

**MOUNT SINAI SCHOOL OF MEDICINE  
POLICIES AND PROCEDURES  
GOVERNING  
SPONSORED PROGRAMS**

Revised 2011 the full document is available at <http://www.mssm.edu/grants/>

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# FOREWORD

Mount Sinai School of Medicine is a leading institution in biomedical research, and its extramural research support continues to grow. Its continued success depends not only upon the quality of its research, but upon its reputation for ethical conduct and compliance with the numerous legal regulations and requirements pertaining to the award process and post-award administration of sponsored programs.

The purpose of this Manual is to assist investigators and their staffs in understanding the legal requirements and Mount Sinai's policies and procedures relating to sponsored programs support and to identify individuals in the institution who can provide assistance and answer questions regarding these requirements. The Manual is divided into two parts: the first part, prepared by the Grants and Contracts Office (GCO), pertains to the award process; the second part, prepared by the Finance Department, pertains to post-award administration.

This Manual is designed to serve as a resource to faculty and staff. It does not replace existing Mount Sinai policies and procedures. Thoroughness compels some overlap with other publications. Investigators and their staffs should be familiar with the *Faculty Handbook*, the *Mount Sinai School of Medicine Handbook for Research*, and *The Mount Sinai Medical Center Compliance Manual*, the manual, *Conflicts of Interest in Research*, and other written policies referred to in this manual.

## **PART I. AWARD PROCESS**

### **Introduction**

The Grants and Contracts Office (GCO) of the Mount Sinai School of Medicine is the centralized administrative office that oversees the sponsored programs application and award process and provides support to faculty regarding research activities. It documents policy, provides on-going information to faculty regarding sponsorship, policy changes, and funding opportunities, and generally assists faculty in all aspects of the pre-award process. The GCO also collects data regarding faculty research performance and reports to senior management regarding institutional performance.

Every sponsored program and/or research proposal must be registered with the GCO. Evaluation by the GCO includes review for accuracy of administrative information and budget, as well as for compliance with Federal, State, New York City, and Mount Sinai School of Medicine regulations, such as those pertaining to biosafety, or to the use of human subjects, vertebrate animals, or recombinant DNA.

The purpose of this part of the Manual is to help Mount Sinai School of Medicine faculty and staff understand the GCO policies and procedures pertaining to research and other sponsored projects and to delineate the significant role and responsibilities of faculty in professionally carrying out scientific pursuits. It is intended to explain to the scientific community at the Mount Sinai School of Medicine how Administration supports and facilitates the pursuit and negotiation of external funding. Part I comprises two major sections:

Section I, Research Proposal Development, Internal Review, and Submission, and Section II, Regulatory and Institutional Requirements.

## **SECTION I. RESEARCH PROPOSAL DEVELOPMENT, INTERNAL REVIEW, AND SUBMISSION**

### **Definition of Research**

For purposes of application and registration with the GCO, research is defined as systematic investigation designed to develop or contribute to generalizable knowledge. Activities meet this definition, even when the overall purpose is not primarily research, but may include training, demonstration, or service programs.

### **Eligibility for Principal Investigator Status**

All full-time, part-time, emeritus, and voluntary faculty of the Mount Sinai School of Medicine and its affiliates are eligible to serve as principal investigators/project directors.

Other professional staff, who hold titles typically associated with independent work, and whose appointments are subject to a rigorous review of credentials, may also serve as principal investigators.

All project directors and/or investigators must have the approval of their Chairs indicated by the Chair's signature on the GCO application form.

*If there is a question of eligibility, please contact the GCO, (212) 824-8300.*

## Application Forms

### Sponsor Forms

Many sponsors still require paper applications, but an increasing number of agencies have gone to an electronic submission process. Mount Sinai School of Medicine utilizes a system-to-system provider InfoEd, for most federal applications utilizing the SF 424 R&R packet. Contact the GCO for information (212) 824-8300 if you are unsure how to obtain or submit a particular sponsor's application forms.

Agencies and foundations that do not provide application forms generally specify a format in their guidelines. These instructions should be carefully followed. Contact the GCO, (212) 824-8300.

### GCO Forms

Mount Sinai School of Medicine internal forms are available on our website at [www.mssm.edu/grants](http://www.mssm.edu/grants). The electronic application forms are available at <https://eresearch.mssm.edu/> A valid username and password are required and InfoEd training is strongly recommended.

The principal investigator must submit the GCO electronic application including any documentation that may be required for your submission.

Approvals are good for one year and must be renewed on an annual basis.

See our website: <http://www.mssm.edu/grants/>

## Budget Preparation

All budgets must follow the specific instructions of the sponsor; and each expenditure must be carefully justified. The GCO will assist faculty in budget preparation. The GCO Budget Form in InfoEd is programmed to calculate fringe benefits on all projects and facilities and administrative cost rates on federal grants based on the selection of the appropriate rate. Questions regarding patient care expenses should be directed to the Compliance office. Questions regarding patient care cost for industry sponsored studies should be directed to the Compliance office. Questions regarding patient care cost for industry sponsored studies should be directed to the Office of Clinical Trials Budget and Billing.

### Fringe Benefits and Facilities and Administrative (F&A) Cost Rates

It is the policy of the Mount Sinai School of Medicine to collect full F&A costs from all funding sources. These reimbursements are necessary to cover actual costs incurred for administrative, facility and other support related to the conduct of research at the Mount Sinai School of Medicine. Any exception requires written approval of the Dean or CFO. Requests for waiver of F&A should be made in writing by the chair and submitted to Stephen Harvey, CFO.

The Federal fringe benefits and F&A cost rates are approved by the Department of Health and Human Services (DHHS) following negotiation with the Department of Finance of the Mount Sinai School of Medicine. Federally negotiated rates apply to all agreements between the Mount Sinai School of Medicine and the Federal Government unless appropriation restrictions have been placed on the funding or other

mandatory stipulations apply. Announcements of revised fringe benefit and F&A cost rates are periodically distributed by the Department of Finance and reported in various publications issued by the Department of Finance and the GCO

## **Required Signatures**

The Department Chair(s) of the involved clinical or basic science department(s) must review approve and endorse the research application within InfoEd. This is an attestation that the project is consistent with the mission of the Department and the School, and that departmental resources will be available consistent with the intent of the proposal. The respective Chair must sign for each key professional identified in the proposal.

*See Faculty Handbook, Chapter IV-15.*

## **GCO Review**

Every sponsored program and/or research proposal must be registered with the GCO. Evaluation by the GCO includes review for accuracy of administrative information and budget, as well as for compliance with Federal, State, New York City, and Mount Sinai School of Medicine regulations, such as those pertaining to biosafety, or to the use of human subjects, vertebrate animals, or recombinant DNA.

The Grants and Contracts Officer and the Director, Grants and Contracts Office, have been designated by the Office of the Dean and the Board of Trustees as the institutional officials who provide institutional endorsement of each extramural proposal. These individuals will provide the needed institutional endorsement within one business day of the receipt of paper proposals. Turn-around times for electronic submissions vary by agency, please contact the

GCO if you are unsure of the internal dead-line. Applications must be complete to receive institutional endorsement.

