee the financial and administrative aspects of grant and contract activities. This section provides SAs with links to key resources and summarizes key points to keep in mind when fulfilling these administrative duties.

5.2 KEY RESOURCES

5.2.1 The University's Sponsored Projects Handbook

Key Links

Sponsored Projects Handbook Administrative Policy Library Sponsored Projects Administration OMB Circulars (U.S. government)
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The [Sponsored Projects Handbook](#) provides practical guidance to academic personnel and administrative staff of Columbia University in the management of sponsored projects funded by both governmental and private organizations. It lays out the research policies and procedures of the University and serves as a reference guide for all investigators and administrators.

Recent enhancements or changes in sponsors' policies and regulations may override the contents of the [Sponsored Projects Handbook](#). SAs should keep in mind that the most current information may be found in the federal Office of Management and Budget (OMB) circulars, other government regulations, and specific sponsor documentation and award documents, as well as the University's [Administrative Policy Library](#).

5.2.2 The Sponsored Projects Administration (SPA) Website

The University's [Sponsored Projects Administration website](#) provides a wealth of resources, including forms, policies, and information helpful for identifying funding opportunities and developing proposals. It provides quick links to other useful websites, including:

- [Columbia Institutional Information Sheet](#)
- [CU Office of Postdoctoral Affairs](#)
- [Effort Reporting](#)
- [Environmental Health and Safety](#)
- [Human Research Protection Program / Institutional Review Board \(IRB\)](#)
- [Institutional Animal Care and Use Committee \(IACUC\)](#)
- [P&S Clinical Trials Office \(CTO\)](#)
- [RASCAL](#) (Research Compliance and Administration System)
- [Research Compliance and Training](#)
- [Science and Technology Ventures](#)

5.2.3 Funding Agency Regulations

Sponsored projects are heavily regulated, particularly by the federal government, which provides most of the University's sponsored funding. Many of the University's policies and procedures have been established to conform to statutes, government-wide directives,

and regulations overseen by various federal agencies and, as applicable, have been extended to non-federally funded sponsored projects.

Of particular importance to the management of CDM's federally sponsored projects are the following publications:

- [OMB Circular A-21](#): Cost Principles for Educational Institutions
- [OMB Circular A-110](#): Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
- [OMB Circular A-133](#): Audits of States, Local Governments, and Non-Profit Organizations
- [NIH Grants Policy Statement](#)
- NSF's [Proposal and Award Policies and Procedures Guide](#)

Since the vast majority of federal funds at CDM are provided by the National Institutes of Health (NIH) to support research and training, SAs should be aware of the extensive information offered by the [NIH Office of Extramural Research](#).

5.3 SPONSORED PROJECTS VS. GIFTS

SAs must be familiar with the distinction between sponsored projects and gifts, as these sources of funding are treated differently by the University. For example, proposals for sponsored projects must be processed through the Office of Sponsored Projects Administration (SPA) or, in certain cases, the Clinical Trials Office (CTO – see Section 5.4.3) and/or Science and Technology Ventures (STV – see Section 12.3).

Key Links

[Sponsored Projects Handbook](#)
[Administrative Policy Library](#)
[CUMC Development Office](#)

As articulated in the University's policy on *Distinguishing Gifts from Sponsored Projects* (available in the [Administrative Policy Library](#)) and in the [Sponsored Projects Handbook](#):

- ***Sponsored projects*** include research, instruction and training, public service, fellowships, and other scholarly and creative activities conducted under the direction of Columbia academic and administrative staff and funded by an outside source. Sponsored projects that support research or other sponsored activities may be grants, cooperative agreements, or contracts. They typically require technical or detailed financial reports, or some other outcome or product of the activity, to be delivered to the funding institution during or at the completion of the activity.
- ***Gifts*** are voluntary, irrevocable, gratuitous transfers of money or other property to support Columbia programs or activities. They 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 or other benefits in return for the transfer of funds to Columbia.

When assistance is required in making a determination as to whether a particular source of funds is a gift or a sponsored project, SAs should contact SPA or the [CDM Development Office](#).

5.4 OFFICES THAT ASSIST WITH SPONSORED PROJECTS

5.4.1 CDM Office of Research Administration

The Office of Research Administration of the College of Dental Medicine is responsible for reviewing grant and contract applications before they are submitted to SPA or the sponsor. ORA assists PIs and SAs with the preparation and review of application budgets and documentation. ORA works directly with SPA, CTO and STV for the execution of all government and non-government grants and/or contracts.

5.4.2 Sponsored Projects Administration

The [Office of Sponsored Projects Administration](#) (SPA) is responsible for reviewing grant and contract applications before they are submitted to the sponsor. SPA acts as both the Administrative and Signing Official on grant and contract applications.

Key Links

[Sponsored Projects Administration](#)
[Sponsored Projects Finance](#)
[Clinical Trials Office](#)

Every department, center, and institute is assigned an SPA Project Officer, who reviews funding applications for completeness and budget accuracy. The SPA Project Officer is the Signing Official. In this role, he/she has institutional authority to legally bind the institution in grants and contract administration matters. See SPA's [Department Assignment webpage](#).

5.4.3 Sponsored Projects Finance

The University has a separate unit for [Sponsored Projects Finance](#) (SPF), located in the Office of the Controller in the Finance Division. Its responsibilities include:

- Sponsored project cash management
- Financial reporting to sponsors
- Negotiation of the University's indirect cost recovery and fringe benefit rates
- Responding to financial audits of sponsored projects

SPF also monitors compliance with federal and other regulations such as effort reporting, mandatory and voluntary cost sharing, and unallowable costs. Furthermore, it reviews and authorizes cost transfers.

Every department, center, and institute has an assigned SPF Project Manager, the list of which is available under the “View Department Contacts” link on the [SPF website](#).

5.4.4 Clinical Trials and the CTO

At the University, a “clinical trial” is defined as a planned experiment designed to assess the efficacy of a treatment in humans by comparing the outcomes in a group of patients treated with the test treatment with those observed in a comparable group of patients receiving a control treatment, where patients in both groups are enrolled, treated and followed over the same time period. The [Clinical Trials Office](#) (CTO), which serves CDM, College of Physicians and Surgeons (P&S) and New York-Presbyterian Hospital (NYP), has the primary administrative responsibility for promoting and assisting investigators in managing clinical trials.

The CTO processes and has signing authority for all funding applications for industry and non-industry (including foundation) sponsored clinical trials that are submitted by PIs holding appointments at CDM. Clinical trial proposals from the other schools at Columbia University Medical Center (CUMC) are processed by SPA.

The CTO and its Project Officers:

- Serve as an intermediary between investigators and the sponsors of clinical trials
- Liaise with potential sponsors who are interested in placing clinical trials at the University
- Support investigators in the development of protocols, help them with budget preparation and contract negotiations, and assist them in post-award financial management and compliance with sponsor requirements and government regulations
- Ensure that sponsored project proposals and agreements comply with University and sponsor policies
- Have certain designated officers who sign grant applications and contracts on behalf of the University
- Prepare invoices, follow up on collections, and reconcile 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 NYP. This committee 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. The CTAC also reviews and recommends meritorious “seed” clinical research projects and other clinical

trial research support provided by the CTO. For further information, see the website for the [Clinical Trials Office](#).

5.4.5 Science and Technology Ventures

Science and Technology Ventures (STV) assumes primary responsibility for the negotiation of industry-sponsored research agreements and signs all agreements for industry-sponsored projects *other than clinical trials*. STV also reviews and negotiates the terms of industry subawards with industry prime funding.

In addition to the funding applications for which it is primarily responsible, STV is the responsible office for negotiating intellectual property terms. See Section 5.9.2 for further information.

5.5 PI ROLES AND RESPONSIBILITIES

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, center, or institute.

