ICAHN SCHOOL OF MEDICINE at MOUNT SINAI
POLICIES AND PROCEDURES GOVERNING SPONSORED PROGRAMS

Revised 2014 the full document is available at

http://icahn.mssm.edu/research/resources/grants-and-contract-office/application-information
# TABLE OF CONTENTS

FOREWORD 4

PART I. AWARD PROCESS 4
Introduction  4

SECTION I. PROPOSAL DEVELOPMENT, INTERNAL REVIEW AND SUBMISSION

Definition of Research  5
Eligibility for Principal Investigator Status  5
Application Forms  5
Sponsor Forms  5
GCO Forms  6
Budget Preparation  6
Fringe Benefits and Indirect Facilities and administrative Cost Rates  6
Cost-Sharing  6
Required Signatures  7
GCO Review  7
GCO Development Services  7
Notices of Funding Opportunities  8
Database Tracking System  8
Office of Research Services  8
Financial Administration of Clinical Trials Services (FACTS)  9
Clinical Trials Agreements  9
Investigational Drugs  10
Investigational Drug Service  10
Purchase and Use of Investigational Drugs  10
Non-Formulary Drugs  10
Formulary Drugs  10
Controlled Substances Used in Research  11
Materials Transfer Agreements, Inventions, and Patents  11
Mount Sinai Innovation Partners (MSIP)  11
Invention Reports  12

SECTION II. REGULATORY AND INSTITUTIONAL REQUIREMENTS

Program for the Protection of Human Subjects (PPHS)  12
Institutional Animal Care and Use Committee (IACUC)  13
Ethical Practices in Research  14
Policy on Conflict of Interest in Research  14
NIH Guidelines for Research Involving Recombinant DNA Molecules  15
Biosafety Program  15
Institutional Biosafety Committee  15
Radioisotopes in Research  16
Assurances and Certifications  17
PART II. POST-AWARD REQUIREMENTS  
Introduction  17

SECTION I. OVERVIEW OF POST-AWARD REQUIREMENTS AND PROCEDURES  
18
Grant and Contract Awards  18
Administration of Awards  18
No-cost Extension  19
Financial Management  19
Monitoring of Awards  19
Reporting  20
Closeout  20

SECTION II. RESPONSIBILITY FOR FINANCIAL COMPLIANCE  20

SECTION III. HIGHLIGHTS OF INTERNAL CONTROL/ FINANCIAL COMPLIANCE ISSUES
Salaries and Wages  21
Cost Transfers  22
Patient Care Costs  22
Allocation of Costs When Work is Closely Related  22
Disposition of Unexpended Balances on Non-Federal Awards  23
Indirect Facilities and Administrative Cost Screening  23

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

SECTION V. GRANT MANAGEMENT GUIDELINES  25
Federal and Non-Federal Sponsors  25
Mount Sinai Specific Guidelines  25
State and Non-Federal Grant Management Guidelines  26

CONTACTS
Research Administration Offices at ISMMS
Contacts for Research Administration Offices at ISMMS
Contacts for Research Services at ISMMS

ABBREVIATIONS USED IN THIS MANUAL

FREQUENTLY USED TELEPHONE NUMBERS
FOREWORD

Icahn School of Medicine at Mount Sinai 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 Icahn School of Medicine 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 application and 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 Handbook for Research, The Mount Sinai Medical Center Compliance Manual, Policy on 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 Icahn 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 Icahn 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 Icahn 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 Icahn 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,
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 Icahn 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 Departments indicated by the Chair’s and/or Departmental Administrator’s electronic signature on the GCO application form.

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

Application Forms

Sponsor Forms

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

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-
GCO Forms

Icahn School of Medicine internal forms are available on our website at http://icahn.mssm.edu/research/resources/grants-and-contract-office and at https://eresearch.mssm.edu/ a valid username and password are required for the electronic forms and InfoEd training is strongly recommended.

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

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

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.