Complete applications include compliance applications (PPHS or IACUC) unless the funding agency has a two step review process that allows a Just-In-Time (JIT) review by the MSSM compliance committees. At the time of writing, the two funding agencies that structure their reviews to allow Institutional JIT are the NIH and the Stanley Foundation. Questions regarding individual funding agency policies should be directed to the GCO staff.

Proposals from faculty of Mount Sinai's academic affiliate institutions seeking the programmatic and/or fiscal oversight of the Mount Sinai School of Medicine must meet all MSSM requirements. These proposals must be accompanied by certification(s) of pending review by the Research and Development Committee, and in some cases, by the Institutional Review Board or Institutional Animal Care and Use Committee of the investigator's institution.

## **GCO Research Development Services**

The GCO provides information regarding funding opportunities, advice when preparing extramural proposals, assistance with budget preparation, and general information regarding policies on human subjects, animal welfare, recombinant DNA, misconduct in science, etc. The GCO interfaces with extramural sponsors and will intervene on behalf of a research investigator regarding funding conflicts, compliance, and sub-contracting issues.

## **Notices of Funding Opportunities**

The GCO prepares comprehensive monthly

announcements regarding funding using information from the Sponsored Program Information Network (SPIN) Database, the National Institutes of Health (NIH), the National Science Foundation (NSF), and other sponsoring agencies. This includes a calendar identifying major research sponsors by deadline date. These are available on the web-site.

Enrollment in InfoEd's SMARTS/GENIUS modules will provide on-line, personalized funding opportunities and permit you and your colleague's access to the latest biomedical research being conducted at Mount Sinai School of Medicine and other academic health centers.

The Federal Information Exchange (FEDIX) is a free email service targeting research and education funding opportunities by area of interest. Users must register on FEDIX at <http://www.nih.gov/grants/guide/index.html> in order to receive daily funding announcements. Not all NIH Institutes participate with this service.

*Individual consultations concerning funding can be arranged by calling the GCO at (212) 824-8300.*

### **Database Tracking System**

The Grants and Contracts Office maintains information regarding each proposal in its database tracking system. This database is the principal source of information regarding successes and failures, sources of sponsorship, and levels of funding across a variety of academic units. Principal investigators must inform the GCO when a grant is funded or not funded, so that institutional records will be accurate. Investigators planning multi-disciplinary projects may request searches of the database to identify potential collaborators.

### **Office of Clinical Research**

Developed in response to the needs of Mount Sinai's ever growing research community, the Office of Clinical Research (OCR) has been established by the Dean's Office to facilitate the conduct of clinical research through a centralized infrastructure. Our goal is to improve communication, consistency and collaboration across the Medical Center to support successful clinical research.

The OCR provides investigators and their research staff with oversight and guidance to the institutional protocol development review and approval process to ensure adherence to both institutional standards and federal regulatory requirements resulting in the most efficient and safe clinical studies.

- Protocol Development Support:

The OCR can provide investigators with intellectual, strategic and technical support to develop clinical studies that translate innovations in basic science into new treatment modalities for clinical practice.

- Regulatory Support:

- ❖ Identify inter-institutional services and collaborators
- ❖ Develop Data & Safety Monitoring Plans as well as Data Management tools and reports
- ❖ Provide study monitors
- ❖ Negotiate Research Budget
- ❖ Propose Patient Recruitment Strategies and Outreach Coordination including clinical trials registrations
- ❖ Make recommendations for Conflict of Interest reporting

- ❖ Provide administrative support to operationalizing protocols at MSMC or at ancillary research sites
- ❖ Offer Clinical Research Training and Education workshops

For further information please contact the staff of the OCR at [clinical\\_research@mountsinai.org](mailto:clinical_research@mountsinai.org) or at 212-824-7294

## **Clinical Trials**

All clinical trials and clinical research protocols must be registered with the GCO and approved by a permitted Institutional Review Board. The Clinical Trial Agreement (CTA) and Letter of Indemnification provided by the sponsor should be submitted for concurrent evaluation to expedite the review process.

The GCO reviews all CTAs and negotiates terms directly with the sponsoring company. Upon completion of contractual negotiations and final approval by an Institutional Review Board (IRB), one of the Institutional Officials of the GCO will endorse the CTA.

### **Office of Clinical Trials Budget and Billing (within the Office of Clinical Research)**

The Office of Clinical Trials Budget and Billing in conjunction with the Grants and Contracts Office is the center for coordinating the financial aspect of your clinical research. As such, CTBB provides the necessary tools for conducting innovative and safe clinical testing in compliance with required financial and regulatory guidelines and billing compliance.

Rules for federal and private payors govern the conditions under which clinical services, items and tests associated with a research study can be

billed to study subjects or their insurers. The complexity of these rules and established procedures requires that the CTBBO reviews all clinical trial GCO submissions. The CTBBO assures that all related documents for the study are consistent.

The CTBBO will evaluate the project budget to determine if reimbursement covers the costs of the study requirements and that the budget includes upfront costs such as administrative start up, pharmacy and IRB fees, PI and CRC time and effort and/or oversight, and overhead.

## **Investigational Drugs**

### **Department of Pharmacy**

Both New York State and the Joint Commission on Accreditation of Health Organizations require that any drug administered within the Hospital be stored, labeled, and dispensed by the Department of Pharmacy.

A schedule of charges for investigational pharmacy services has been developed by Pharmacy and approved by the School Administration. It is intended as a guide to the Pharmacy Research Coordinator in calculating appropriate charges for each research protocol. Charges will be assessed on an individual project basis with an opportunity for discussion with the Pharmacy Research Coordinator.

All budgets must include the cost of drugs and services as established by the Pharmacy. Protocols not funded for these products and services will be reviewed by the Department of Pharmacy to determine feasibility of support. In order to make these assessments, researchers must complete the PPHS's Drug Information Sheet ([www.mssm.edu/pphs](http://www.mssm.edu/pphs)) and submit it the Pharmacy for review and approval prior to

submission of a research project to the GCO and IRB. In the case of emergency use, researchers can contact the IRB or the Pharmacy. Further information is also available on the IRB Guidelines and Policies Manual which is also on the IRB web-site.

### **Purchase and Use of Investigational Drugs**

The proposed use of drugs under research investigation is subject to review by the IRB, and must be accompanied by information relating to any applicable Investigational New Drug application. An investigator may obtain drugs for research provided that:

- FDA and Institutional regulations are met for shipment and receipt of drugs,
- The research protocol is IRB-approved, **and**
- Provision for cost and handling of drugs used in the protocol meets the following financial requirements:

### **Non-Formulary Drugs**

Non-formulary drugs must either be supplied at no cost by a study sponsor or funds must be designated/ budgeted by the principal investigator's Department prior to purchase.