Key Links

[Faculty Handbook](#)
[Administrative Policy Library](#)
[Sponsored Projects Handbook](#)

5.5.1 Role of the 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 responsibilities are delineated in the University's [Faculty Handbook](#) and the policy on *Principal Investigator Responsibility for Financial Oversight of Grants and Contracts*, available in the [Administrative Policy Library](#). In addition, the PI's particular duties are spelled out under "Role of the Principal Investigator" in the [Sponsored Projects Handbook](#).

The [Faculty Handbook](#) also contains information on the following topics:

- Fundamental principles governing externally funded research
- Research misconduct
- Offices relating to research management and compliance
- Technology development and transfer
- Conflicts of interest

5.5.2 PI Eligibility

The PI (the individual submitting the application) on a research, training, or service proposal assumes full administrative, fiscal, and scientific responsibility for the conduct of the project. The PI of a project must be a Columbia University officer of instruction with a fulltime appointment and have the rank of instructor or higher.

- Fulltime officers of research with the rank of senior research scientist/scholar or research scientist/scholar are also entitled to serve as PIs and no special approval is required.
- Fulltime officers of research with the rank of associate research scientist/scholar and postdoctoral research scientists/scholar may serve if approved by the Executive Vice President for Health and Biomedical Sciences and Dean of the Faculties of Health Sciences and Medicine.

The applicable rank is that which will be in effect at the time the application is awarded.

In certain cases, individuals who are not fulltime officers of instruction or research may serve as PIs. If seeking an exception, an officer should submit a request through ORA, who will work with SPA. Approval may be sought on a project-by-project basis or for all projects of the officer. The request to serve as PI must include the individual's *curriculum vitae* and, if it relates to a specific project, an abstract of the project. Also required is the countersignature of the appropriate department chair or center/institute director in order to acknowledge the financial responsibility of the department, center, or institute for the proposed project or projects. The SPA Project Officer reviews the request and seeks the final authorization from the CDM Dean's Office.

Additional information concerning eligibility to serve as a PI may be found in the [Faculty Handbook](#).

5.5.3 When the PI Changes

If a person serving as principal investigator devotes substantially less effort to the work than anticipated in the approved proposal, leaves the University, or otherwise relinquishes active direction of the project, the outgoing PI or another CDM person on the project should work with the SA and SPA or the CTO to: 1) ensure continuity in the management of the project, 2) specify the level of authority on the project designated to other CDM personnel, and 3) properly notify the sponsor and obtain approval for a new PI if required.

In exceptional cases, such as the sudden departure or removal of the PI, the department chair or center/institute director is responsible for taking action to ensure continuity and appropriate project oversight and direction. However, the CDM Dean's Office reserves the right to name a temporary or permanent PI at any time.

For discussion of transfers of a sponsored project to another institution or from another institution to Columbia, see Section 5.10.

5.6 SA ROLES AND RESPONSIBILITIES

5.6.1 Role of the Section Administrator

Key Links

Sponsored Projects Handbook

Effort Reporting website
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The SA 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 SA who is most involved in the day-to-day administrative activities related to the project. Therefore, it is imperative that the PI and the SA interact closely and frequently to review and discuss financial and administrative matters.

Drawn in large part from the “Role of the Departmental Administrator” in the [Sponsored Projects Handbook](#), the following lists the key areas for which SAs are responsible:

- Working with SPA and the CTO to make sure that budgets and awards are created accurately in the University’s financial systems in accordance with the approved award
- Ensuring the PI has a copy of the notice of award and discussing with the PI any special award requirements
- Understanding sponsor restrictions on costs and discussing them with the PI
- Supporting implementation of requirements for human research protection and responsible care and use of animals in research
- Processing charges to the sponsored project based on guidance from the PI
- Monitoring the award, conducting monthly reconciliations of accounts, and having PIs or their designees review monthly reports on budget vs. actual expenses
- Confirming that charges to awards are appropriate and accurate in adherence to University policies and in compliance with applicable laws and sponsor regulations
- Assigning a Primary Effort Coordinator (see [Section 5.6.2](#)) and ensuring that effort reporting monitoring and certification requirements are met (see the [Effort Reporting website](#))
- Monitoring subrecipients in financial and contractual management and providing technical support as needed
- Assisting with the preparation of Financial Status Reports
- Monitoring timely submission of technical reports
- Helping to ensure compliance with University and sponsor stipulations on copyright and patent interests
- Planning and implementing the operational transfers and closeouts of projects

5.6.2 Effort Coordinators

Every school, department, center, or institute with at least one member who receives sponsored project funding must designate an *effort coordinator*. The CDM Business Office assumes the responsibility of the *primary effort coordinator* and appoints the appropriate SAs as *secondary effort coordinators*. The effort coordinator plays a key role in effort reporting compliance. Responsibilities include:

- Being knowledgeable about the University's effort reporting policies and procedures
- Reminding the faculty of their obligations for ongoing effort monitoring and annual certification
- Supporting the faculty in carrying out those obligations
- Monitoring effort reporting of faculty and research staff for whom they are responsible
- Processing completed effort certifications during the annual effort certification period
- Transferring costs as appropriate
- With the chair/director and CDM administrators, ensuring that effort compliance requirements are met

All effort coordinators must complete mandatory training, which is offered regularly throughout the year and includes: 1) effort reporting policy and process; and 2) training in the University's electronic effort reporting system (Effort Certification and Reporting Technology - ECRT).

More information about effort reporting policy, process, and training is available at the University's [Effort Reporting website](#). Questions may be sent by e-mail to the Effort Reporting Help Desk, at effort-reporting@columbia.edu.

5.7 OBTAINING FUNDING

5.7.1 Essential Elements for Locating Funds

- ✓ Contact the CDM Office of Research Administration for funding opportunities. ORA would have the most up-to-date information on internal and external resources with special interest in dentistry or related fields.
- ✓ See the [Sponsored Projects Handbook](#) for how to locate public and private funding, including sources of seed funding within the University
- ✓ Access CU Research Initiatives' resources on funding opportunities at their [Funding Resources website](#)

Key Links

[Sponsored Projects Handbook](#)
[CU Research Initiatives website](#)
[Administrative Policy Library](#)
[Institutional Information for Applications](#)
[RASCAL](#)

- ✓ To obtain intramural funding for pilot and collaborative initiatives, tap into the resources available through the Irving Institute for Clinical and Translational Research's [Pilot and Collaborative Translational and Clinical Studies Resource](#)
- ✓ Contact SPA or the CUMC Office of Alumni and Development for assistance in making a determination as to whether a particular source of funds is a gift or a sponsored project (see Section 15.3.1)

5.7.2 Essential Elements for Proposal and Budget Development

- ✓ ***Sponsored Projects and Clinical Trial Applications:*** Work with the CDM Office of Research Administration (ORA) on the preparation of proposals and budgets.
- ✓ ***Confidential Disclosure Agreements:*** For industry proposals submitted through the ORA and CTO, send the sponsor's *Confidential Disclosure Agreement* to the ORA as soon as it is received, and the ORA with the CTO in turn will begin collaborating with the department, center, or institute on the proposal
- ✓ ***Institutional Information:*** For completing grant/contract applications, use the key information provided in [Institutional Information for Applications](#), such as the University's legal name, address, contact information, taxpayer ID numbers, indirect cost (IC) rates, fringe rates, and other important budgetary items
- ✓ ***Administrative Salaries and Supplies:*** Do not include administrative salaries and supplies in a proposal budget unless allowed as per University policies on *Charging Administration and Clerical Salaries to Federal Grants and Contracts* and *Charging Office Supplies and Other Administrative Expenses (other than salaries) to Federal Awards* (available in the [Administrative Policy Library](#))
- ✓ ***Equipment:*** When budgeting equipment in a proposal, take care to include shipping, installation, and other costs associated with acquisition
- ✓ ***Computers:*** If requesting funds from U.S. government sources for computers (which are rarely an allowable expense), provide a justification explaining the use of the equipment vis-à-vis the research to be carried out and an assurance that it will be used exclusively for that research
- ✓ ***Indirect Costs/F&A:*** Include indirect costs in all proposal budgets, whether to public or private funding sources, and make sure the proper IC rates are used (see [Institutional Information for Applications](#))
- ✓ ***Cost Sharing:*** Avoid committing the University to cost sharing to the extent possible when seeking funding, and only proceed if the costs are identified and approved by the person with authority over the funds at the time the commitment is made (see the *Columbia University Policy on Cost Sharing* in the [Administrative Policy Library](#))
- ✓ ***Conflict of Interest (COI) Disclosures:*** If not already on file, have "key personnel" on the proposal complete an annual COI disclosure in [RASCAL](#); for human subjects research, have personnel submit individual, protocol-specific COI disclosure forms
- ✓ ***RASCAL Submission:*** Complete the online RASCAL submission for the specific proposal

For more information on budget development, see "Preparing a Sponsored Project Budget" in the [Sponsored Projects Handbook](#). For more information on required

approvals when preparing and submitting a proposal, see the “Special Approval Summary Chart” in the [Sponsored Projects Handbook](#) and the [Research Compliance and Training website](#).

