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Introduction
The continued success of Icahn School of Medicine at Mount Sinai (ISMMS) as a leading institution in biomedical research depends not only upon excellence in research but also upon maintaining excellence in ethical conduct and in complying with legal, regulatory, extramural funding agency, and institutional research and sponsored project requirements.

This manual serves as a comprehensive resource to assist the research community in navigating through the policies and procedures related to research and sponsored projects. The manual is divided into three parts. To avoid duplicating information, website links to policies and procedures are included in the manual wherever possible.

Part I: Pre-Award
Part I covers topics related to project start up, the pre-award research and sponsored project application process, and the research and research related agreement review and approval process. It begins with the Office of Research Services (ORS) and Grant Application Resource Center (GARC), which offer resources for application development. ORS is the central resource where research faculty and staff obtain guidance and assistance in navigating the various processes and workflows in the conduct of research. The majority of Part I is devoted to Grants and Contracts Office (GCO) policies and procedures. GCO oversees the research and sponsored project application process. The Foundation and Corporate Relations Department and Committee on Special Awards (CoSA) may also be involved in the application process and are included in this section. The Financial Administration of Clinical Trials (FACTS) and the Investigations Drug Service of the Pharmacy Offices are included in Part I as they offer services in the project start up and initiation phases. The last section of Part I provides information on the research and research related agreement review and approval process, which involves different institutional offices at Mount Sinai depending on the agreement.

Part II: Regulatory Requirements and Approvals
Part II covers initial and ongoing regulatory requirements and approvals throughout the lifecycle of a research or sponsored project. Regulatory oversight is required from project initiation through close out. This section includes the offices that have regulatory boards or committees that approve or disapprove some aspect of the project in terms of safety and/or ethical concerns. This section includes institutional requirements and oversight information from the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Conflict of Interest (COI) Office, Human Embryonic Stem Cell Research (ESCR) Committee, Program for the Protection of Human Subjects (PHHS), Dual Use of Research Concern (DURC) Committee, Radiation Safety, and Research Integrity. Research compliance and education resources are also included in Part II.

The regulatory offices offer an array of resources available to educate and guide investigators through their respective policies and procedures. Refer to the websites of the offices for additional information. In addition, please refer to Office of Research Services.

Part III: Post Award
Part III covers topics related to post-award financial administration and the managing and closing out of a sponsored project award. FACTS is a division of the Department of Finance and its post award activities are included here.

While the majority of Part III of the manual is devoted to Sponsored Project Accounting (SPA) policies
and procedures, please refer to Part I of this manual for ongoing sponsored project activities such as submission of yearly renewal (i.e., non-competitive, no cost extension) and close out applications as well as NIH prior approval requests. The oversight office is the Grants and Contracts Office (GCO). Please refer to Part II of the manual for ongoing and close out activities for regulatory requirements (e.g., IRB, IACUC, etc.).

Intellectual property, technology disclosure, and invention reporting via the Mount Sinai Innovation Partners (MSIP) Office is part of the management and close out process for research and sponsored projects and is included in Part III.

Investigators and their staff should be familiar with the Faculty Handbook, The Mount Sinai Health System Code of Conduct: A Guide to Our Corporate Compliance Program (intranet), Policy on Conflicts of Interest in Research, and other written policies and procedures referred to in this manual.
PART I. Pre-Award Process

Section I. Project Initiation – Office of Research Services (ORS)

A. Services

The Office of Research (ORS) serves as a central resource for the Mount Sinai Health System (MSHS) research community. These services include:

- Research 411
  Contact ORS with any question about navigation of the MSHS research processes, resources and services
- Research Orientation for New Staff and Faculty
  ORS offers tools, flowcharts and in-person orientation sessions for new research staff & faculty
- Consulting Services:
  - Clinical trials.gov registration & maintenance assistance
  - Investigational New Drug (IND) applications consulting
  - Investigational Device Exemption (IDE) consulting
  - Research subject recruitment & retention consulting
  - ResearchMatch.Org support
  - EXPERT (Early eXpert Protocol Evaluation of Research Techniques)
- Training, Education & Communication:
  - Department specific education & training research infrastructure, processes & procedures
  - Oversight of the research listserv
  - Research Digest – quarterly summary of information about research infrastructure

B. Resources

Investigators may wish to become acquainted with the Getting Started section of Mount Sinai’s Research Portal. In addition, below are resources to help investigators navigate the first steps in conducting research.