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

It is the policy of Icahn 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 Icahn 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 Icahn School of Medicine. Federally negotiated rates apply to all agreements between Icahn 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

Cost-Sharing

Cost sharing or matching funds are required by some sponsors as a condition of award (Mandatory Cost Sharing.) Usually, these commitments must be included in the proposal.
In addition, cost sharing may be volunteered on the part of the Institution. (Voluntary Cost Sharing.) If a proposal lists cost sharing, either Mandatory or Voluntary, the commitment becomes a requirement of the agreement and the School must adhere to providing and documenting the cost-sharing. Whenever cost sharing is proposed in an application a cost sharing form must accompany the submission.

**Required Signatures**

The Department Chair(s) of the involved clinical or basic science department(s) or an authorized designee 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 designee must sign for each key faculty member and or professional identified in the proposal.

**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 Icahn 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; Director, Grants and Contracts Office and Associate 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 ISMMS compliance committees or the memorandum document available on the GCO web-site has been attached. 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 Icahn School of Medicine academic affiliate institutions seeking the programmatic and/or fiscal oversight of the Icahn School of Medicine must meet all school 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 is available on the web-site.

Enrollment in InfoEd’s SMARTS/GENIUS modules will provide on-line, personalized funding opportunities.

*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 Research Services (ORS)**

Developed in response to the needs of Icahn School of Medicine ever growing research community, the Office of Research Services (ORS) 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 ORS 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.

ORS is an integrated office available to assist investigators and research personnel with regulatory oversight requirements and administrative processes for protocol development and
ORS offers a range of services to basic science, translational, and clinical investigators and research personnel. These services include:

- Consultations on pre-protocol development
- Internal regulatory support to obtain IACUC and IRB approvals
- External regulatory support, including assistance with IND/IDE submissions to the FDA, Clinicaltrials.gov postings, and grant applications
- Guidance on protocol management, including monitoring services and data safety monitoring plans
- Research study recruitment and retention support, including assistance with developing brochures, newsletters, and web marketing (e.g., researchmatch.org)
- Facilitated training and mentoring for research personnel
- Assistance with accessing other valuable research resources and tools including biostatistics and research information technology

For further information please contact the staff of the OCR at research.services@mssm.edu or at 212-824-7294

---

**The Financial Administration of Clinical Trials Services - FACTS**

The Financial Administration of Clinical Trials Services in conjunction with the Grants and Contracts Office is the center for coordinating the financial aspect of your clinical research. As such, FACTS 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 FACTS reviews all clinical trial GCO submissions. FACTS assure that all related documents for the study are consistent.

The FACTS 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.

**Clinical Trials Agreements**

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.

FACTS reviews all industry funded 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 FACTS will endorse the CTA.

**Investigational Drugs**

**Investigational Drug Service**

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 drug services has been developed by Pharmacy and approved by the School Administration. It is intended as a guide to the Pharmacy Research Coordinator and study coordinator to use 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 IDS’ Authorization Form (www.mssm.edu/pphs or www.mssm.edu/ids) and submit it the Pharmacy for review. 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 Icahn School of Medicine. 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 or the institution must be registered with both agencies to use controlled substances for research purposes. The Investigational Drug Services maintains their own New York State Class IV Research License and DEA 223 Registration on behalf of the institution to support the investigators with this requirement.

A research protocol proposing the use of controlled substances must include that information on the IDS Authorization Form 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.
- Designation and use of controlled substances under the IDS’ NYS and DEA license numbers.

The Pharmacy Research Coordinator is available to answer questions regarding this requirement. To find out which controlled substances are on formulary and their classification/schedule, refer to the latest Mount Sinai Medical Center Drug Formulary for additional information. Pharmacy Investigational Drug Coordinator: (212) 241-2493.

---

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

**Office of Mount Sinai Innovation Partners - MSIP**

The Office of Mount Sinai Innovation Partners 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 Icahn
School of Medicine is governed by PHS regulations for patents and inventions arising out of activities supported by a PHS grant. The MSIP 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 MSIP.