Note on NIH Just-in-Time Procedures: NIH permits applicants whose applications fall within a certain percentile or priority score range that makes them likely to be funded to submit certain additional information that is needed to make an award but is not required with an original application (e.g., IRB approval). The applicant can submit this information “just in time” only when it is specifically requested by NIH. See “Just in Time Notification” in the [Sponsored Projects Handbook](#).

5.7.3 Essential Elements for Proposal Review and Approval

- ✓ **PI Certification:** Through RASCAL, secure written assurances from all PIs on the project prior to submitting any application
- ✓ **Departmental Approval:** Always obtain approval through RASCAL from the relevant section chair, center/institute director, dean, or other authorized official of the school prior to submitting a proposal
- ✓ **Collaborative Projects:** If collaborating with another department or school, obtain approval through RASCAL from one of their authorized officials as well
- ✓ **International Activity:** If the funding application proposes international activity in any form, arrange for compliance with U.S. and others’ laws and regulations that may apply to the conduct of international research, collaborations, and procurements (see [Section 5.15](#))
- ✓ **Export Controls:** If the project design involves military technology or technology with both military and civilian application, check whether U.S. laws governing export controls are implicated; to exempt University research from these laws, have it meet the definition of “fundamental research” by avoiding any proposal terms that restrict publication or project participation based on nationality (see the [International Research website](#) and check “Key Laws and Regulations”)
- ✓ **International Project Operations:** If the funding application proposes establishing ongoing operations in a new international locale, obtain appropriate University approvals (see Section 5.15)
- ✓ **SPA/CTO Approval:** Working with ORA, always obtain SPA or CTO approval *prior to* submitting a proposal (see steps in the process in [Section 5.7.4](#))
- ✓ **Federal Forms and Certifications:** If submitting a proposal to a U.S. government agency, prepare the required federal standard forms and certifications in conjunction with SPA or the CTO, which is responsible for signing them
- ✓ **Non-CU Proposals:** If submitting a proposal for outside funding through an institution other than Columbia University, work with ORA to obtain written permission from the Provost through the CUMC Dean’s Office
- ✓ **STV Consultations:** If a research proposal has intellectual property or sublicensing issues and/or is for submission to an industry sponsor, consult with CDM ORA who will work with the Office of Science and Technology Ventures (STV) prior to submitting it for funding

- ✓ **Proposal Negotiations:** If the terms and conditions of an award need to be negotiated or the sponsor is proposing to reduce the budget, work closely with the CDM ORA. **For more details on PI** certification, departmental approval, under what conditions an award may be accepted, and other associated topics, see the [Sponsored Projects Handbook](#).

5.7.4 Institutional Review and Approval

All funding applications must be reviewed and approved by SPA or the CTO with approval of the department chair or center/institute director. The procedure is as follows:

1. Proposals to federal agencies that require electronic submission through [grants.gov](#) (such as those for NIH funding) must be written in [InfoEd](#), which is the University's web-based suite of IT modules designed to assist researchers and administrators in the grants management cycle. The CDM ORA prepares these electronic submissions.
2. CDM ORA requires submission of the **final version** of the proposal **at least 10 business days in advance** of the sponsor's deadline, ORA will submit to SPA and the CTO which require submission of the **final version** of the proposal **at least 5 business days in advance** of the sponsor's deadline – with no exceptions. If any special approvals are required, additional processing time may be necessary, especially if the sponsor requires such approvals at the proposal stage.

Note: *The deadline used by electronic systems such as NIH's eRA Commons or grants.gov is the actual moment the agency's computer receives and logs the proposal as received. Adequate time for transmission and Internet traffic means that SPA or the CTO must have the final application for submission five business days prior to the sponsor's due date. Even if a sponsor states a deadline outside of normal business hours (e.g., 8 p.m. or 12 midnight), the PI must plan to submit a proposal within normal Columbia University business hours, between 9 a.m. and 5 p.m.*

3. When submitting a proposal to ORA, the PI includes any special program announcements or sponsor guidelines that one must follow in proposal preparation. This enables the ORA to review and advise the PI of any necessary changes and also any special handling requirements.
4. ORA reviews the proposal to ensure compliance with sponsor and University policies and guidelines and, upon completion, contacts the PI to advise him/her of any errors or omissions in the proposal.
5. The PI, ORA and SPA/CTO work together to finalize the proposal.
6. The electronic approvals of ORA, the PI, department chair or center/institute director, and the appropriate authorized University individual (usually the SPA/CTO Project Officer) are obtained. In addition, if NYP resources are used, electronic approval of

the hospital is obtained. The proposal is signed on behalf of the University by a Director or Associate Director, who may, if required, countersign a covering letter certifying the University's approval of the project.

7. With all approvals on file, SPA/CTO formally submits the proposal if it is for any governmental entity or one of several non-governmental institutions. If for another sponsor, SPA/CTO returns a hard copy of the signed proposal to ORA or the department, center, or institute for mailing.

For non-electronic submission only:

8. Proposals should not be bound in any fashion. Indeed, some sponsors request that proposals be submitted unbound and in most cases photocopied on single-sided sheets. Most sponsors prefer that proposals be fastened with staples only. If intending to submit proposals in binders, the PI should first contact the sponsor to ensure that this is permissible.
9. The SPA/CTO Project Officer keeps two full copies of the final application submission, while the PI and SA should each keep one full copy on file, bearing in mind the need to maintain the confidentiality of salary information.

5.8 INITIATING AN AWARD

Essential elements for initiating an award are:

- ✓ ***Notices of Awards:*** If the PI or SA receives a notice of an award (award notification), notify ORA, and forward it to SPA/CTO for signature and processing; in all cases, PIs and SAs should become familiar with the requirements and restrictions noted therein
- ✓ ***IBC Approval:*** Obtain Institutional Biosafety Committee (IBC) approval, if the research entails handling hazardous materials such as potentially infectious tissues or bodily samples or involves gene transfer
- ✓ ***Radioactive Materials:*** If using radioactive materials, obtain approval from the Radiation Safety Coordinator (RSC) prior to commencing research (see the [Radiation Safety Code & Guide](#))
- ✓ ***IRB and IACUC Approvals:*** Ensure that required IRB and IACUC reviews are completed (see Section 5.13 and Section 5.14)
- ✓ ***Clearances, Surveillance, Training:*** As required for individuals working on a research project, undergo medical surveillance (see the University's [Medical Surveillance Policy and Procedure](#)), obtain clearance from [Environmental Health & Safety](#) (EH&S), and acquire other training related to sponsored projects (see [RASCAL Training Center](#))

Key Links
Sponsored Projects Handbook
Research Compliance and Training website
Radiation Safety Code & Guide
Medical Surveillance Policy and Procedure
Environmental Health & Safety
RASCAL Training Center

- ✓ **Account Set-Up:** Support SPA/CTO with fulfilling the requirements for account set-up (see “Account Setup” in the [Sponsored Projects Handbook](#), which includes details on account numbering); in situations where an award is pending but receipt of the official notification is delayed, request that SPA/CTO set up the account in advance, based on a departmental guarantee, in order to avoid cost transfers
- ✓ **Pre-Award Costs:** Obtain written authorization from the sponsor prior to incurring pre-award costs and establish an advance account, as specified in the [Sponsored Projects Handbook](#)

For further information, see the “Special Approval Summary Chart” in the [Sponsored Projects Handbook](#) and the [Research Compliance and Training website](#).