- Research Listserv
- Research Start-up Table and Required Training
- Grant/Protocol Flow Chart
- Agreement Navigator Tool
- Find Funding
- IT Systems
- Find a Collaborator
- Grant Application Resource Center
- Research Services Toolkit
  ORS maintains a portfolio of Regulatory Start-up, Project Management, IND, and IDE tool and templates.

C. Research Services and Research Administration Contact Information

- Research Administration Offices

For further information please contact ORS at research.services@mssm.edu or at 212-824-7294.
Section II. Grant Application Resource Center (GARC)

A. Services
The Grant Application Resource Center (GARC) provides Mount Sinai investigators with information and tools to facilitate their preparation of grant applications and protocols.

B. Resources
- Research Wizards
- Standardized Language
- Statistical Support
- Research Information Technology

C. Contact Information
To provide feedback, email GARCfeedback@mssm.edu.

Section III. Grants and Contracts Office (GCO)

A. Services
The Grants and Contracts Office (GCO) is the centralized administrative office that oversees the research and sponsored project application and award process. The GCO 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, including assisting with budget preparation.

The GCO reviews each project for administrative and budgetary accuracy as well as for compliance with federal, state, city, and internal regulations, such as those pertaining to biosafety, human subjects, vertebrate animals, and recombinant DNA.

The GCO interfaces with extramural funding agencies and will intervene on behalf of an investigator regarding funding conflicts, compliance, and subaward issues.

The GCO collects data regarding faculty research performance and reports to senior management regarding institutional performance. Information for each proposal is maintained in its database tracking system, which is the principal source of information regarding success rate and other award metrics.

Investigators planning multi-disciplinary projects may request searches of the database to identify potential collaborators.

B. Policies and Procedures

1. 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 with titles typically associated with independent work and whose appointments are subject to a rigorous review of credentials, may also serve as principal investigators.
The departmental chair and/or administrator approve the principal investigator in the application submission routing process.

2. Submission Process
All research and sponsored project applications, excluding BRANY projects, are prepared in the InfoEd software program and routed for approval through the department(s) in which there are key personnel. An application must be submitted each year of the project. All projects must be submitted through InfoEd and reviewed by the GCO prior to submission to an external funding agency, even those that do not require an institutional signature. Refer to Submission, Review, and Approval Process Pictorial for information.

For purposes of submitting an application to 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. For other terms used in the research and sponsored project process, please refer to GCO’s Glossary of Common Terms, which is organized in the following sections: Application Types, Award Instruments, Software Terms, Personnel Types, and Other Basic Terms.

Refer to GCO’s Application Submission Checklist and corresponding instructions for additional submission information and best practices for a successful submission. Also, please refer to the InfoEd training requirement policy.

3. Roles and Responsibilities
   a. Departments
      i. Principal Investigator (PI)
         In all instances, the PI approves the InfoEd application. The PI may prepare or may delegate preparation of the InfoEd application. Once a PI approves his/her InfoEd application, it is routed to the academic departments in which there are faculty or key personnel. Once the GCO approves, the PI or his/her team is responsible for submitting the application to the extramural funding agency unless the technical or funding agency requirements are such that GCO must submit the application. See PI certification language below.
         1) NIH Funded Projects – Not NRSA
            This is an NIH application that is not an NRSA and I certify that the following statements are true and accurate:
            1. The information submitted within the application is true, complete and accurate to the best of my knowledge.
            2. Any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
            3. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.
         2) NIH Funded Projects – NRSA
This is an NRSA application and I certify that the following statements are true and accurate:

1. The information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's (Mentor's) knowledge;
2. Any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor(s) (Mentor) to criminal, civil, or administrative penalties;
3. The Sponsor(s) (Mentor) will provide appropriate training, adequate facilities, and supervision if a fellowship is awarded as a result of the application;
4. The Fellow has read the Ruth L. Kirschstein National Research Service Award Payback Assurance and will abide by the Assurance if an award is made, and that the award will not support residency training.