### **Formulary Drugs**

Drugs used according to the FDA approved dose, route and method of administration, but not supplied by the study sponsor, will be covered by Mount Sinai. Drugs used in a non-FDA-recommended fashion must be supplied by the study sponsor at no charge or funds must be designated/budgeted by the principal investigator's Department prior to purchase.

The Mount Sinai Formulary is available on the Mount Sinai Intranet

(<http://intranet1.mountsinai.org>), click "Medical Services" tab on top of screen, then click "Pharmacy" on left hand menu bar, then choose "online formulary" and type in the name of the drug (either brand or generic) and click "search".

### **Controlled Substances Used in Research**

In order to use controlled substances for research purposes, a researcher must be registered with both The State of New York and the Drug Enforcement Administration.

A research protocol proposing the use of controlled substances must include that information on GCO Form 1 and the PHHS IRB Drug Information Sheet and elect one of the following options:

- Provision of the principal investigator's NYS and *DEA research license numbers*, **or**
- Provision of the name, license numbers and signature of an alternate investigator who will be responsible for the use and control of such substances in the research protocol, **or**
- Designation and use of controlled substances under the Center Comparative Medicine & Surgery CCMS license, provided the procedures are supervised by CCMS staff.

The Pharmacy Director is available to answer questions and will provide a list of controlled substances and their classification/schedule. Refer to the latest *Mount Sinai Medical Center Drug Formulary* for additional information.  
*Pharmacy Director: (212) 241-6171.*

### **Materials Transfer Agreements, Inventions, and Patents**

## **Office of Technology and Business Development**

The Mount Sinai Office of Technology and Business Development (OTBD) oversees and assists in the commercial development of selected technology. The Director is appointed by the President and the Dean to negotiate contracts relating to intellectual property.

As a recipient of Public Health Service (PHS) funding (e.g., NIH grants and contracts), the Mount Sinai School of Medicine is governed by PHS regulations for patents and inventions arising out of activities supported by a PHS grant. The OTBD must ensure compliance with the intellectual property, transfer, and development policies of sponsoring agencies.

All materials transfer agreements must be reviewed and endorsed by the Director of the OTBD.

### **Invention Reports**

Investigators must disclose to the OTBD, and the OTBD must promptly and fully report to the Assistant Secretary for Health, HHS, all inventions made in the course of federally funded research. The PHS awarding office provides instructions for these reports, which must be filed prior to the publication of any description of the invention.

In addition to immediate invention reports, when applying for either competing or non-competing continuation support of PHS-funded research projects, investigators must include either a list of all inventions made during the preceding budget period or a certification that no inventions were made during the applicable period.

A Final Invention Statement and Certification is required within 90 days following the expiration or termination of an award. All inventions conceived or first actually reduced to practice during the course of work under the project, whether or not previously reported, must be listed on the statement. Each statement requires the signatures of the project director or principal investigator and the Director of the Office of Technology and Business Development.

*Refer to the Mount Sinai School of Medicine Faculty Handbook - Policies on Intellectual Property: Ownership and Commercial Development, Chapter VIII-13.*

## **SECTION II. REGULATORY AND INSTITUTIONAL REQUIREMENTS**

The GCO evaluation of each research proposal includes referral to the appropriate institutional review committees for evaluation and approval.

### **Program for the Protection of Human Subjects (PPHS)**

The Mount Sinai School of Medicine Program for the Protection of Human Subjects is the official oversight program for the protection of human subjects in research. They function under a Federal Wide Assurance (FWA00005656) granted by the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS). Both terms of the FWA and PPHS policies indicate that human subjects research conducted at Mount Sinai will be guided by ethical principles and be in compliance federal policy, as applicable. Without the Assurance, PHS support may not be provided for research involving human subjects.

IRBs have the responsibility and authority to approve, require modification of, or disapprove any research activity involving human subjects, which includes identifiable private information and biological materials derived from human subjects.

Mount Sinai has five institutional IRBs, four of which meet monthly. Almost all human research is required to obtain IRB review from the Mount Sinai IRBs. The Mount Sinai School of Medicine also accepts IRB review from the Biomedical Research Alliance of New York (BRANY) IRBs for select types of research. Obtaining review by an IRB other than Mount Sinai's IRBs requires prior authorization, and is evaluated on a case by case basis.

IRB approval must be secured prior to the start of research activity. It is the responsibility of researchers to meet established deadlines in order to secure IRB review of research. Research protocols must receive IRB continuing reviews at intervals determined by the IRB, but not less than every 12 months. Researchers must submit applications for continuing review in a timely fashion to avoid gaps in IRB approval.

The IRBs review each applicable research proposal and related materials, including informed consent documents. The Mount Sinai IRBs employ a pre-review and feedback technique, to assist researchers with timely review process.

IRB review and approval are independent of the initial endorsement by the institutional official of the extramural research proposal, and IRB approval does not constitute endorsement of the research or a commitment of the institution to provide resources to conduct the research.

The PPHS Executive Director, IRB Chairs, and PPHS support staff are available to provide assistance regarding human subject research matters.

*Further information on IRB compliance issues can be obtained from the IRB Guidelines and Policies Manual, the IRB Procedures Manual, and the Programs for Protection of Human Subject's website; [www.mssm.edu/pphs](http://www.mssm.edu/pphs) .*

### **Institutional Animal Care and Use Committee (IACUC)**

As required by Public Health Service (PHS) policy on humane care and use of laboratory animals, the Animal Welfare Act (AWA) and AWA regulations (AWAR), the Mount Sinai School of Medicine (MSSM) has an Institutional Animal Care and Use Committee (IACUC). IACUC membership includes a Chair, an attending veterinarian, several practicing scientists, one ethicist and one lay member not affiliated with MSSM.

The regulatory mandate of the IACUC is to oversee all aspects of the institutional animal care and use program to ensure compliance with the AWA, AWAR, PHS policies and the National Research Council "Guide for the Care and Use of Animals". MSSM IACUC activities are conducted according to specific procedures described in an Animal Welfare Assurance documents (A3111-01) filed by MSSM with the NIH Office of Laboratory Animal Welfare (OLAW). The assurance document is reviewed every four years by OLAW.

The IACUC is responsible for reviewing and approving, requiring modification of, or disapproving any research or teaching activity involving the use of vertebrate animals. Full Committee review of study protocols is

mandated for: i) all studies involving species protected by the AWA, ii) studies requiring potentially painful or distressful conditions (e.g. cancer), or iii) at the request of any member of the IACUS. Protocol review generally requires 4-6 weeks.

*Further information regarding IACUC functions and activities may be obtained by calling the IACUC administrative office at 212-241-0153 or visiting the IACUC website at [www.mssm.edu/iacuc](http://www.mssm.edu/iacuc).*

### **Ethical Practices in Research**

It is the policy of the Mount Sinai School of Medicine to conduct research responsibly and ethically. The institution has guidelines for the conduct and reporting of research, as well as formal procedures for receiving, reviewing, investigating and reporting allegations of unethical practices in research.