5.9 MANAGING AN AWARD

5.9.1 Essential Elements for Award Management

<p>Key Links Sponsored Projects Handbook Administrative Policy Library SPA’s Internal Forms webpage Sponsored Projects Finance Effort Reporting website Guide for Inventors</p>

- ✓ **Grant/Contract Compliance:** Comply with sponsor rules and regulations and associated obligations in financial management, effort reporting, procurement, property management, travel, subaward management, and other matters
- ✓ **Financial Management:** Follow University procedures for financial management of awards, including charging expenditures, handling cost transfers, and monitoring and reviewing award status (see “Financial Management of Sponsored Projects” in the [Sponsored Projects Handbook](#) and this manual’s Section 9.4.2 and Section 10: Procurement)
- ✓ **Effort Reporting:** Ensure that Salary Accounting Forms to assign effort to appropriate funding sources are done on a timely basis, with timely updates as appropriate; ensure that effort devoted to sponsored projects is monitored during the fiscal year by PIs; and ensure that the annual certification confirming that the salaries charged to sponsored projects are reasonable in relation to the effort devoted to those projects is completed within the certification period (see the [Effort Reporting website](#) for the full text of the effort reporting policy as well as guidance, tools, training information, and other resources)
- ✓ **Large Requisitions:** Prior to submitting a requisition over \$10,000 to CU Procurement Services, obtain SPA approval if the requisition is on a federally funded project
- ✓ **Participant Support Costs:** Adhere to sponsor regulations regarding participant support costs, as laid out in the University’s policy on *Participant Support Costs*, available in the [Administrative Policy Library](#) (see Section 9.13.4)
- ✓ **Equipment Not in the Original Budget:** If required under the award, seek sponsor and SPA/CTO approval prior to procuring major equipment not originally identified in the budget (such re-budgeting has an impact on direct and indirect costs)

- ✓ **Budget Monitoring:** Make sure that for each sponsored project, PIs are reviewing on a monthly basis the budget vs. actual expenses and completing a form attesting that the expenses are valid and within the approved budget (see Section 9.12)
- ✓ **Financial Reporting:** Submit reconciliations to [Sponsored Projects Finance](#) no later than 30 days prior to the date that the financial report is due to the sponsor (see Section 9.19)
- ✓ **Cost Transfers:** Make requests for **cost transfers from sponsored projects** whenever it is determined that a charge previously assigned to a sponsored project was incorrect; make requests for **cost transfers to sponsored projects** within 90 days following the end of the month in which the original charge was posted, including salary cost transfers related to actual effort expended (see Section 9.16.3)
- ✓ **Rebudgeting:** If planning to rebudget among categories in an award's budget, seek prior approval by SPA/CTO, which will determine if the rebudgeting has significant programmatic impact and whether recalculation of the allocation for indirect costs is required
- ✓ **Modifications and Amendments:** Seek prior SPA or CTO approval before proceeding with modifications to existing awards and negotiate the changes with the sponsor in close collaboration with SPA/CTO (see "Account Setup and Modification" in the [Sponsored Projects Handbook](#))
- ✓ **Audits:** If contacted by an external auditor about grant/contract funding, refer the auditor to [Sponsored Projects Finance](#) in the University's Office of the Controller, as they are responsible for coordination of all grant/contract audits (see Section 9.23)
- ✓ **Program Income:** Comply with U.S. government regulations for income generated as a by-product of the work performed under a federally funded project (see the University's policy on *Treatment of Program Income on Sponsored Project Accounts* in the [Administrative Policy Library](#))

5.9.2 Intellectual Property

- ✓ Have on file for each person involved in a project, as required, a letter agreeing to assign to the University any patentable inventions which the individual conceives or reduces to practice at the University (see the *Invention Agreement* on [SPA's Internal Forms webpage](#))
- ✓ Ensure compliance with University stipulations not to infringe the copyright and patent interests of others and to preserve the University's own copyright and patent interests
- ✓ Use consultant agreements that specify that Columbia University owns the copyright to materials the consultant may produce (see the University's *Copyright Policy*, available in the [Administrative Policy Library](#))
- ✓ For all inventions made with U.S. government funding, have University employees disclose and sign all papers necessary to file patent applications on those inventions

Section 12.3 covers these topics in more depth. See also the [Guide for Inventors](#), on STV's website for faculty, which covers proprietary rights in the intellectual products of faculty activity.

5.9.3 Record Retention

- ✓ Support PIs in fulfilling their responsibility to establish and maintain electronic and hard-copy filing systems, and to manage and retain research data in sufficient detail and for a period of time to fulfill sponsor, IRB, and other University requirements
- ✓ Retain any correspondence with the sponsor, any report submitted to the sponsor, or other such exchange

See details in the [Sponsored Projects Handbook](#)'s section on retention and access to research data.

5.10 TRANSFERRING OR CLOSING OUT AN AWARD

5.10.1 Essential Elements for Transferring an Award

In handling transfer of awards, it is important to keep in mind that grants and contracts are always made to the institution rather than to a PI. Key elements are:

Key Links

[Sponsored Projects Handbook](#)
[Administrative Policy Library](#)
[Sponsored Projects Finance](#)
[Clinical Trials Office](#)
[Finance Division Forms Library](#)

- ✓ If a PI – with consent from his/her departmental chair or center/institute director – plans to transfer an award to or from Columbia, notify [Sponsored Projects Finance](#) or the [Clinical Trials Office](#) as soon as possible to alert them
- ✓ Prior to sending official notification to the sponsor, have the PI submit a letter of resignation to his/her departmental chair or center/institute director and ensure his/her termination of employment corresponds to the proposed date of award transfer
- ✓ If transferring an award from Columbia requires terminating grant- or contract-supported positions, discuss the situation *in advance* with the CDM HR Office. If intending to transfer an NIH award to another institution, contact the CDM ORA immediately. ORA will notify NIH approximately 60 days before the date of the transfer, and request permission to transfer via a letter signed by the PI, department chair or center/institute director, and a SPA official
- ✓ Once institutional approvals have been obtained from the University and the sponsor, and prior to termination, complete any statements required by the sponsor

For NIH grants, these statements include a *Final Invention Statement and Certification* (Form HHS 568) and an *Official Statement Relinquishing Interests and Rights in a Public Health Service (PHS) Research Grant* (Form PHS 3734). See [NIH Forms and Applications](#). The PI and ORA should work with the SA on the latter form to ensure that correct figures for the estimated unexpended balance are presented and that full details, including serial numbers, are included for equipment to be transferred.

- ✓ Send the statements required by the sponsor to Sponsored Projects Finance with a signed verification of the accuracy of the reported unexpended balance, obtain SPF approval, and submit the statements to the sponsor
- ✓ When preparing for a transfer, make sure all project reporting requirements are up to date
- ✓ When using animals and human subjects, hold discussions with the IRB, the IACUC, and the Institute of Comparative Medicine (ICM) on the transfer procedures for protocols
- ✓ If proposing to move equipment when the PI relocates, submit the *Equipment Inventory Adjustment Form* (in the [Finance Division Forms Library](#)) to the Office of the Controller to request approval (see [Section 5.10.2](#) for guidelines on equipment transfer)
- ✓ Properly close out the award at the PI's prior institution and provide a final financial accounting to the sponsor; once the sponsor concurs, monitor that the award balance is actually transferred to the new institution

For more guidance on transferring an award to or from the University, contact ORA and see "Transfer of Grant to or from Columbia" in the [Sponsored Projects Handbook](#).