3) All Other Projects
This is a research and/or sponsored programs application and I certify that the following statements are true and accurate:

1. The information submitted within the application is true, complete, and accurate to the best of my knowledge.
2. Any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
3. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.

ii. Departmental Administrator/Chair
Refer to the InfoEd Routing List for approval contacts and alternates. Some departments have a two tiered process whereby an administrator and chair review and approve (or reject) an application. In other departments, only an administrator or chair approves. The Departmental Administrator/Chair approves the InfoEd application for each key personnel and faculty member in his/her department identified with the proposal. See certification language below.

If I have chosen Approved I certify the below:

If I have chosen Disapproved, I do not certify the below and do not want the application to go forward:

If I have chosen Revisions Needed I do not certify the below, but ask that the Investigator make corrections and then re-route.

1. All salary information is accurate.
2. Proposed departmental/institutional resources are or will be made available.
3. The application is consistent with the Institutional Mission.
4. If there is proposed cost sharing, the cost sharing form has been completed and attached.

Refer to the Listing of Centralized Pre-Award Contacts within ISMMS’s Departments for contact information.

b. Grants and Contacts Office (GCO)
   i. The GCO reviews the application for accuracy of administrative information and compliance with extramural and institutional regulations. GCO reviews projects only after receiving a complete and final proposal submission. This includes completed and signed Sinai Central Conflict of Interest and Suspension and Debarment forms, as appropriate.
   ii. Authorized Organization Representative (AOR)
       The AOR institutionally endorses sponsored project applications and agreements. The Office of the Dean and the Board of Trustees have designated the Grants and Contracts Officer, GCO Director, and GCO Associate Director with this authority.

Refer to the GCO Staff Listing by Department for each department’s designated contacts.

4. Deadlines
Routing the application through the departments for approval occurs before GCO receipt. Once the GCO receives the complete and final application, including completed and signed Conflict of Interest and Suspension and Debarment forms as appropriate, the deadline schedule applies below.

<table>
<thead>
<tr>
<th>Application Type</th>
<th>GCO Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISMMS Sponsored Projects</td>
<td>1 Business Day</td>
</tr>
<tr>
<td>Federal Non-Competitive Applications</td>
<td>2 Business Days prior to extramural funding agency deadline</td>
</tr>
<tr>
<td>Federal Competitive Grant and Contract Applications</td>
<td>5 Business days prior to extramural funding agency deadline by 11 am</td>
</tr>
<tr>
<td>All other sponsored project applications</td>
<td>Please contact the GCO for sponsored projects with complex budgetary and/or administrative requirements. 1 business day may not apply.</td>
</tr>
</tbody>
</table>

5. Compliance Application (PPHS/IACUC) Requirement
   a. Requirement
       For human subject and animal research projects, PIs must submit a corresponding compliance application (PPHS and/or IACUC), to the respective compliance office for these types of projects:
• Internal or unfunded projects (i.e., “ISMMS” sponsored projects)
• Industry sponsored projects (unless it is a competitive, peer reviewed application)
• Transfer, non-competitive and no cost extension applications

For GCO’s best practices document entitled “Application Submission Process: Which Applications and Forms Do I Work on First?” Click on the appropriate General or Unfunded Human Subject Studies link.

b. Just In Time (JIT) Policy and Use of Compliance Waiver Form
The submission of a corresponding compliance application is not required at the time of GCO submission under the following circumstances:

i. The funding agency has a documented two step review process that allows a “Just-In-Time” (JIT) review by the ISMMS compliance committees. The NIH and the Stanley Foundation have JIT policies.

ii. PI is submitting a competitive application without a JIT policy. In this case, the PI must include the signed compliance waiver form with the InfoEd application. Submitting a compliance waiver for competitive NIH and Stanly Foundation projects is not necessary.