**Invention Reports**

Investigators must disclose to the MSIP, and MSIP 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. This statement is now filed electronically by GCO after consultation with MSIP.


---

**SECTION II. REGULATORY AND INSTITUTIONAL REQUIREMENTS**

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

The Icahn School of Medicine Program for the Protection of Human Subjects, accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), 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 Icahn School of Medicine 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.
Icahn School of Medicine has five institutional IRBs, four of which meet monthly. Almost all human research is required to obtain IRB review from the Icahn School of Medicine IRBs. The Icahn School of Medicine also accepts IRB review from the Biomedical Research Alliance of New York (BRANY) IRB and other commercial IRB’s for select types of research. Obtaining review by an IRB other than Icahn School of Medicine 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 Icahn School of Medicine 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 Icahn School of Medicine (ISMMS) 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 Icahn School of Medicine.

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”. Icahn School of Medicine IACUC activities are conducted according to specific procedures described in an Animal Welfare Assurance documents (A3111-01) filed by Icahn School of Medicine 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 procedures or conditions (e.g. cancer), or iii) at the request of any member of the IACUC.

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.

Ethical Practices in Research

It is the policy of the Icahn 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 following handbooks


_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 Icahn School of Medicine Research Integrity Officer (RIO) at (212) 241-3006

Research Compliance is part of Icahn School of Medicine 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

Icahn School of Medicine 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 Icahn School of Medicine 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://icahn.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/institutional-policies/financial-conflicts-of-interest-in-research](http://icahn.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/institutional-policies/financial-conflicts-of-interest-in-research).

Icahn School of Medicine 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 Bio-Safety 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 Icahn 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 evaluation of research protocols to determine if the appropriate risk groups and biosafety levels have been identified by the Principal Investigator, design and improvement of disposal procedures for biological, chemical, and carcinogen waste and the preparation, submission, and maintenance of records, reports, and documents as may be required by government regulations.

**Icahn School of Medicine Institutional Biosafety Committee**

Icahn School of Medicine will maintain an Institutional Biosafety Committee consistent with the National Institutes of Health (NIH) Guidelines published in [Federal Register, July](http://icahn.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/institutional-policies/financial-conflicts-of-interest-in-research).
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 Icahn School of Medicine 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, synthetic DNA molecules, DNA expression products, pathogen, oncogene, toxins and toxic chemical use in research conducted at ISMMS. 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 ISMMS for compliance with the NIH Guidelines and CDC/NIH BMBL.

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

Radioisotopes in Research

Research involving radioisotopes falls under the purview of the Radiation Safety Committee (RSC) which establishes policies and oversees the use of radioisotopes. The Radiation Safety Office (RSO), under the guide of the Radiation Safety Officer, implements the policies and requirements established by RSC.

The Icahn School of Medicine holds a broad-scope license for use of radioisotopes in non-human research from City of New York. All Principal Investigators whose work requires radioisotopes must submit an application to the RSO for approval as “Authorized Users” by the RSC.

Information regarding application, necessary equipment, experience, qualifications and training can be obtained by contacting the RSO. An internal list of approved “Authorized Users” under
the institutional broad scope Non-human use radioactive materials license is maintained by the radiation safety office. This internal authorization is valid only for 5 years and will renewed upon request.

Radiation Safety Office maintains a comprehensive website which can be accessed at http://intranet1.msnyuhealth.org/radiation/index.html. All application materials for Authorization, Radiation Safety Trainings, Radiation Safety Manual, etc. are available at this website. Radiation Safety Office can be reached at (212) 241-2269 for live help during normal working hours.

Assurances and Certifications

Icahn 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
- HIPAA
- Civil Rights, including: race, color or national origin handicapped individuals
- sex discrimination

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 Icahn School of Medicine sponsored project guidelines and for reviewing and approving transactions.
- Internal control/compliance issues applicable to typical grant revenue and expense categories.
- Icahn School of Medicine program for monitoring compliance with Federal and Icahn School of Medicine regulations.
- Icahn 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 Icahn School of Medicine 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 Icahn School of Medicine 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 Icahn School of Medicine 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 Icahn School of Medicine 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 Icahn School of Medicine 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 on the GCO website at www.icahn.mssm.edu

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, Icahn School of Medicine 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 Icahn School of Medicine’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 Icahn School of Medicine’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. Icahn School of Medicine’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 Icahn School of Medicine 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 Icahn 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 Icahn School of Medicine’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 Icahn School of Medicine’s grant management policies and procedures is summarized in Table I.