5.10.2 Equipment Transfer Guidelines

When a PI transfers to another institution, the transfer of project equipment is subject to the following guidelines:

- Equipment purchased from CU institutional (general) funds may not be transferred.
- Equipment purchased with funds from an ongoing grant or contract is usually moved along with the transfer of the grant/contract to the new institution, *if* the equipment is needed for continuation of the project. Prior approval from the sponsor is nearly always required.
- Equipment purchased with funds from a grant or contract that has terminated or will terminate by the time the PI transfers may not be transferred. (Equipment purchased under a grant or contract that has ended belongs to Columbia University unless otherwise specified in the award.)
- Equipment retained by the University may be sold at a price commensurate with its depreciated cost or given at no cost to the new institution. The arrangement must have prior approval from the CDM Dean's Office. Proceeds from these transferred assets are credited to research in the department, center, or institute where the grant or contract was originally funded.

5.10.3 Essential Elements for Closing out an Award

The PI is responsible for programmatic and operational close-out of a sponsored project, including 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. The SA provides support to this process and plays an important role in ensuring that all the details are attended to, particularly the financial ones, and that the project is closed out in a timely way and according to the terms of the award. Essential elements are:

- ✓ If intending to terminate a project prior to the award's end date, send to the sponsor an official notification of intent to terminate, with signatures of the PI, department chair or center/institute director, and an SPA official.
- ✓ For larger projects with major operations, consider drafting a written plan for the close-out process, including the strategy for phasing out each major activity, specifics for staff lay-offs and transitions, and details on closing out subawards
- ✓ When the end of an award may require terminating grant- or contract-supported positions, discuss the situation *in advance* with the CUMC HR Client Manager (see [Section 7.30.4](#)) or CUMC Office of Faculty Affairs (see Section 8.25)
- ✓ Submit all technical reports required by the sponsor
- ✓ If an account is overspent (i.e., expenses on the University's Financial Accounting System - FAS - exceed the funding award), clear the overdraft in order to close the account (see "Overdrafts" in the [Sponsored Projects Handbook](#))
- ✓ Provide SPF with accurate and timely financial reconciliations on which to base the financial reports required for close-out
- ✓ Check that the indirect costs reported to the sponsor are calculated at the proper rate
- ✓ Make any charges and/or adjustments necessary 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
- ✓ Close any bank accounts and petty cash funds, reconcile travel advances, terminate services and contracts, and close out subawards
- ✓ In concert with the Office of the Controller and, in particular, with SPA, close both advance accounts and FAS sponsored/restricted accounts

A sponsored/restricted account may be closed out when the account is in balance, i.e., when project-to-date expenses on FAS agree with the total amount of expenditures on the Financial Status Report (FSR) submitted to the sponsor.

Sponsored Projects Finance is generally responsible for financial reporting at close-out. U.S. government regulations require that FSRs be submitted within 90 calendar days following the expiration of either the budget year of the project, or more commonly, following the expiration of a competitive segment of the award. For other sponsors, reporting deadlines vary and are dictated by the policies of those sponsors or stated terms and conditions of the award.

For more details, contact [Sponsored Projects Finance](#) and see the [Sponsored Projects Handbook](#) and policies in the [Administrative Policy Library](#) such as *Financial Reporting and Closeout of Sponsored Projects*, *Project Administration Account Closeouts*, and *Overdrafts on Sponsored Project Accounts*.

5.11 SUBAWARDS

5.11.1 University Policy and Procedures

Key Links

Sponsored Projects Handbook Administrative Policy Library
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SAs involved in any aspect of subaward management should be thoroughly familiar with the University's *Policy on Sponsored Project Subawards*, which is available in the [Administrative Policy Library](#). The *Policy on Sponsored Project Subawards* covers unit-level and individual responsibility and accountability for the establishment and management of subawards and compliance with sponsor requirements. It also provides definitions and descriptions of the mechanisms and players. SAs should know the distinctions among a subaward, a subcontract, a subgrant, a purchase service agreement, a trial protocol agreement, a subrecipient, a subgrantee, a subcontractor, and other related terms.

For more detail on policies and procedures, see the University's *Policy on Sponsored Project Subawards* in the [Administrative Policy Library](#) and the relevant U.S. government circulars referenced in that policy. See also the [Sponsored Projects Handbook](#), which has two primary sections relevant to subawards: "Special Approvals: Subawards" and "Monitoring and Reviewing the Status of Individual Sponsored Projects: Subawards."

5.11.2 Compliance and "Flow-Down Provisions"

Subawards must conform to federal and state laws and the restrictions placed by the sponsor upon the primary award, whether the primary award is a grant, cooperative agreement, or contract. That is, subrecipients must comply with all ***flow-down provisions*** from the prime award that apply as well through the subaward mechanism. The responsibility of Columbia University is to flow down to subrecipients all applicable obligations, such as those associated with effort reporting.

5.11.3 SA Responsibilities

Subaward responsibilities are defined in the University's *Policy on the Sponsored Project Subawards*, available in the [Administrative Policy Library](#). The policy stipulates that:

- Subrecipient monitoring for all ***non-clinical subawards*** is a shared responsibility of the PI, SA, chair/director, SPA, and the Research Policy and Indirect Cost Department of the Office of the Controller (RP&IC). Subrecipient monitoring for all ***clinical trial subawards*** is the shared responsibility of the PI, the SA, the chair/director, SPA, the CTO, and RP&IC.
- The preparation and negotiation of subawards other than clinical trials conducted at CDM are the responsibilities of the ORA and SPA.

- The preparation and negotiation of subawards for clinical trials are the responsibilities of the ORA and CTO
- SPA is responsible for the final approval and execution of all subaward agreements/contracts and for initiating all procurement actions needed to encumber the University financial systems

PIs may delegate responsibility for day-to-day subaward management to others, most notably to the SA. SAs frequently are responsible for assisting with some or all of the following:

- Identify and assess potential subrecipients
- Advise subrecipients of applicable U.S. government laws and regulations, and appropriate flow-down provisions from the prime award
- Provide technical support to subrecipients in financial monitoring and contractual management, as needed
- Ensure subrecipient compliance with subaward reporting requirements
- Conduct financial monitoring, including timely review of reports
- Take appropriate action, including notification to SPA, in cases of recurrent or otherwise significant non-compliance with subaward terms and conditions

5.11.4 Essential Elements for New Subawards

- ✓ Follow University procedures prior to submitting an application for funding that includes subawards (see the University's *Policy on Sponsored Project Subawards* in the [Administrative Policy Library](#))
- ✓ Collaborate with SPA and, where applicable, the CTO throughout the process of preparing and executing subawards following receipt of a notice of award
- ✓ Collaborate with SPA and, where applicable, the CTO when making arrangements for any new subaward, providing them with copies of the statement of work (also known as the Scope of Work – SOW), budget, budget justification, and other documentation specified in Appendix A of the University's policy on subawards (in the [Administrative Policy Library](#))
- ✓ Establish subawards for periods no longer than one year, renewable for additional periods as appropriate
- ✓ Confirm that prospective subrecipients are not among federally debarred or otherwise prohibited entities or individuals by referencing the U.S. Department of Commerce's [Lists to Check](#) (see special approvals for international research in the [Sponsored Projects Handbook](#))
- ✓ Have a *Sole/Single Source Justification Form* or memo on file in the case of non-competitive procurements
- ✓ Where required for subawards over \$500,000 to certain recipients, conduct a risk assessment before executing a Risk Assessment Subaward (see the University's *Policy on Sponsored Project Subawards* in the [Administrative Policy Library](#))
- ✓ Have an authorized official of the subrecipient organization sign final versions of SOWs and budgets to indicate their concurrence with the contents