6. Budgetary
   a. Policy
Budgets must follow the specific instructions of the extramural funding agency. Base salaries must be accurate. Costs must be allowable, allocable, reasonable, necessary and consistently applied regardless of the source of funding. Please see the Uniform Guidance for additional information. Also, refer to Part III for other common funding agency regulations.

Sponsored projects are generally awarded with a portion of the funds covering the direct costs of conducting the work described in the proposal and a component for Facilities and Administration (F&A) costs, which reimburses the Icahn School of Medicine (ISMMS) for administrative, space, and other costs.

Direct costs are those that can be specifically identified to the sponsored project 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 proposed work.

b. Use of Institutional Fringe Benefits and Facilities and Administrative (F&A) Cost Rates
Budgets must include fringe benefits and F&A costs using the rates established by Mount Sinai. GCO posts the rates in the Administrative Information Sheet. Further information about F&A rates is provided in Sponsored Projects Accounting’s Policies and Procedures for Charging Indirect Costs to Sponsored Projects Received from Extramural Sponsors, Gifts,
Donations, and Other Receipts (170). Announcements of revised fringe benefit and F&A cost rates are periodically issued by the Sponsored Project Accounting Office (SPA).

c. Fringe Benefits and Facilities and Administrative (F&A) Cost Waiver
   Any exception requires written approval of the Dean or CFO. Requests for waiver of F&A should be made in writing by the chair or departmental administrator and submitted to Stephen Harvey, CFO.

d. Cost-Sharing
   Cost-sharing occurs when Mount Sinai, rather than the external funding agency, is responsible for bearing a cost or a portion of a cost on a sponsored project. If a proposal includes either mandatory or voluntary cost sharing, the commitment becomes a requirement of the agreement and the School must comply. Please refer to the cost sharing policy for complete information. A fully signed cost sharing form must be included in the InfoEd application.

7. Assurances and Certifications
   As part of the federal sponsored project process, Mount Sinai is required to document its ability and willingness to comply with the following federal regulations:
   
   | 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, national origin, religion, sex, age, or disability |

8. Policies and Procedures on Website
   Refer to GCO’s Policies and Procedures section of the website for the most up to date list of policies and procedures.
   a. Policies and Procedures
   - Administrative Information Sheet
   - Application Submission Checklist Instructions
   - Application Submission Process: Which Applications and Forms do I Work on First? General
   - Application Submission Process: Which Applications and Forms do I Work on First? For Unfunded Human Subject Studies
   - Budgeting Students and Post Graduates on Federal Research, Fellowship, and Training Grants - Includes Administrative and Application Submission Information
   - Budgeting for an ISMMS Faculty Member with a VA Appointment
   - Cost Sharing
   - External Electronic Submission Systems that Require User Registration through the GCO
   - Federal Suspension and Debarment Reminder
   - Foreign Travel Request Reminder
   - Freedom of Information Act (FOIA) Requests
b. Checklists

- Application Submission Checklist
- NIH ASSIST
- NIH Competitive Subaward Checklist: ISMMS as the Prime Institution
- NIH Competitive Subaward Checklist: ISMMS as the Subawardee
- Subawardee, Consultant, and Vendor Determination Checklist

c. Forms

See the following section for information on the required software systems for submitting research and sponsored project submissions. Other forms listed below may either be required under certain circumstances or are optional. Please see the Forms section of the GCO website for the most up to date information.

- Budget Template
- COI Form for Subawardees Under ISMMS Policy - New, Competitive Renewals, and Transfer Applications
- COI Form for Subawardees Under ISMMS Policy - Non-competitive, no cost extension, and supplement applications, new financial interests or new investigator
- Compliance (IRB/IACUC) Application Waiver Form
- Cost Sharing Form
- NIH Initial No Cost Extension Request and Progress Report Form
- NIH Prior Approval Form for Rebudgeting Activity at High Risk of Indicating a Change in Scope
- Prior Approval Request Form for Establishment of a Fund Number Prior to Award
- Subaward / Consortium Statement of Intent Template: ISMMS as the Prime Institution
• Subaward / Consortium Statement of Intent Template: ISMMS as the Subawardee

d. Other Resources
  • Pre-Award Contacts within ISMMS’s Departments
  • Pre-Award Contacts within the GCO