<table>
<thead>
<tr>
<th>Table I: Transactions Requiring Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Required from . . .</td>
</tr>
<tr>
<td>Supplies, salary adjustments, equipment</td>
</tr>
<tr>
<td>Time and effort reporting</td>
</tr>
<tr>
<td>Cost transfers</td>
</tr>
<tr>
<td>Budget transfers &lt;$25,000 (prior institutional approval required)</td>
</tr>
<tr>
<td>Budget transfers &gt;$25,000 (prior institutional approval required)</td>
</tr>
<tr>
<td>Travel (domestic)</td>
</tr>
<tr>
<td>Travel (foreign)</td>
</tr>
<tr>
<td>Patient care billing</td>
</tr>
<tr>
<td>Financial reporting to sponsors</td>
</tr>
<tr>
<td>Cash management</td>
</tr>
<tr>
<td>Fringe benefit rate calculation and negotiation</td>
</tr>
</tbody>
</table>

**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 Icahn School of Medicine’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**

Icahn 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 Icahn School of Medicine 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
- Operations & Maintenance
- General Administration
- Equipment Depreciation
- Interest
- Departmental Administration
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 Icahn 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 Icahn School of Medicine 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.

- Icahn School of Medicine 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 Icahn School of Medicine 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 Icahn School of Medicine 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.
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.
☐ 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>
<thead>
<tr>
<th>TABLE II: GRANTS AND CONTRACTS SERVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expenditures</strong></td>
</tr>
<tr>
<td>Salaries &amp; wages</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Fringe benefits</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Prepare comprehensive fringe proposal with support documentation for review by DHHS.
<table>
<thead>
<tr>
<th>Travel</th>
<th></th>
<th>Submission of travel voucher with documentation in accordance with travel policy. No.115E</th>
<th>Is documentation submitted for travel reimbursement complete, accurate and authorized according to both Federal and Mount Sinai Policy?</th>
<th>All travel requests and travel vouchers for grants and contracts are reviewed and approved by Sponsored Projects Accounting. Policies and procedures included in the School Finance website. Fly America Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies, subscriptions, other miscellaneous expenses</td>
<td></td>
<td>Purchase order</td>
<td>Is adequate documentation submitted to support payment?</td>
<td>All transactions above the threshold described in Section IV and in Financial Memorandum No. 179 require prior review and approval by Sponsored Projects Accounting Accounts Payable ensures voucher package is complete before bill is paid Policies and procedures included in <em>Finance at a Glance on School Finance website</em></td>
</tr>
<tr>
<td>Patient care costs</td>
<td></td>
<td>Investigator will send a memorandum identifying the patient(s) and/or unit number Laboratory or special services area will then send bills for services against that patient or unit number</td>
<td>Both third party payers and grants are charged for services Third party payer is charged when grant should be charged Gray area where patient is receiving routine care while registered as a research patient Investigator responsible for directing the billing to the correct payer</td>