Principal investigators and project directors must ensure that all faculty and staff involved in research are familiar with the guidelines and policies described in the **Faculty Handbook** (<http://www.mssm.edu/forfaculty/handbook/>) and the **Handbook for Research** ([http://www.mssm.edu/forfaculty/handbook\\_rs/index.shtml](http://www.mssm.edu/forfaculty/handbook_rs/index.shtml)) including but not limited to the **Policies and Procedures on Ethical Practices in Research**. (<http://www.mssm.edu/forfaculty/handbook/cha p6h.shtml>)

*The Office of Research Integrity* (ORI) of the Department of Health and Human Services (DHHS) has responsibility for protecting the integrity of PHS extramural and intramural research programs. Every institution that receives PHS support must have an Assurance on file with the ORI.

*Further information regarding procedures for addressing concerns of Research Misconduct can be obtained from the Mount Sinai Research Integrity Officer (RIO) at (212) 241-3006*

**Research Compliance** is part of the MSSM robust compliance program whose role is to provide oversight, education and monitoring of the research activities in the institution.

*Further information regarding procedures for addressing concerns of Research Compliance can be obtained from the Research Compliance Office at (212) 241-4391*

### **Policy on Conflict of Interest in Research**

Mount Sinai encourages scientific collaboration with industry and supports collaborative research geared towards developing new and improved diagnostic and therapeutic products. However, economic relationships with industry have the potential for directly and significantly affecting the approval, design, conduct, monitoring or reporting of a research study.

To safeguard the academic integrity of Mount Sinai and its investigators, the institution has rigorous Financial Conflicts of Interest in Research Policy predicated on full disclosure and appropriate management. The Policy sets forth the requirements for disclosing potential conflicts of interest in research and specifies the procedures for reviewing such disclosures and determining what corrective measures, if any, should be instituted. The policy is posted on line at <http://www.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/institutional-policies/financial-conflicts-of-interest-in-research/policy>

The Mount Sinai Policy on Financial Conflicts of Interest in Research applies to all projects

required to be submitted by the Grants and Contracts Office, whether federally funded, funded by other public and private sources, or supported by the institution. Principal investigators and project directors must ensure that all persons covered by the policy on conflicts of interest comply fully with its disclosure requirements.

### **NIH Guidelines for Research Involving Recombinant DNA Molecules**

The Institutional Biosafety Program was established in accordance with PHS policies and guidelines published by the NIH Office of Recombinant DNA Activities. Its purpose is to provide for the safe conduct of recombinant DNA research and to ensure compliance with the NIH Guidelines. When applicable, investigators must indicate on the GCO Forms when Recombinant DNA activity is involved and identify the appropriate Biosafety Level for Physical Containment. The Institutional Biosafety Officer will determine whether the research described falls within the NIH Guidelines and if further evaluation is required.

*Refer to NIH Guidelines for Research Involving Recombinant DNA Molecules, available in the GCO.*

### **Biosafety Program**

The Mount Sinai School of Medicine Biosafety Program monitors all laboratory activities involving biohazards and potentially infectious materials to ensure that proper precautions are observed. Biohazards, infectious agents or biologically derived infectious materials that present a risk or potential risk to the health of humans or animals, either directly through infection, or indirectly through damage to the environment. Infectious agents can replicate and

give rise to large populations in nature when small numbers are released from a controlled situation. Special duties include the design and improvement of disposal procedures for biological, chemical, and radiological waste and the preparation, submission, and maintenance of records, reports, and documents as may be required by government regulations.

### **Mount Sinai School of Medicine Institutional Biosafety Committee**

The Mount Sinai School of Medicine (MSSM) will maintain an Institutional Biosafety Committee consistent with the National Institutes of Health (NIH) Guidelines published in [Published in Federal Register, July 5, 1994 \(59 FR 34496\)](#) and its most recently published amendment.

Membership of the committee will consist of no fewer than 5 individuals with experience and expertise in recombinant DNA (rDNA) technology and other biosafety issues. At least two members shall not be affiliated with the MSSM and should represent the interests of the surrounding community with respect to public health and protection of the environment. At least one member shall have expertise in animal containment principles and one member shall be a Biological Safety Officer. The responsibilities of the IBC include, but are not limited to the following:

- a. Review rDNA, pathogen, oncogene, toxins and toxic chemical use in research conducted at MSSM. These reviews shall include:
  - (1) Independent assessment of containment levels
  - (2) Assessment of the facility's procedures, practices, training and expertise of the personnel

involved in research involving rDNA, pathogens, oncogenes, toxins and toxic chemicals.

- (3) Verification and assignment of the classification of the rDNA research in accordance with the NIH Guidelines.

b. Notify the Principal Investigator of the results of the IBC review and approval.

c. Set appropriate containment levels for experiments as specified in the most recent edition of the NIH Guidelines.

d. Provide for the adjustment of containment levels for certain experiments as specified in the NIH Guidelines and CDC/NIH BMBL (latest edition).

e. Conduct periodic reviews of rDNA, pathogen, oncogene, toxin and toxic chemical research conducted at the MSSM for compliance with the NIH Guidelines and CDC/NIH BMBL.

f. Adopt emergency plans covering spills and personnel contamination from containment laboratories.”

requirements established by RURSC.

The Mount Sinai School of Medicine holds a broad-scope license for use of radioisotopes in non-human research from the Bureau of Radiological Health of the City University of New York. All researchers whose work requires radioisotopes must submit an application to the RSO for inclusion on the institutional broad license. Information regarding application, qualifications and requirements can be obtained by contacting the RSO. Applications are evaluated and approved by the RSO and the RURSC.

*Information on radioisotope compliance can be obtained in the Radiation Safety Manual, available in the Radiation Safety Office (212) 241-2269.*

## **Radioisotopes in Research**

Research involving radioisotopes falls under the purview of the Radioisotopes Utilization and Radiation Safety Committee (RURSC) which, establishes policies and oversees the use of radioisotopes. The Radiation Safety Office (RSO), under the leadership of the Radiation Safety Officer, implements the policies and

## **Assurances and Certifications**

Mount Sinai School of Medicine, as the grantee organization or recipient of Federal funds, must certify that policies and procedures have been established concerning:

- Human Subjects
- Vertebrate Animals
- Debarment and Suspension
- Drug-free Workplace
- Lobbying
- Delinquent Federal Debt
- Research Misconduct
- Financial Conflict of Interest
- Smoke-free Workplace
- Civil Rights, including:
  - race, color or national origin
  - handicapped individuals
  - sex discrimination
  - age discrimination
- HIPAA

## **PART II. POST-AWARD REQUIREMENTS**

### **Introduction**

This part of the Manual is designed to help departmental administrators and principal investigators understand:

- Post-award requirements and procedures for administering sponsored projects.
- Who is responsible for ensuring compliance with Federal, non-Federal and Mount Sinai sponsored project guidelines and for reviewing and approving transactions.
- Internal control/compliance issues applicable to typical grant revenue and expense categories.
- Mount Sinai's program for monitoring compliance with Federal and Mount Sinai School of Medicine regulations.
- Mount Sinai School of Medicine resources for obtaining additional information and assistance regarding applicable policies and requirements.