C. Software Systems

1. InfoEd
   InfoEd is the software program the GCO uses to internally route and manage all research and
   sponsored project applications. InfoEd is also used to submit competitive NIH and other federal
   sponsored projects electronically to these agencies. These applications are called “System to
   System Submissions” or “S2S.” InfoEd is the system used to transmit the application directly to
   the sponsor. If the project is a competitive National Institute of Health (NIH) single project
   application (e.g., New R03, Resubmission K08, Competitive Renewal R01) or another competitive
   federal sponsored project such as a new DOD grant or a new NASA grant, PIs must use InfoEd to
   submit the application directly to the agency. PIs do not apply via grants.gov.

   All other applications are called “Non System to System Submissions” or "non-S2S." For non-S2S
   applications, the system is used internally at ISMMS only and not to submit the application to the
   extramural funding agency.

2. Sinai Central
   Sinai Central is the software program in which Conflict of Interest (COI) forms and Suspension
   and Debarment (S&D) forms are completed and signed. The PI or his/her delegate must create
   an Investigator Form (IF) on Sinai Central for every project (e.g., new, yearly renewals,
   supplement requests, no cost extension applications) submitted to the GCO each project year
   except final reports. The purpose of completing an IF is to generate the yearly COI and S&D
   forms associated with the project for personnel to sign. Refer to the IF instructions for complete
   information. S&D forms are required only for Federal and State funded projects, which includes
   projects in which Mount Sinai is the subawardee. Instructions are also available for completing
   the COI and S&D forms.

3. PEAK
   PEAK is the software program Investigators use to complete mandatory Financial Conflict of
   Interest training. The certification must be renewed every four years. Investigators can locate
   the training in PEAK > Online Courses > Research.

4. Extramural Funding Agency Specific System
   Funding agencies may use an on line system for the submission and receipt of sponsored project
   applications. In this case, investigators would submit via InfoEd and the funding agency system.
   Include a copy of the funding agency application within the InfoEd application.

   NIH and other Health and Human Services (HHS) Agencies, the National Science Foundation
   (NSF), and New York State (NYS) agencies require the PI and other users to register though
   Mount Sinai’s GCO. Please refer to the External Electronic Submission Systems that Require User
   Registration through the Grants and Contracts Office (GCO).
D. Contact Information
Refer to the GCO Staff webpage. For a listing by department, refer to GCO Departmental Assignments.
Tel: 212-824-8300
Email: grants@mssm.edu
Sponsored Project Agreements Email: contracts@mssm.edu

E. Resources
GCO has available various submission checklists, prepares monthly funding opportunities packets, and offers classes. Refer to the Application Information, Funding Opportunities, and Training and Education webpages for additional information.

Section IV. Committee on Special Awards (CoSA)
A. Overview
The Committee on Special Awards (CoSA) is part of the Dean's Research Council and is charged with identifying new strategies for improving ISMMS’s ability to compete for the numerous highly prestigious awards and grants for the faculty are invited to apply for each year.

CoSA works closely with faculty with the appropriate scientific expertise to critically evaluate research applications to identify the most suitable candidates to compete successfully for awards. CoSA identifies and reviews special awards as well as awards for which new investigators, newly recruited faculty, and senior faculty are eligible.

Many foundations restrict the number of grant applications that can be submitted from any single institution. CoSA recommends applications to the Dean for his approval through an internal selection process which faculty can apply.

CoSA assists in the preparation of applications and letters of support required from the Dean. In addition, CoSA provides any administrative support required for processing and mailing the application to the sponsor.

B. Policies and Procedures.
Refer to the CoSA’s webpage for more information.

C. Approval/Requirement
Once chosen by CoSA, PIs must submit the project to the GCO prior to submission to the funding agency through the standard process. Working with CoSA does not change the requirement to submit through GCO.