- ✓ Work with ORA and SPA or the CTO to obtain sponsor approval where required for new subawards or major changes to existing ones, including no-cost extensions (NCEs) and cost extensions (continuations)

5.11.5 Essential Elements for Post-Award Management

- ✓ Name one or more University staff members explicitly as the liaisons between the University and the subrecipient organization, with clearly defined responsibilities in the areas of both financial and technical oversight
- ✓ Maintain electronic and physical records of all documentation and communications pertaining to each subaward, and follow the University's and the sponsor's record retention policy
- ✓ Plan adequately for the time it takes between receipt of a notice of award and issuance of the first payments to subrecipients
- ✓ Wait to process advance requests until the PI has in hand the expenditure and technical reports required from the subrecipient
- ✓ Review all subrecipient invoices or expense reports, comparing them to the subaward budget and disallowing unreasonable, unallowable, or unallocable costs (see specific requirements in Appendix D of the University's *Policy on Sponsored Project Subawards* in the [Administrative Policy Library](#))
- ✓ Sign off on all invoices and expense reports, and retain copies in the department/center files (see specific requirements in Appendix D of the University's policy on subawards in the [Administrative Policy Library](#))
- ✓ As necessary to evaluate subaward implementation, visit subrecipients' project sites, provide technical assistance, and check on progress against SOWs
- ✓ Document technical and financial visits to subrecipients
- ✓ Through SPA or the CTO, obtain sponsor approval prior to the subrecipients' making expenditures for restricted items (e.g., in the case of federal funding, expenditures for building alterations and renovations, subawards to other organizations, consultants, international travel, and major equipment)
- ✓ Require that, where applicable, subrecipients maintain a property log and submit it on an annual basis with the final expenditure report
- ✓ Require subrecipients to submit effort reporting certifications, documenting work on University-funded activities
- ✓ Notify SPA or the CTO of any developments that have a significant impact on the activities supported by the subaward, including any problems, delays, or adverse conditions that may materially impair the subrecipient's ability to meet the objectives identified in the subaward SOW

5.11.6 Essential Elements for Subaward Extensions and Close-Out

- ✓ Notify the subrecipient 30 days prior to the expiration of a subaward and, as appropriate, facilitate their requesting a no-cost extension (NCE) or cost extension (continuation)

- ✓ Send a close-out letter to the subrecipient 30 days prior to the end date of a subaward, if it has been determined that the subaward will not be extended
- ✓ Formally close out the subaward within 60 days of the conclusion of the period of performance, unless SPA or the CTO grants an extension of time (see specific requirements in Appendix F to the University's *Policy on Sponsored Project Subawards* in the [Administrative Policy Library](#))

5.11.7 Subaward Standard Operating Procedures

Mailman School's International Center for AIDS Care and Treatment Programs (ICAP) conducts programs extensively through subrecipient organizations and has comprehensive standard operating procedures ([ICAP SOPs](#)) for subaward management. These standard operating procedures are a good resource for other CUMC programs and projects that are giving subawards, especially those operating internationally. PIs and DAs should adapt and adopt them as appropriate for the size and nature of their project and in accordance with proper risk management.

5.12 RESEARCH COMPLIANCE

5.12.1 Conflict of Interest Policies

Columbia University requires all of its employees and consultants to be in compliance with laws and University and sponsor policies regarding medical research. SAs must be familiar with the relevant conflict of interest (COI) policies and support CDM efforts to prevent the appearance of or real conflicts of interest. These policies are:

Key Links

Faculty Handbook

Administrative Policy Library

COI in Research website

P&S COI Policy website
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RASCAL

Columbia University Medical Center Conflict of Interest Policy (1994): This University COI policy governs CUMC employees' research and administrative activities and is available in Appendix G of the revised [Faculty Handbook](#). The policy establishes safeguards to prevent medical faculty, employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties.

Conflict of Interest Policy Regarding Education and Clinical Care for CDM Faculty (2009): This University COI policy governs CDM employees' education and clinical care activities and is available at CUMC Academic Affairs' [P&S COI Policy website](#). The policy establishes safeguards to prevent perceived or real conflicts of interest in academic-industry relationships, where potential questions may arise regarding the intellectual independence of faculty who are involved with commercial enterprises. It provides direction regarding support from commercial entities for educational activities (including meals), gifts, consultation, continuing medical education (CME), non-CME

presentations and publications, travel, speakers' bureaus, ghost writing, inventions, and drug and device representatives and samples.

A new University-wide *Policy on Conflict of Interest in Research* is currently being considered by the University Senate. When approved, the final version will be posted in the [Administrative Policy Library](#).

For more information on the University's conflict of interest policies, including those not specific to medical research, see Section 2.3. See also the revised [Faculty Handbook's Appendix E: Statement of University Policy on Conflicts of Interest](#) and *Appendix F: Columbia University Guidelines for Situations Involving Potential Conflicts of Interest Between Scholarly and Commercial Activities*.

5.12.2 Compliance Filings in RASCAL

To ensure compliance in the conduct of research, University personnel must use [RASCAL](#), the University's Research Compliance and Administration System, for the following:

- ***HIPAA and Human Subjects Protection Training Certifications:*** See Section 5.13.
- ***Human Subjects Protection Approval:*** See Section 5.13.
- ***Conflict of Interest Disclosure for Research and Administration:*** Annual conflict of interest disclosure statements regarding research must be filed by all University officers, including officers of administration, when first hired and on an annual basis thereafter. Each year on the anniversary of an employee's hire date, he/she will receive a reminder to complete and file the form in RASCAL.
- ***Annual Conflict of Interest Disclosure:*** Annual conflict of interest disclosure statements must be filed by all officers of instruction, officers of research (except post docs), and officers of administration. Officers of instruction and research must file an annual conflict of interest disclosure form when first hired and on an annual basis thereafter in RASCAL. Around the anniversary of the filing of the first form, individuals should receive an automatic reminder from RASCAL to complete the current year's form. Officers of administration file their annual disclosures through the [Office of Internal Audit's COI website](#).
- ***Protocol-Specific Conflict of Interest Disclosure:*** Protocol-specific conflict of interest disclosures for research with human subjects must be submitted for each protocol that has human subjects. For further information, see the University's [Conflict of Interest in Research website](#).
- ***CDM Annual Conflict of Interest Disclosure Regarding Education and Clinical Care:*** Annual conflict of interest disclosure statements of significant commercial support pertaining to education/training and clinical service must be filed annually by all P&S officers of instruction and research (full-time and part-time, clinical and non-clinical). For further information, see the frequently asked questions (FAQs) available on CUMC Academic Affairs' [P&S COI Policy website](#).

Note that COI disclosures must be current for all officers and faculty on a sponsored project in order for the University to permit any proposal to be submitted to a sponsor or any award account to be established.

5.13 HUMAN RESEARCH PROTECTION PLANS

5.13.1 Resources

CUMC's [Human Research Protection Program](#) website has a plethora of information for those conducting research with human subjects and dealing with the Institutional Review Board. It offers resources such as policies, procedures, forms, a list of acronyms, and recommendations on computer- and internet-based research protocols. It also provides links to the U.S. Department of Health and Human Services' (HHS) reference collection and policies, and to national and international standards.

Key Links

[Sponsored Projects Handbook](#)
[Administrative Policy Library](#)
[RASCAL](#)
[Human Research Protection Program](#)
[IRB Policies and Guidance](#)

Another important resource is [RASCAL](#), which is used for creation of human subjects protocols and submission to the IRB. Included are:

- Consent Form Builder tools that assist in the building of consent forms
- Creation of a PDF of the consent forms with the IRB approval stamp, when approved
- Agenda/Minute Module for IRB administrative management
- Approval routing for the Cancer Center, the CTO, Radiation Safety, HIPAA, and the Clinical and Translational Science Award (CTSA) program

Among all these resources, of particular relevance to SAs are the *IRB Standard Operating Procedures* and policies at [IRB Policies and Guidance](#) and the conflict of interest policies covered in [Section 5.12](#).