<td>Every patient on a research protocol signs a research consent form which is included in the patient file. Department administrator and investigator are responsible for directing the bill for services to the correct payer.</td>
</tr>
<tr>
<td>Cost transfers</td>
<td></td>
<td>A full explanation of the reason for the transfer Certification of the correctness of the new charge by the principal investigator</td>
<td>Frequent errors in recording costs may indicate weaknesses in the investigator’s review and approval process. Transfers from one budget period to the next may be an indication of cost overruns</td>
<td>Cost transfers are not processed by Fund Sponsored Projects Accounting unless accompanied by the required documentation. Internal control review of investigator review and approval procedures when an excessive number of cost transfers are required to close out an award.</td>
</tr>
<tr>
<td>Trainee stipend</td>
<td></td>
<td>Statement of Appointment No debt delinquencies in Federally sponsored programs Pay-back agreement Termination notice Green card</td>
<td>Level of appointment may not be in accordance with Federal guidelines, resulting in either excess or deficient payment Assurance that there is no other Federal source of funding for trainee’s pay.</td>
<td>All statements of appointment from the Department are audited by Sponsored Projects Accounting according to Federal guidelines We ensure that all information verifying compliance with trainee requirements is submitted to the sponsor</td>
</tr>
<tr>
<td>Indirect F &amp; A costs</td>
<td>Indirect F&amp;A Cost Rate Agreement or rate stipulated by sponsor</td>
<td>Investigators may use wrong rate in filing application</td>
<td>GCO and SPA checks applications for appropriate indirect F&amp;A cost rates</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Separate Department group within Sponsored Projects Accounting responsible for preparation of indirect F&amp;A cost proposal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>A review is conducted by the School’s Reimbursement/Compliance department to screen all indirect F&amp;A pools to ensure unallowable expenses are eliminated</td>
<td></td>
</tr>
<tr>
<td>Cost reimbursement: Federal contracts NYS grants All non-Federal awards</td>
<td>Submit reimbursement request based on expenditures to sponsor, either monthly or quarterly</td>
<td>Reimbursement request may not agree with actual expenditures</td>
<td>Separate group in Sponsored Projects Accounting ensures that all reimbursement requests are reconciled to the general ledger by individual award</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sponsor may disallow expenses as not being included in original award.</td>
<td>All expenditures in excess of $1,000 are compared by Sponsored Projects Accounting to the approved budget</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Expense compliance risks are discussed periodically with departmental administrators at the Administrators’ Forum</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Checks received from donors</td>
<td>Award Letter</td>
<td>Are the funds gift or grant? Are there financial reporting requirements? Should a separate account be established?</td>
<td>Communication by Sponsored Projects Accounting with investigator, sponsor and Development Office to ensure funds are recorded properly</td>
<td></td>
</tr>
</tbody>
</table>
Research Administration Offices at ISMMS