D. Contact Information
Contact information and committee membership can be found on CoSA’s Committee Member webpage.

Section V. Department of Corporate and Foundation Relations
A. Overview
The Department of Corporate and Foundation Relations, residing within the Development Office, is charged with establishing and maintaining institutional relationships with private independent foundations and selected corporations. The Department facilitates philanthropic support from foundation and corporate sources for research and clinical activities, as well as community-based
programs throughout the Mount Sinai Health System. Corporate and Foundation Relations assists faculty with overall strategy for approaching institutional donors. In addition, we provide an array of services including editing and composing letters of inquiry and proposals, assembling necessary supporting materials, interacting with foundations and corporate prospects on behalf of faculty, and providing necessary reports and stewardship.

The Department also takes the lead in identifying programs and faculty at Mount Sinai who best fit the philanthropic funding goals of foundations and corporations and develops strategies for leveraging alignment of donor and faculty goals and interests.

B. Policies and Procedures
Investigators who plan to approach an independent foundation for any purpose, or an organization or corporation for unrestricted research support (no Intellectual Property involved) should contact Corporate and Foundation Relations for assistance.

Application Process information can be found on the Corporation and Foundation Relations website.

C. Approval/Requirement
PIs must submit the project to the GCO prior to submission to the funding agency through the standard process in those instances where funding is determined by a peer reviewed process. Working with Development does not change the requirement to submit through GCO.

D. Contact Information
Contact Corporate and Development Relations at (646) 605-8701 or by e-mail.

Section VI. Financial Administration of Clinical Trials Services (FACTS)
A. Overview
The Financial Administration of Clinical Trials Services (FACTS) office, a division of the Department of Finance, is the center for coordinating the financial aspects of a clinical trial from the pre-award submission process to post award management of industry funded clinical trials. See Part III section VI for information about FACTS post award services.

Preaward services include:
- Negotiating and Executing Industry Funded Clinical Trial Agreements
- Assistance with budget development and negotiation
- Assistance with Medicare Coverage Analysis (MCA)
- Submission of Centers for Medicare and Medicate Services (CMS) letters for device trials
- Ensuring consistency of all clinical trials documents
- Ensuring that payment for registry studies represents fair market value

See this FACTS presentation (intranet) for more information on overall services.

B. Policies and Procedures
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. FACTS prepares a Medicare Coverage Analysis (MCA) when required. A MCA is the document that
determines the appropriate payor (e.g., funding agency, Medicare or third party payor) for each item and service required in a clinical research trial. Please visit the FACTS website and the links below for policy and procedure information.

Biomedical Research Alliance of New York (BRANY) projects
Budgets
Budget Development and Analysis (intranet)
Frequently Asked Questions
Medical Device Trial Challenges (intranet)
Medicare Coverage Analysis (MCA)

C. Approval/Requirement
1. Budget review and negotiation can be done while project is under review at GCO.

D. Contact Information
For further information, please contact FACTS at facts@mssm.edu or at 646-605-7251. A staff listing is posted on the FACTS website.

Section VII. Investigational Drug Service (IDS) - The Department of Pharmacy
A. Overview
The Investigational Drug Service (IDS) is a research pharmacy charged with maintaining the control and accountability of investigational agents (FDA approved and non-approved) in compliance with Good Clinical Practices (GCPs), Good Manufacturing Practices (GMPs) and other regulations and laws as appropriate. The IDS provides dedicated research support including protocol review, storage, preparation, dispensing and education to groups and investigators engaged in research.

The Joint Commission requires that the hospital safely manages investigational medications (MM.06.01.05). To comply with this standard, all drugs administered within the Hospital must be approved by IDS.

B. Policies and Procedures
1. Policies and Procedures on Website
   IDS Review Form: Drug/Biologic Management Plan
   Guidance for IDS Review Form: Drug/Biologic Management Plan
   IDS Services - includes IDS Usage Fees

   Additional Department of Pharmacy polies and procedures are available on the 1. Intranet > Pharmacy and 2. Intranet Medical Services > Pharmacy, including the use of investigational drugs procedure. Refer to the IRB Investigator Manual for additional information on drugs in human subject research (FDA approved and unapproved).