### **SECTION I. OVERVIEW OF POST-AWARD REQUIREMENTS AND PROCEDURES**

#### **Grant and Contract Awards**

Post-award grant and contract requirements apply when an extramural sponsor issues a grant or contract award letter to a Mount Sinai School of Medicine (MSSM) principal investigator. The award letter and related budget enable the Sponsored Projects Accounting Department to

create an account that can accept revenue and expense transactions related to the award. Each account receives a unique number and is active for the time span of the award.

Grants and contracts are generally awarded with a portion of the award covering the direct costs of conducting the work described in the proposal and a component for Facilities and Administration (F&A) costs, which reimburses MSSM for administrative, space, and other costs. The principal investigator is responsible for review and approval of all direct cost charges according to the award budget. The MSSM Sponsored Projects Accounting Department is responsible for reviewing the adequacy of documentation supporting certain direct cost transactions, maintaining support documentation that justifies the indirect costs and fringe benefit costs charged to the award, and assisting investigators and administrators with questions of compliance with financial policies and regulations.

Financial Memoranda, issued by the Finance Department, provide information regarding the MSSM's financial policies and procedures, concerning capital equipment purchase orders, indirect costs, rebudgeting, etc.

#### **Administration of Awards**

Administration of the grant or contract award is guided by the Federal, State, non-Federal and Mount Sinai guidelines listed in Part II, Section V of this manual. The Sponsored Projects Accounting Department is available to answer any questions related to post-award administration and to consult with administrators and investigators on financial issues related to the listed regulations and guidelines.

Federal grant management guidelines allow some flexibility in making post-award programmatic

changes and budget revisions in Public Health Service (PHS) non-construction grants awarded on the basis of an approved grant budget broken down by object class (personnel, travel, supplies, etc.) and specifying funds that are available to carry out approved activities.

Unless otherwise restricted by the terms of the Notice of Award, the grantee may rebudget subject to the sponsor's policies, within and between budget categories in the approved total budget of the project to meet unanticipated needs or to accomplish certain programmatic changes. Investigators must exercise proper stewardship over the sponsor's funds and ensure that all charges to the awards are allowable, allocable, and reasonable.

Rebudgeting Federal funds requires prior approval. Prior Approval Forms are available in the GCO.

### **No-cost Extension**

A no-cost extension may be required when the principal investigator needs time beyond the scheduled termination date to complete the project or to collect additional data to strengthen a proposal for competitive continuation. In such instances, the principal investigator must notify the GCO in writing at least 15 days prior to grant termination and explain why additional time is required. In accordance with NIH expanded authorities, approval will be granted by the institutional official of the GCO for a one-year, no-cost extension. If the principal investigator fails to request a no-cost extension from the GCO prior to the final 10 days of the award, a letter to the NIH Grants Specialist must be prepared requesting authorization for a no-cost extension. It must be signed by the investigator and reviewed and endorsed by the Grants and Contracts Office.

### **Financial Management**

To assist investigators in controlling receipts and disbursements according to Federal, non-Federal, and institution-specific requirements, MSSM provides its own grant management guidelines included in the financial policy memoranda and *Finance at a Glance* available on the School Finance Website under Grants and Restricted Funds. Generally, these guidelines link PHS grant management requirements to Mount Sinai's transaction approval and processing requirements.

### **Monitoring of Awards**

Federal awarding offices monitor their grants to identify potential problems and areas where technical assistance might be necessary. Federal awards are audited annually by MSSM's external auditors according to the provisions of the Office of Management and Budget (OMB) Circular A-133, *Audits of Institutions of Higher Education and Other Non-Profit Institutions*. MSSM's F&A cost and fringe benefit rates are reviewed and approved by the Department of Health and Human Services Division of Cost Allocation according to the provisions of OMB Circular A-21, *Principles for Determining Costs Applicable to Grants, Contracts and Other Agreements with Educational Institutions*. Generally, the sponsor's monitoring function is designed to determine whether MSSM internal accounting and other control systems provide reasonable assurance that:

- Financial operations are properly conducted.
- Financial reports are presented fairly and accurately.
- Applicable laws, regulations, and other grant terms have been complied with.
- Resources are managed economically and efficiently.

- Desired results and objectives are being achieved efficiently.

Monitoring of a grant or contract continues as long as the sponsor retains a residual interest (e.g. equipment purchased with Federal funds) in the project or activity, whether or not the sponsor is providing active grant support.

### **Reporting**

Most grants and contracts (PHS awards in particular) require both financial and programmatic performance reporting. In such cases the Sponsored Projects Accounting Department prepares the financial report according to the sponsor's requirements and reviews the report with the principal investigator and obtains his/her approval before submission to the sponsor. For PHS awards, the final financial status report must be submitted within 90 days of the expiration or termination of the grant unless an extension is obtained. There must be no remaining unpaid obligations, and the exact amount of any unused funds must be shown.

### **Closeout**

Generally, it is both the award sponsor's and Mount Sinai School of Medicine's policy to close out grants and contracts as soon as possible after the expiration of an award that will not be extended. Closeout includes timely submission of all required reports, disposition of real property, equipment, and supplies, and adjustments for any amounts due the sponsor. Closeout of a grant or contract does not affect the requirements for Federal equipment accountability or records retention nor does it affect the sponsor's right to audit the award and recover any inappropriately expended amounts revealed by the audit.

## **SECTION II. RESPONSIBILITY FOR FINANCIAL COMPLIANCE**

The principal investigator is responsible for ensuring that the direct costs charged to each extramurally sponsored award are allowable, allocable and reasonable according to both the sponsor's and MSSM's policies and procedures. Direct costs are those that can be specifically identified to the grant or contract award and generally include:

- Compensation of employees for time and effort devoted specifically to the execution of the award's objectives.
- Equipment and other approved capital expenditures.
- Other expenses incurred specifically to carry out the grant agreement.

The Sponsored Projects Accounting Department is responsible for consulting with investigators and administrators on questions of compliance, reviewing the documentation supporting the transaction categories described below, and maintaining documentation supporting indirect F&A and fringe benefit costs charged to extramurally supported awards.

All grant and contract direct cost transactions must be reviewed and approved by the principal investigator or a designee before being charged to the award. Time and effort reports require the approval of the faculty member/employee as well as the supervisor or designee with firsthand knowledge of the faculty member/employee's activities. Transfers of costs to or from grant-supported projects may be necessary to correct bookkeeping or clerical errors. When an error is discovered, the investigator must promptly provide support documentation, a full explanation of how an error occurred, and certification of the correctness of the new charge.

An explanation which states merely that the transfer was made “to correct error” or “to transfer to correct projects” is not sufficient.

The hierarchy of responsibilities for ensuring compliance with Federal and School of Medicine grant management policies and procedures is summarized in Table I.