5.13.2 Essential Elements for Human Research Protection

Most of the following requirements and procedures are the full responsibility of the PI, but may be of importance to the SA in fulfilling his/her administrative responsibilities for sponsored projects. More information may be found in the [Sponsored Projects Handbook](#) and on CUMC's [Human Research Protection Program](#) website.

For all research with human subjects, including special projects, University personnel are required to follow these steps:

- ✓ Be familiar with CUMC's [Human Research Protection Program](#) (HRPP)
- ✓ Develop the protocols for the research

- ✓ Enter the required information in the [RASCAL](#) Proposal Tracking Module
- ✓ As with all proposals, have the proposal reviewed and approved by SPA or the CTO and submit the funding application
- ✓ If a sponsored project requires the use of human subjects, or tissue or other human material that may be identifiable, confer with CUMC's IRB Office to determine whether advance review and approval are required

Note that the CUMC IRB also acts as the Privacy Board under the Privacy Rule of HIPAA, which governs the use of data involving protected health information in research studies. See the University's HIPAA Policy in the [Administrative Policy Library](#) for more information.

- ✓ **Application:** Complete and submit an *Application for the Approval of the Use of Human Subjects in Research* (IRB protocol form) on [RASCAL](#) (see the *User's Guide to the RASCAL IRB Module*, link at [Human Research Protection Program](#))
- ✓ **IRB Meetings:** Refer to the meeting schedules of CUMC's four IRBs (see "Meeting Schedule" link in the middle of the page at [Human Research Protection Program](#))
- ✓ **IRB Approval:** Do not begin research until IRB approval or certification of exemption is received
- ✓ **Sponsor Approval:** Once IRB approval is received, submit a copy of the approval to the sponsor
- ✓ **Stem Cell Research Requirements:** If conducting stem cell research, be familiar with and comply with the University's *Policy on the Conduct of Research with Human Embryos and Human Embryonic Stem Cells* and *Human Embryo and Human Embryonic Stem Cell Research Special Operating Procedures* (see links at [IRB Policies and Guidance](#))
- ✓ **Required Training:** Ensure that all personnel working on a project with human subjects complete mandatory training in human subjects research protection, which is accessed through the [RASCAL Training Center](#) and is provided by the Collaborative Institutional Training Initiative (CITI) (see the [CU Human Research Protection Program's website](#) for details)
- ✓ **Recording Consent:** If a research study involves the audio, video, photographic, or any other recording of research subjects, obtain prior IRB approval for the consent form (for a sample form and more details, see the IRB policy on *Audio/Video/Photographic Recording of Human Subjects*, link at [IRB Policies and Guidance](#))
- ✓ **Informed Consent:** In accordance with federal regulations, obtain informed consent from every human subject or the subject's legally authorized representative, unless the requirement has been waived by the IRB or the research is exempt from IRB review (see links to policy, forms, and tip sheets at [IRB Policies and Guidance](#))
- ✓ **Payments to Human Subject:** Conform to the special conditions that apply to reimbursement to human subjects, as all receipts for human subjects need to be HIPAA compliant and, according to IRS regulations, annual compensation (subject incentives) to study subjects of \$600 or greater is considered taxable compensation and reportable to the IRS (see the University's policy on *Petty Cash* in the [Administrative Policy Library](#))

- ✓ **Collaborative Research:** If the CUMC IRB is acting in liaison with the IRB of other institutions, adhere to the respective IRB Authorization Agreements (“Cooperative Amendments” – see links for the New York State Psychiatric Institute IRB and Western IRB (WIRB) on the [Human Research Protection Program](#) website)
- ✓ **Unanticipated Problems Involving Risk:** Report to the designated IRB of record both serious and non-serious unanticipated problems that involve risks to subjects or others and are related to research (see the University’s policy on *Reporting to the IRB of Unanticipated Problems Involving Risk*, link at [IRB Policies and Guidance](#))
- ✓ **Noncompliance Policy:** Upon receipt of an allegation of noncompliance with laws, regulations, or institutional or governmental policies governing the protection of human subjects in research, immediately take action in accordance with the University’s policy on *Noncompliance with Human Subject Regulations* (link at [IRB Policies and Guidance](#))
- ✓ **Record Retention:** Follow sponsor requirements for retention of records associated with IRB activities, as summarized in the *IRB Standard Operating Procedures* (link at [IRB Policies and Guidance](#))

5.14 ANIMAL PROTOCOLS

5.14.1 Use of Animals

The responsible care and use of animals in research is a matter of utmost importance to Columbia University and of considerable interest to the public. The University’s animal facilities are managed by veterinarians who are

Board-certified specialists in animal care. The policies and procedures for animal care are reviewed regularly by internal committees, by state and federal regulators (the Office of Laboratory Animal Welfare – OLAW – and the United States Department of Agriculture - USDA) and by an independent outside accrediting agency.

Columbia University reviews each proposal for animal research against the basic principles of the “3Rs,” which guide the medical community at large:

- **Replace** the use of animals whenever possible
- **Reduce** the number of animals needed to a minimum
- **Refine** tests to cause animals the least possible distress

If departments, centers, or institutes are conducting medical research with animals, the PI and SA should be thoroughly familiar with the University’s [Medical Research with Animals website](#). A good reference to help respond to those asking about University research involving the use of animals is the [Frequently Asked Questions](#) on the Medical Research with Animals website.

Key Links

- [Sponsored Projects Handbook](#)
- [Administrative Policy Library](#)
- [Medical Research with Animals website](#)
- [Institutional Animal Care and Use Committee](#)
- [Institute of Comparative Medicine \(ICM\)](#)
- [ICM Forms](#)
- [ICM billing office](#)
- [Office of Laboratory Animal Welfare \(NIH\)](#)

5.14.2 Federal Regulations and IACUC Approval

Research involving animals is federally regulated under the [Animal Welfare Act](#) (AWA) and the [Health Research Extension Act of 1985](#). These laws are administered and enforced by USDA and NIH's OLAW. USDA has issued extensive regulations under the Animal Welfare Act; in addition, OLAW requires all institutions that conduct animal research supported by the Public Health Service to comply with the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) (the PHS Policy). For further information, see the [OLAW website](#).

As required under federal regulations, Columbia University maintains an [Institutional Animal Care and Use Committee](#) (IACUC) to review projects that involve animals and to oversee the training of personnel and the maintenance of animal facilities. The University's IACUC rigorously scrutinizes every section of a research and/or teaching protocol that involves animals and only approves the use of animals when satisfied that there are compelling reasons to do so. The IACUC only approves the use of animals when the information that will be gained is considered useful in saving human lives or treating disease and/or when the information cannot be gained without the use of animals.

5.14.3 Essential Elements for Animal Care and Use

- ✓ If a project requires the use of vertebrate animals, obtain prior approval from the Institutional Animal Care and Use Committee (IACUC)
- ✓ Even if the sponsor accepts evidence that IACUC review is pending, ***do not proceed*** with research involving animals – including ordering the animals from a supplier – ***until*** the IACUC has approved the protocol
- ✓ Order all animals through the [Institute of Comparative Medicine](#)'s (ICM's) Animal Purchasing Office, using the *Animal Requisition Form* (see link on the [ICM Forms webpage](#))
- ✓ To request space for housing animals, complete and submit a *Requesting Animal Housing Space Form* (see link on the [ICM Forms webpage](#))
- ✓ To gain access to ICM facilities, complete the appropriate [training](#) assigned by the IACUC
- ✓ If contemplating changes to the previously approved use of animals, seek prior approval from IACUC
- ✓ If contemplating transferring animals from one CUMC facility to another or from one CUMC IACUC-approved protocol to another, initiate the process by completing and submitting a *Transfer Request Form* to the ICM (see link on the [ICM Forms webpage](#))

5.14.4 Procurement of and Services for Animals

Animals are a restricted item requiring approval prior to purchase. In accordance with U.S. law, such purchases must be made under the supervision and assistance of a qualified veterinarian.