2. Budgets
All budgets must include the costs of drugs and services as established by the IDS. 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 for the study coordinator to use in budgeting appropriate funds for each research protocol. Charges will be assessed on an individual project basis with an opportunity for discussion with the Pharmacy Research Coordinator. Protocols not funded for these products and services will be reviewed by the Department of Pharmacy to determine feasibility of support.

3. 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 directly supplied by a study sponsor or funds must be designated/budgeted by the principal investigator’s department prior to purchasing the non-formulary agent.
  - Formulary Drugs
    The Mount Sinai Formulary is available on the Mount Sinai Intranet, under Medical Services and Pharmacy. Drugs used in a non-FDA approved fashion must be supplied by the study sponsor or funds must be designated/budgeted by the principal investigator’s department prior to purchase for use in the trial.

FDA approved drugs being used for a research procedure or for a research visit even if used according to the FDA approved dose, route and method of administration, but not supplied by the study sponsor, should be covered by study funds or by Icahn School of Medicine.

4. Controlled Substances Used in Research

In order to use controlled substances for research purposes in humans, the researcher must be registered with both The State of New York Depart of Health and the Drug Enforcement Administration. Alternatively, the institution may be registered with both agencies to use controlled substances for research purposes. As a service to the investigators, IDS maintains a New York State Class IV Research License and DEA 223. Registration on behalf of the institution is to support the investigators with this requirement. This license covers the institution, when using schedule II - IV controlled substances within a research protocol. Refer to Mount Sinai’s Controlled Substances Policy (Intranet) for additional information.

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.

C. Approval/Requirement
Authorization from the IDS is accomplished at the time of the research application submission to the Program for the Protection of Human Subjects (PPHS) via IDEATE. If the protocol is not submitted to the PPHS through IDEATE, the researchers must complete the IDS’ Authorization Form and submit it to the Pharmacy for review.

A research protocol proposing the use of controlled substances must include that information on the IDEATE submission and/or IDS Authorization Form. In addition, for projects using controlled substances, IDS will meet with members of ISSM research administration to determine if the project will be covered under the IDS license.

D. Contact Information
The Pharmacy Investigational Drug Coordinator is available to answer questions at (212) 241-2493. In the case of emergency, researchers can contact the IRB, the IDS, or the Office of Research Services (ORS). For general information, please see the Contact Us section of the IDS website.

Section VIII. Mount Sinai Innovation Partners (MSIP)
A. Overview
The mission of Mount Sinai Innovation Partners (MSIP) is to ensure Mount Sinai discoveries and innovations are translated into healthcare products and services that benefit patients and society. MSIP strategies are to:

- Proactively develop and maintain partnerships with members of the Mount Sinai community based on mutual trust and respect
- Proactively develop and maintain effective external commercial relationships and partnerships
- Challenge ourselves to continuously evolve and deploy best in class practices to translate innovations and discoveries from bench-to-bedside
- Invest in the people, processes and systems infrastructure required to effectively and efficiently achieve our mission
- Manage our business as a portfolio of investments as we seek to achieve an equitable return for Mount Sinai

See Part I section X for information about MSIP’s role in agreement negotiation and Part III section IX for information about MSIP’s role in invention reporting and technology disclosure.

B. Policies and Procedures
Frequently Asked Questions

C. Approval/Requirement
During the pre-award process to the GCO, investigators answer the appropriate questions in the eForm of the InfoEd application regarding inventions. In addition, please see the Disclose Your Technology link above for more information.

D. Contact Information
For further information, please contact MSIP at MSIPinfo@mssm.edu or at 646-605-7301. Please click on the Find Your MSIP Representative link.
Section IX. Research Information Technology Department

A. Overview
Mount Sinai’s Research Information Technology department provides services and resources to support the school's research mission. Services include:

- Electronic Research Administration (i.e., InfoEd)
- Data Storage
- Data Classification
- Mount Sinai Data Warehouse
- Specimen Management
- eLearning
- Epic and Research

B. Policies, Procedures and Forms
The policies, procedures and forms below are the ones related to InfoEd, the software system used to submit research and sponsored project applications.

- Login
- Form to Request User Access, Add Personnel, and Other Types of Requests
- Instructions
- Policy: Training Requirement
- Routing List
- Wizard - What Kind of Proposal Should I Create?