Click on an office to visit their website.

Revised December 19, 2013
<table>
<thead>
<tr>
<th>OFFICE</th>
<th>CONTACT</th>
<th>TELEPHONE #</th>
<th>EMAIL ADDRESS</th>
<th>WEBSITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosafety Committee</td>
<td>Philip G. Hauck</td>
<td>212-241-5169</td>
<td><a href="mailto:philip.hauk@mssm.edu">philip.hauk@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/research/resources/institutional-biosafety-program">http://cahn.mssm.edu/research/resources/institutional-biosafety-program</a></td>
</tr>
<tr>
<td>Conflicts of Interest in Research</td>
<td>Terence Beck</td>
<td>212-241-0845</td>
<td><a href="mailto:terence.beck@mssm.edu">terence.beck@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/research/resources/conflict-of-interest-co/financial-conflicts-of-interest-in-research">http://cahn.mssm.edu/research/resources/conflict-of-interest-co/financial-conflicts-of-interest-in-research</a></td>
</tr>
<tr>
<td>Financial Administration of Clinical Trials Services (FACTS)</td>
<td>Rosaria McEntee</td>
<td>212-731-7067</td>
<td><a href="mailto:facts@mssm.edu">facts@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/facts">http://cahn.mssm.edu/facts</a></td>
</tr>
<tr>
<td>Grants and Contracts Office (GCO)</td>
<td>Jessica Moise</td>
<td>212-424-8500</td>
<td><a href="mailto:grants@mssm.edu">grants@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/grants">http://cahn.mssm.edu/grants</a></td>
</tr>
<tr>
<td>Mount Sinai Innovation Partners (MSIP)</td>
<td>Sybil Lombillo</td>
<td>212-459-9680</td>
<td><a href="mailto:techology@mssm.edu">techology@mssm.edu</a></td>
<td><a href="http://www.ip.mountsinai.org/">http://www.ip.mountsinai.org/</a></td>
</tr>
<tr>
<td>Institutional Animal Care and Use Committee (IACUC)</td>
<td>Giorgio Martinelli</td>
<td>212-241-0153</td>
<td><a href="mailto:iacuc@mssm.edu">iacuc@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/iacuc">http://cahn.mssm.edu/iacuc</a></td>
</tr>
<tr>
<td>Investigational Drug Service (IDS)</td>
<td>Ivy Cohen</td>
<td>212-241-2493</td>
<td><a href="mailto:ivy.cohen@mssm.edu">ivy.cohen@mssm.edu</a></td>
<td><a href="http://www.mountsinai.org/ids">http://www.mountsinai.org/ids</a></td>
</tr>
<tr>
<td>Institutional Review Board (IRB)</td>
<td>Lori Jennex</td>
<td>212-242-8200</td>
<td><a href="mailto:irb@mssm.edu">irb@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/irb">http://cahn.mssm.edu/irb</a></td>
</tr>
<tr>
<td>Office for Research Services (ORS)</td>
<td>Rosemarie Gagliardi</td>
<td>212-424-7234</td>
<td><a href="mailto:research_services@mssm.edu">research_services@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/ors">http://cahn.mssm.edu/ors</a></td>
</tr>
<tr>
<td>Program for the Protection of Human Subjects (PPHS)</td>
<td>Lori Jennex</td>
<td>212-242-8200</td>
<td><a href="mailto:irb@mssm.edu">irb@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/pphs">http://cahn.mssm.edu/pphs</a></td>
</tr>
<tr>
<td>Radiation Safety Human Use Subcommittee</td>
<td>Monika Anand</td>
<td>212-424-7501</td>
<td><a href="mailto:monika.anand@mssm.edu">monika.anand@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palettes/radiation-safety">http://cahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palettes/radiation-safety</a></td>
</tr>
<tr>
<td>Research Compliance</td>
<td>Vivian Mitropoulos</td>
<td>212-241-4391</td>
<td><a href="mailto:vivian.mitropoulos@mssm.edu">vivian.mitropoulos@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/research/resources/research-integrity">http://cahn.mssm.edu/research/resources/research-integrity</a></td>
</tr>
<tr>
<td>Research Information Technology</td>
<td>William Fultz</td>
<td>212-459-1522</td>
<td><a href="mailto:william.fultz@mountsinai.org">william.fultz@mountsinai.org</a></td>
<td><a href="http://cahn.mssm.edu/researchit">http://cahn.mssm.edu/researchit</a></td>
</tr>
<tr>
<td>Sponsored Projects Accounting</td>
<td>Raj Appavo</td>
<td>212-731-3463</td>
<td><a href="mailto:raj.appavo@mountsinai.org">raj.appavo@mountsinai.org</a></td>
<td><a href="http://cahn.mssm.edu/about-us/services-and-resources/finance/sponsored-projects-accounting">http://cahn.mssm.edu/about-us/services-and-resources/finance/sponsored-projects-accounting</a></td>
</tr>
<tr>
<td>Center for Comparative Medicine and Surgery (Vivarium)</td>
<td>Reginald Miller</td>
<td>212-241-3088</td>
<td><a href="mailto:reginald.miller@mssm.edu">reginald.miller@mssm.edu</a></td>
<td><a href="http://cahn.mssm.edu/research/resources/center-for-comparative-medicine-and-surgery">http://cahn.mssm.edu/research/resources/center-for-comparative-medicine-and-surgery</a></td>
</tr>
</tbody>
</table>