<b>Table I: Transactions Requiring Approval</b>	
	<b>Approval Required from . . .</b>
Supplies, salary adjustments, equipment	Principal investigator or designee authorized by the principal investigator
Time and effort reporting	Faculty member/employee <i>and</i> supervisor (or designee) with first hand knowledge of faculty member/employee’s activities
Cost transfers	Principal investigator or designee authorized by the principal investigator
Budget transfers <\$25,000 (prior institutional approval required)	Principal investigator, Chair, GCO, and Fund Sponsored Projects Accounting
Budget transfers >\$25,000 (prior institutional approval required)	Sponsoring agency, principal investigator, chair, GCO, and Fund Sponsored Projects Accounting
Travel (domestic)	Principal investigator
Travel (foreign)	Principal investigator, Chair, GCO, and Dean’s Office
Patient care billing	Principal Investigator
Financial reporting to sponsors	Sponsored Projects Accounting, Principal Investigator
Cash management	Sponsored Projects Accounting
Fringe benefit rate calculation and negotiation	Sponsored Projects Accounting

## **SECTION III. HIGHLIGHTS OF INTERNAL CONTROL/ FINANCIAL COMPLIANCE ISSUES**

To assist departmental administrators and principal investigators in meeting the requirements associated with common revenue and expenses charged to sponsored awards, the Sponsored Projects Accounting Department has prepared a summary of the documentation, internal control/compliance issues, and MSSM's program to minimize the chance that these categories of revenue and expense may be disallowed in an audit. The summary included in Table II is for common receipts and charges to sponsored awards. Questions about appropriate approvals and documentation relating to categories of receipts and expenses that may not be listed in Table II should be directed to the Sponsored Projects Accounting Department.

### **Salaries and Wages**

All faculty members or employees whose salaries are charged to a grant, and their supervisors with first-hand knowledge of the faculty member's or employee's activities, are responsible for reviewing and certifying the accuracy of their time and effort reports. Salaries and wages represent more than 60% of all charges to sponsored awards. The effort report is the primary document supporting the validity of salary and wage charges to grants and contracts. If there are errors in the effort report or the allocation of effort is not reasonable in relation to the work performed, it is the responsibility of the employee to correct the report. The Sponsored Projects Accounting Department is available to answer any questions about the effort report and assist in correcting errors on effort allocations.

### **Cost Transfers**

A significant number of cost transfers processed during the close-out period of a grant award may indicate the need for improvement in the investigator's procedures for reviewing and approving transactions and monitoring the progress of the grant as compared to the approved budget.

Late (processed more than 90 days after the original charges) and inappropriately documented cost transfers have the highest risk of being disallowed in an audit. School Finance will request the Internal Audit Department to review the internal controls and monitoring procedures used by individual investigators when a significant number of cost transfers are required to close out an award.

### **Patient Care Costs**

Investigators should ensure that the proper payer (either third party or the grant award) is billed when a patient receives routine care while registered as a research patient. When the patient's medical record contains a research consent form and funds are available on a sponsored project to cover patient care, it is the investigator's responsibility to direct the bill for services to the correct payer. Significant unobligated funds remaining in the patient care component of the budget when a sponsored award is closed indicate that billing errors may have occurred. In such cases, School Finance will request the Internal Audit Department to review the accuracy of patient care billing on the award.

When using second generation investigational devices, compliance with Medicare billing regulations is essential. Under these regulations, Medicare will reimburse for Category B devices

and related services provided the use is part of an FDA-approved clinical trial and other conditions are met. Medicare will not reimburse for Category A experimental/ investigational devices and related services. For further information on these requirements, contact the *Office of the General Counsel (212)241-8105*.

### **Allocation of Costs When Work is Closely Related**

When salaries and/or other activities are supported by two or more sources, issues arise as to how these costs should be allocated among the sources of support. It is Federal policy that if a cost benefits two or more projects or activities in proportions that can be determined, the cost should be allocated according to 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 can be allocated to benefitted projects on any reasonable basis.

PHS has determined that when salaries or activities are supported by two or more PHS grants and the specified conditions given below are met, costs may be charged to any of those grants. Under these conditions, costs may be assigned entirely to one project, with prior written approval from the Grants Management Officer of the PHS awarding office. These conditions are:

- The projects are scientifically and technically related.
- The projects are under the direction of the same principal investigator.
- The projects have been funded by the same PHS awarding office.
- There is no change in the scope of the individual grants involved.

- The relating of costs will not be detrimental to the conduct of work approved under each individual award.
- The relatedness will not be used to circumvent the terms and conditions of an individual award.

These rules apply to allocating costs between two or more *Federal* grants when the work is closely related. When extramural funding includes non-Federal sources of support, the investigator should allocate salary charges based on the actual work performed. Nonsalary charges for supplies and equipment should be charged directly to the projects they benefit.

### **Disposition of Unexpended Balances on Non-Federal Awards**

Mount Sinai School of Medicine policies allow the transfer of any unexpended balance on a non-Federal award to a departmental fund or an already established unrestricted fund if the following requirements are met:

- The sponsor must provide a letter stating that all contractual requirements have been fulfilled and that no refunds are due the sponsor.
- A final report must be submitted to the Grants and Contracts Office.
- The principal investigator must submit a memorandum to Sponsored Projects Accounting stating that there are no outstanding obligations to the MSSM for special services or laboratory analysis.

### **Facilities and Administrative Cost (F&A) Screening**

All expenses included in either administrative or facilities F&A cost pools are screened according to OMB Circular A-21 requirements to ensure

that unallowable expenses are eliminated from the F&A rate calculation. The cost pools subject to screening include:

- Building Depreciation
- Equipment Depreciation
- Operations & Maintenance
- Interest
- General Administration
- Departmental Administration
- Sponsored Programs Administration
- Library
- Student Services

#### **SECTION IV. MEDICAL CENTER RESOURCES FOR COMPLIANCE QUESTIONS AND OBTAINING ADDITIONAL INFORMATION**

All questions relating to post-award compliance issues should be directed to the Mount Sinai School of Medicine Sponsored Projects Accounting Department at (212)731-3338.

The Sponsored Projects Accounting Department is available to consult with investigators and administrators on questions of compliance and can provide copies of any grant management regulations and guidelines listed in Part II, Section V of this manual.

Services provided by the Sponsored Projects Accounting Department include:

- Financial reporting to sponsors and investigators.
- Cash management.
- F&A cost rate calculation and negotiation.
- Fringe benefit rate calculation and negotiation.
- Consultation with faculty and administrators on grant management compliance issues.

- Quarterly meetings with departmental administrators.