At Columbia University, the purchase of live vertebrate animals used for research is centralized through the animal purchasing function of the [Institute of Comparative Medicine](#). This centralization provides for: 1) control of source selection from approved vendors, 2) competitive pricing among vendors, 3) planning and coordination of arrivals to meet research and husbandry operational criteria, 4) healthy lab animals for medical research, and 5) accounting of annual animal usage. SAs whose departments, centers, or institutes conduct animal research should be thoroughly familiar with this process.

Commodity Codes: There are four commodity codes in the University's purchasing module in the financial front-end system (FFE) that are specific to animal-related procurements:

- 5410 - Lab animal - live vertebrate animals
- 5420 - Lab animal - supplies
- 5430 - Lab animal - specialized services
- 5440 - Lab animal - equipment and related products

These codes were set up by the CU Purchasing Office to identify animal-related procurements that are not ordered directly through the ICM. When a code is chosen, the requisition is sent electronically to the ICM for review and prior approval. (The commodity codes should not be confused with the expense sub-codes that are used in the University's financial accounting system (FAS).)

As mentioned previously, the procurement of all live vertebrate animals must be done through ICM's Animal Purchasing Office. There are occasions when the purchase of live vertebrate animals is tied to a contract with a non-approved vendor (see *Off-Site Vendors* below). When those animals are ready for shipment, the PI is required to order them through the ICM.

If a researcher attempts to requisition an animal-related item outside of this system, the University's Purchasing Office will intercept it and send it to the ICM for review. To avoid delays, all requisitions for live vertebrate animals must be initiated within the ICM system, while those for animal-related commodities must be initiated through CU Purchasing Office's prior approval system.

Off-Site Vendors: On occasion a researcher will contract with an off-site vendor for the purpose of "constructing" genetically engineered mouse models or for custom antibody production. When a researcher requires these services, he/she must requisition them using the 5430 commodity code and, if required, enter into the requisition's description field the animal protocol number that will cover the project. The researcher must also contact the IACUC to determine whether the off-site activities must be covered by an

approved protocol at Columbia University. The ICM checks the protocol in RASCAL to verify that the vendor is named in that document.

Invoices: The ICM bills the principal investigator's project on a monthly basis for the various services that it provides to the research community. These services include animal procurement (acquisitions), room and board (per diem), and special services (veterinary medicine, pathology, surgery, import/export and biotech support). The format of the monthly invoice follows the three charge categories below:

- **Animal Acquisitions:** With an active and approved animal protocol, laboratory animals can be ordered either online from the [ICM website](#) or by submitting a hard-copy *ICM Animal Requisition Form*. The details of each order are recorded in this section as a transaction. Information includes the requisition number, order date, species and quantity ordered, cost per animal, shipping, and crating. The animal orders detail is in chronological order and subtotaled for the monthly activity.
- **Per Diem:** Investigators are charged daily fees for housing and care of animals based on species. Every room that houses laboratory animals has a census sheet that corresponds to the species, the animal protocol number, the PI, and the University account number. The ICM is responsible for keeping track of the census, e.g., adding new arrivals, noting cage separations, and conducting weekly random audits. However, the PI is responsible for deducting animals removed permanently from the room.

At the end of the month the total accumulated caredays are tallied and the species per diem rate is applied, resulting in the monthly per diem charge for that room. PIs whose projects use multiple species and house them in different rooms/facilities will have multiple lines of transaction details in this section of the invoice. These details are subtotaled for the monthly activity.

- **Special Services:** The ICM provides various specialized services to PIs' projects. With the exception of surgery, these services can be requisitioned online from the [ICM website](#). Surgical services need to be scheduled through the [Comparative Clinical Services Office](#). These details are subtotaled for the monthly activity.

The monthly invoice will include a **surcharge** on per diem and technical services when these services are charged to a non-sponsored account. The percentage rate of the surcharge is set annually and in alignment with the University's indirect cost rates negotiated with the federal government.

The Billing Process: At the end of the month, the primary source documents are collected, reviewed, and submitted to the billing office. Animal purchase requisitions are reconciled, census sheets are calculated for total caredays, and special services requisitions are entered into the billing system. The billings are always a month in delay

because it takes the first three weeks of the following month to (1) compile the data, (2) generate the billing, and (3) allow the PIs to review their projects' charges.

Interdepartmental invoices (IDIs) are then generated by service/facility, debiting the project's University account in the 3000 subcode and crediting the ICM service center account in the 75xx subcode. The ICM service is found in the *description* field, the invoice number in the *transaction location* field, and the IDI number in the *batch reference* field of the FAS account statement. To facilitate the troubleshooting of charges, it is critical that the ICM receive the data from these fields. For changes in charge instructions or for troubleshooting billing errors, contact the [ICM Billing Office](#) directly.

5.15 INTERNATIONAL PROJECTS

5.15.1 International Risk Management Procedures

Key Links

Sponsored Projects Handbook

Administrative Policy Library

Research Compliance and Training
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International Research and Service Projects:
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Risk Management Procedures
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The University supports and encourages international research and service and is committed to helping PIs address and manage the special requirements and risks involved in international projects. Columbia University has established [International Research and Service Projects: Risk Management Procedures](#) in recognition that these sponsored projects involve special risks. The procedures specify that there will be:

- Early identification of large, complex, or high-risk international projects through assessment of a set of criteria (see [Section 5.15.2](#))
- Initial review of such projects, in the funding application stage, to spot major issues
- A more comprehensive review when it is certain that a project will be funded
- Ongoing, regular monitoring of certain projects

PIs and SAs associated with international projects should be thoroughly familiar with the University criteria for these procedures, including the University's criteria for review and applicable external laws and regulations.

5.15.2 University Criteria for Review

Generally, only those international projects that meet one or more of the following criteria will be reviewed under the University's international risk management procedures:

- a. The direct costs of the project exceed \$1 million per year, of which at least 50% will be expended outside the United States (either directly or through one or more subcontracts).
- b. The project involves ongoing University operations in a non-U.S. country, such as the establishment of an office, leasing of space, or an on-the-ground presence for more than a nominal period.
- c. The project is located in, funded by, or involves a collaboration with persons in a country on the Treasury Department's [Office of Foreign Assets Controls list of embargoed countries](#) (see [Section 5.15.3](#))
- d. The project involves the use of high risk materials (e.g., radioactive materials or certain biologic materials).

5.15.3 External Restrictions

International projects are governed by the laws of both the United States and the country in which the activities take place, and may be regulated by a variety of U.S. and internationally based government agencies, such as the U.S. Departments of State, Commerce, and Treasury. Resources include:

- The [Sponsored Projects Handbook](#), which covers some of the key laws and regulations that may apply to the conduct of international research or collaborations with non-U.S. researchers, e.g., U.S. sanctioned countries and U.S. export controls on transferring technology, commodities, and software.
- The U.S. Department of Commerce's [Lists to Check](#), which should be used to confirm that prospective subrecipients, vendors, and other entities and individuals are not among those that are federally debarred or otherwise prohibited

5.15.4 International Operations and Management Requirements

If a funding application proposes establishing ongoing operations in a new locale, certain approvals are required. The PI should write to the CDM Associate Dean for Finance to request that the Associate Dean initiate contact with the Office of the General Counsel, responsible for approving new country registration, and the Treasurer's Office, responsible for approving new international bank accounts. The letter or e-mail should be accompanied by an executive summary to include the sponsor's request to work in the specific country, activities to be undertaken, and the proposed budget.

Carrying out research or otherwise conducting work outside the United States, especially in resource-poor countries, requires special management arrangements in a variety of areas. A useful reference for CDM departments and centers is the [Mailman SPH International Projects Manual](#). It lays out the University's requirements for establishing operations outside the U.S. and managing finances, human resources, legal arrangements, and other matters when operating in resource-poor countries.