Revised December 9, 2013
# Contacts for Research Services at ISMMS 1.0

**SERVICES** | **CONTACT**
--- | ---
Bio-Medical Engineering | jhong.wu@mssm.edu
Flow Cytometry | anqi.chang@mssm.edu
Human Embryonic/Induced Pluripotent Stem Cell | avant.d,sourav@mssm.edu
Human Immune Monitoring | immuremonitoring@mssm.edu
In-Vivo Molecular Imaging | chek.tao@mssm.edu
In-vitro | jeffeye@mssm.edu
Microscopy | sgp@med.uchicago.edu
Microscopy | peter.heere@peter.edu
Mouse Genetics/Gene Targeting | jeffeye@mssm.edu
Pathology and Bioinformatics | mihail.donovan@mssm.edu
Pathology and Bioinformatics | venus@ocean.cair@mssm.edu
Mount Sinai/JJ Peters VA Medical Center Brain Bank | NEIB@mssm.edu

**INSTUTUTES FOR TRANSLATIONAL SCIENCES – CONDUTS (ITSA)**
Biosciences, Epidemiology, and Research Design (BERD) | rachel.dooner@mssm.edu
Center for Community and Academic Research Partnerships (CCARP) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Center for Patient Oriented Research, Training, Education and Development (CePRED) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Clinical Research Centers (CRC) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Experimental Therapeutics Institute (ETI) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Ironman Institute for Personalized Medicine (IPM) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Office of Research Services (ORS) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Research Information Technology | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx
Translational and Molecular Imaging Institute (TMII) | https://esp.mssm.edu/Public/ConductsRequestForServices.aspx

**EXPERIMENTAL THERAPEUTICS INSTITUTE (ETI) CORES**
Integrated Screening | louis.lamers@mssm.edu
Medicinal Chemistry Core | asf@med.uchicago.edu
Structure Based Drug Discovery | michael.kim@mssm.edu

**TRANSLATIONAL AND MOLECULAR IMAGING INSTITUTE (TMII)**
Center for Comparative Medicine and Surgery (Vivarium) | rebecca.michael@anl.gov
GRANT APPLICATION RESOURCE CENTER (GARC) | research.services@mssm.edu
DATA WAREHOUSE | MDMW.GROUP@mssm.edu
GENETICS CORE FACILITY | rebecca.michael@anl.gov
HIGH PERFORMANCE COMPUTING | jeffeye@mssm.edu
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
FACTS  Financial Administration of Clinical Trials Services (Mount Sinai)
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)
MSIP  Mount Sinai Innovation Partners (Mount Sinai)
NIH  National Institutes of Health
NSF  National Science Foundation
OCR  Office of Clinical Research
OMB  Office of Management and Budget
OHRP  Office of Human Research Protection
ORI  Office of Research Integrity
PHS  Public Health Service
PPHS  Program for the Protection of Human Subjects (Mount Sinai)
RSO  Radiation Safety Office (Mount Sinai)
RSC  Radiation Safety Committee (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

<table>
<thead>
<tr>
<th>Department</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative Medicine and Surgery</td>
<td>(212) 241-6685</td>
</tr>
<tr>
<td>Program for the Protection of Human Subjects</td>
<td>(212) 824-8200</td>
</tr>
<tr>
<td>Sponsored Projects Accounting Department</td>
<td>(212) 731-3338</td>
</tr>
<tr>
<td>Grants and Contracts Office</td>
<td>(212) 824-8300</td>
</tr>
<tr>
<td>Office of Clinical Research and</td>
<td>(212) 824-7294</td>
</tr>
<tr>
<td>Financial Administration of Clinical Trials Services</td>
<td></td>
</tr>
<tr>
<td>Office of Research Integrity</td>
<td>(212) 241-3006</td>
</tr>
<tr>
<td>Research Compliance</td>
<td>(212) 241-4391</td>
</tr>
<tr>
<td>Office of the General Counsel</td>
<td>(212) 241-8105</td>
</tr>
<tr>
<td>Office of Mount Sinai Innovation Partners</td>
<td>(212) 659-9680</td>
</tr>
<tr>
<td>Pharmacy Director</td>
<td>(212) 241-6171</td>
</tr>
<tr>
<td>Radiation Safety Office</td>
<td>(212) 241-2269</td>
</tr>
</tbody>
</table>