In addition to the compliance program for individual revenue and expense categories (Table II), the following MSSM compliance controls benefit overall grant and contract administration:

- An annual audit is conducted by the School's external auditors, Ernst & Young, according to the audit requirements of OMB Circular A-133.
- MSSM faculties engaged in research are required to submit an updated Financial Conflicts of Interest in Research Disclosure form: a) whenever their financial interest change during the project year and b) with annual resubmissions to the GCO. Additionally, all full-time and part-time faculty members and select Voluntary faculty are required to report and update the annual online Report of Relationships with Outside Entities (monitored by Internal Audit, the Medical Center's Compliance Office and MSSM Conflicts of Interest Office).
- School Finance holds quarterly meetings with Departmental Administrators to discuss grant management compliance issues that may arise.
- Provide workshops conducted by NCURA to the Department Administrators and staff who handle research grants.
- Detailed ledger reports that include a listing of expenditures for each grant or contract are provided to the investigators monthly.
- The institution has its own policies and procedures that supplement and help

ensure compliance with the sponsor's grant and contract requirements

- User-friendly grant and contract policies and procedures are included on the *School of Finance* website under Grant and Restricted Funds including other grant management references and tools. This section of the website also includes Sponsored Project Accounting Alerts manual.
- A training webcast of Pre and Post Award Grant Finance and Compliance issues is mandatory for all MSSM research investigators and administrators in Sinai Central.

The Sponsored Projects Accounting Department reviews the following transactions charged to sponsored awards for proper documentation according to sponsor guidelines:

School Finance conducts a quarterly Administrators' Forum to discuss grant management compliance issues.

- Salary and wages (personnel action forms/HRTS Transactions / time and effort reports)
- Domestic and foreign travel (Including use of US Flag Air Carrier service for all air travel funded by the U.S. government)
- All Equipment purchases in excess of \$1,000.
- Non Capital Purchase orders greater than \$2,500 and Individual line items greater than \$1,000.
- All Consultant and professional services. (all contracts in excess of \$1,000).
- All Hospitalization and ancillary charges (100% review).
- Lease agreements for equipment (100% review).
- Institutional recharges for service and

merchandise (review of all journal entries).

## **SECTION V. GRANT MANAGEMENT GUIDELINES**

### **Federal and Non-Federal Sponsors**

The following regulations guide the School's administration of Federal and non-Federal grants and contracts.

- OMB A-110. *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.*
- OMB A-133. *Audits of Institutions of Higher Education and Other Non-Profit Institutions.*
- Title 45 Part 74. *Administration of Grants.*
- PHS Grants Policy Statement.*
- OMB Circular A-21. *Principles for Determining Costs Applicable to Grants, Contracts and Other Agreements with Educational Institutions.*
- Agency Specific Regulations.

### **Mount Sinai Specific Guidelines**

**(See School Finance website under Grants and Restricted Funds/Policies)**

- Asset Management Policies and Procedures (100A)
- Inter-institutional Transfer of Assets Purchased Through Grants (101A)
- Travel Policy (115E)
- Rebudgeting of Grant Funds DHHS Public Health Service and National Science Foundation (137D)
- Consultation Services – Purchase Orders and Invoices (155)
- Policies and Procedures for charging F&A Costs to Sponsored Projects Received from

## Extramural Sponsors, Gifts, Donations, and Other Receipts (170)

- Charging Administrative and Clerical Salaries to Federal Grants and Contracts (171)
- Charging Office Supplies and Other Administrative Expenses (other than Salaries) to Federal Awards (172)
- “Unallowable Expenses” (173)
- Time and Effort Reporting Policies and Procedures (174)
- Faculty Joint Appointments – Memorandum of Understanding (175)
- Grant and Contract Cost Transfers (176)
- Accounting Policies and Procedures for Sponsored Projects Received from Extramural Sponsors, Gifts, Donations and Other Receipts (170)
- Policies and Procedures for Administrative X Charges to Endowment and Similar Funds (158)
- Active Account Documents (177)
- Small Business Subcontracting Plan (177A)
- Program Income (178)
- Transaction Approval for Expenditures (179)
- Guidelines for Allocation and Uses of “R” Dollars (180)
- Sponsored Projects Financial Reporting and X Financial Closeout (181)
- Subawards (182)
- Other Grant Management References and Tools.
  - PI Exit Checklist
  - Research Grant Pocket Compliance Guide
  - GCO/Sponsored Projects Policies and

## Procedures Governing Sponsored Programs

- MSSM Monthly Expenditure Review Checklist.
- OMB A-110. *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.*
- OMB A-133. *Audits of Institutions of Higher Education and Other Non-Profit Institutions.*
- Title 45 Part 74. *Administration of Grants.*
- PHS Grants Policy Statement.*
- OMB Circular A-21. *Principles for Determining Costs Applicable to Grants, Contracts and Other Agreements with Educational Institutions.*
- Agency Specific Regulations.

## State and Non-Federal Grant Management Guidelines

- Foundations: Agency specific.
- Voluntary health agencies: Agency specific.
- State contracts: Agency specific.
- Industry and pharmaceutical company awards: Company specific.

With the exception of agency specific requirements, School Finance internal controls over State and non-Federal awards follow the Federal grant management guidelines.

**TABLE II: GRANTS AND CONTRACTS SERVICES**

<b>Expenditures</b>	<b>Documentation</b>	<b>Internal Control/Compliance Issues</b>	<b>Mount Sinai Compliance Program</b>
Salaries & wages	Time & Effort Report	<input type="checkbox"/> Does the effort report accurately reflect effort (within 5%) spent on extramurally supported activities? <input type="checkbox"/> Overlapping funding sources. <input type="checkbox"/> Are changes to personnel actions to reflect changes in effort processed in a timely fashion?	<input type="checkbox"/> Time and Effort reports for all employees charged to grants and contracts are distributed by Sponsored Projects Accounting. <input type="checkbox"/> Effort reporting package contains instructions for employee. <input type="checkbox"/> Effort reports are approved by both employee and supervisor. <input type="checkbox"/> It is the responsibility of the employee and his/her supervisor to ensure that the timecard effort report is accurate. <input type="checkbox"/> Changes to the effort should be made on the report and returned to Sponsored Projects Accounting as a basis for retroactive changes to the salaries charged to the grant. <input type="checkbox"/> Effort reporting requirements are reviewed periodically at Administrators' Forum
Fringe benefits	Rate agreement negotiated with DHHS annually	No exceptions are made for charging the Federally approved fringe benefit rate to all extramurally sponsored salaries and wages.	Prepare comprehensive fringe proposal with support documentation for review by DHHS.

Equipment	<input type="checkbox"/> Evidence of bidding <input type="checkbox"/> Evidence of sole source procurement <input type="checkbox"/> Voucher package <input type="checkbox"/> Institutional prior approval <input type="checkbox"/> PHS approval if over \$25,000 and involves a change in scope	<input type="checkbox"/> Are documentation and approvals for equipment purchases complete, accurate and authorized?	<input type="checkbox"/> Purchasing Department enforces bidding requirements <input type="checkbox"/> Sponsored Projects Accounting reviews requisitions <input type="checkbox"/> Institutional prior approval system administered according to Federal guidelines. <input type="checkbox"/> Policies and procedures included in <i>Finance at a Glance.on the School Finance website</i>
Travel	<input type="checkbox"/> Travel request <input type="checkbox"/> Submission of travel voucher with documentation in accordance with travel policy. No.115E	<input type="checkbox"/> Is documentation submitted for travel reimbursement complete, accurate and authorized according to both Federal and Mount Sinai Policy?	<input type="checkbox"/> All travel requests and travel vouchers for grants and contracts are reviewed and approved by Sponsored Projects Accounting <input type="checkbox"/> Policies and procedures included in the School Finance website. <input type="checkbox"/> Fly America Act
Supplies, subscriptions, other miscellaneous expenses	<input type="checkbox"/> Purchase order	<input type="checkbox"/> Is adequate documentation submitted to support payment?	<input type="checkbox"/> All transactions above the threshold described in Section IV and in Financial Memorandum No. 179 require prior review and approval by Sponsored Projects Accounting <input type="checkbox"/> Accounts Payable ensures voucher package is complete before bill is paid <input type="checkbox"/> Policies and procedures included in <i>Finance at a Glance on School Finance website</i>

Patient care costs	<input type="checkbox"/> Investigator will send a memorandum identifying the patient(s) and/or unit number <input type="checkbox"/> Laboratory or special services area will then send bills for services against that patient or unit number	<input type="checkbox"/> Both third party payers and grants are charged for services <input type="checkbox"/> Third party payer is charged when grant should be charged <input type="checkbox"/> Gray area where patient is receiving routine care while registered as a research patient <input type="checkbox"/> Investigator responsible for directing the billing to the correct payer	<input type="checkbox"/> Every patient on a research protocol signs a research consent form which is included in the patient file. <input type="checkbox"/> Department administrator and investigator are responsible for directing the bill for services to the correct payer.
Cost transfers	<input type="checkbox"/> A full explanation of the reason for the transfer <input type="checkbox"/> Certification of the correctness of the new charge by the principal investigator	<input type="checkbox"/> Frequent errors in recording costs may indicate weaknesses in the investigator's review and approval process. <input type="checkbox"/> Transfers from one budget period to the next may be an indication of cost overruns	<input type="checkbox"/> Cost transfers are not processed by Fund Sponsored Projects Accounting unless accompanied by the required documentation. <input type="checkbox"/> Internal control review of investigator review and approval procedures when an excessive number of cost transfers are required to close out an award.
Trainee stipend	<input type="checkbox"/> Statement of Appointment <input type="checkbox"/> No debt delinquencies in Federally sponsored programs <input type="checkbox"/> Pay-back agreement <input type="checkbox"/> Termination notice <input type="checkbox"/> Green card	<input type="checkbox"/> Level of appointment may not be in accordance with Federal guidelines, resulting in either excess or deficient payment. <input type="checkbox"/> Assurance that there is no other Federal source of funding for trainee's pay.	<input type="checkbox"/> All statements of appointment from the Department are audited by Sponsored Projects Accounting according to Federal guidelines <input type="checkbox"/> We ensure that all information verifying compliance with trainee requirements is submitted to the sponsor

Indirect F & A costs	<input type="checkbox"/> Indirect F&A Cost Rate Agreement or rate stipulated by sponsor	<input type="checkbox"/> Investigators may use wrong rate in filing application	<input type="checkbox"/> GCO and SPA checks applications for appropriate indirect F&A cost rates <input type="checkbox"/> Separate Department group within Sponsored Projects Accounting responsible for preparation of indirect F&A cost proposal <input type="checkbox"/> A review is conducted by the School's Reimbursement/Compliance department to screen all indirect F&A pools to ensure unallowable expenses are eliminated
Federal Letters of Credit: PHS, NSF, Department of Education, Department of Energy	<input type="checkbox"/> Quarterly Letter of Credit Accountability Report <input type="checkbox"/> Federal Cost Transactions Report	<input type="checkbox"/> Letter of credit draw downs in excess of immediate cash requirements	<input type="checkbox"/> Quarterly cash reconciliation for all letters of credit

<p>Cost reimbursement: Federal contracts NYS grants All non-Federal awards</p>	<p><input type="checkbox"/> Submit reimbursement request based on expenditures to sponsor, either monthly or quarterly</p>	<p><input type="checkbox"/> Reimbursement request may not agree with actual expenditures <input type="checkbox"/> Sponsor may disallow expenses as not being included in original award.</p>	<p><input type="checkbox"/> Separate group in Sponsored Projects Accounting ensures that all reimbursement requests are reconciled to the general ledger by individual award <input type="checkbox"/> All expenditures in excess of \$1,000 are compared by Sponsored Projects Accounting to the approved budget <input type="checkbox"/> Expense compliance risks are discussed periodically with departmental administrators at the Administrators' Forum <input type="checkbox"/> Financial reporting to sponsors is controlled by the Sponsored Projects Accounting Department. Expense activity is reviewed by Sponsored Projects Accounting in relation to the approved budget as part of the financial reporting process</p>
<p>Checks received from donors</p>	<p><input type="checkbox"/> Award Letter</p>	<p><input type="checkbox"/> Are the funds gift or grant? <input type="checkbox"/> Are there financial reporting requirements? <input type="checkbox"/> Should a separate account be established?</p>	<p><input type="checkbox"/> Communication by Sponsored Projects Accounting with investigator, sponsor and Development Office to ensure funds are recorded properly</p>

## **ABBREVIATIONS USED IN THIS MANUAL**

AALAC	American Association for Laboratory Animal Care
CCMS	Center for Comparative Medicine and Surgery (Mount Sinai)
CTA	Clinical Trial Agreement
DHHS	Department of Health and Human Resources
FDA	Food and Drug Administration
FEDIX	Federal Information Exchange
GCO	Grants and Contracts Office (Mount Sinai)
IACUC	Institutional Animal Care and Use Committee (Mount Sinai)
IRB	Institutional Review Board (Mount Sinai)
NIH	National Institutes of Health
NSF	National Science Foundation
OCR	Office of Clinical Research
CTBB	Clinical Trials Budget and Billing Operations
OMB	Office of Management and Budget
OHRP	Office of Human Research Protection
ORI	Office of Research Integrity
OTBD	Office of Technology and Business Development (Mount Sinai)
PHS	Public Health Service
PPHS	Program for the Protection of Human Subjects (Mount Sinai)
RSO	Radiation Safety Office (Mount Sinai)
RURSC	Radioisotopes Utilization and Radiation Safety Committee (Mount Sinai)
SPIN	Sponsored Program Information Network
SPA	Sponsored Projects Accounting
F&A	Facilities and Administrative Costs

## **FREQUENTLY USED TELEPHONE NUMBERS**

Comparative Medicine and Surgery	(212) 241-6685
Program for the Protection of Human Subjects	(212) 824-8200
Sponsored Projects Accounting Department	(212) 731-3338
Grants and Contracts Office	(212) 824-8300
Office of Clinical Research and Clinical Trials Budget and Billing	(212) 824-7294
Office of Research Integrity	(212) 241-3006

Office of the General Counsel	(212) 241-8105
Office of Technology and Business Development	(212) 659-9680
Pharmacy Director	(212) 241-6171
Radiation Safety Office	(212) 241-2269