For information about IDEATE, the software system used to submit human subject and animal proposals to the PPHS and IACUC offices respectively, please visit those office websites for information.

C. Approval/Requirement
All research and sponsored project applications excluding BRANY projects must be prepared in InfoEd.

D. Contact Information
For technical assistance with InfoEd (i.e., How Do I...”) please use this form or e-mail Research IT at infoed@mssm.edu. For other questions, please contact researchit@mssm.edu.

Section X. Agreement Review and Approval

A. Overview
Research and research related agreements require institutional review and approval. Principal Investigators are not authorized to endorse agreements on behalf of Mount Sinai. Common agreements that require institutional review and endorsement are as follows:

1. Confidentiality/ConfidentialDisclosure/Non-Disclosure Agreements
2. Consulting Agreements
3. Gift Agreements, including foundations
4. Grant Agreements, including foundations
5. Industry Funded Research Agreements
6. Licensing Agreements
7. Material Transfer Agreements
8. Purchasing
9. Data Use Agreements
10. Service Agreements
11. Subawards and Site Agreements

These agreements are included in the Agreement Navigator, a tool that directs faculty and staff to the appropriate office(s) involved in the review and approval process.
Regulatory office review and approval is independent of the Grants and Contracts Office (GCO). These offices neither endorse the research nor commit the institution to provide resources in the conduct the research.

Section I. Animal Research - Institutional Animal Care and Use Committee (IACUC)

A. Overview
The Institutional Animal Care and Use Committee (IACUC) is responsible for reviewing and approving, requiring modification of, or disapproving any research or teaching activity involving the use of vertebrate animals.

IACUC oversees all aspects of the institutional animal care and use program to ensure compliance with these federal regulations: the Animal Welfare Act (AWA), AWA regulations (AWAR), Public Health Service (PHS) policy on humane care and use of laboratory animals, and the National Research Council “Guide for the Care and Use of Animals.”

IACUC activities are conducted according to specific procedures described in an Animal Welfare Assurance documents filed by ISMMS with the NIH Office of Laboratory Animal Welfare (OLAW). The Assurance document is reviewed every four years by OLAW.

B. Policies and Procedures
Visit the IACUC intranet site for more information regarding the IACUC application and additional resources.

C. Approval/Requirement
Principal Investigators must submit an IACUC application or progress report each year of the project. Approvals are granted for a period of 3 years; for the second and third year of such period, only a Progress Report is required at the beginning of each project year. See GCO’s Compliance Requirement (i.e., submission of IACUC application) for additional information on GCO’s process.

D. Contact Information
Contact IACUC at (212) 241-0153 or by e-mail. Complete information can be found on the staff page.

Section II. Biosafety - Institutional Biosafety Committee (IBC)

A. Overview
The Institutional Biosafety Committee oversees all laboratory activities involving recombinant and synthetic nucleic acid molecules, biohazards, and potentially infectious materials to ensure that proper precautions are observed. As such, the IBC provides additional evaluation of IACUC and IRB protocols. Special review responsibilities include review of select agents and toxins, blood borne pathogens, xenotransplantation, stem cell research, Dual Use Research of Concern (DURC), and nanotechnology. As part of the review process, the IBC evaluates research protocols to determine if the appropriate risk groups and biosafety levels have been identified by the Principal Investigator. The IBC also serves as a resource for obtaining information on how to conduct research activities in a safe manner.

The IBC monitors all activities as required by the National Institutes of Health (NIH) “Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.” Additional guidance is provided
by Biosafety in Microbiological and Biomedical Laboratories (BMBL) which outlines biosafety practice and policy in the United States. The IBC ensures that the research that the Icahn School of Medicine at Mount Sinai conducts or sponsors complies with the NIH Guidelines irrespective of the source of funding.

For information on the Dual Use of Research Concern Committee (DURC), please see Part II section VI.

B. Policies and Procedures
The Biosafety Manual is a comprehensive general resource document summarizing content from the BMBL 5th Edition and the NIH Guidelines, acquainting investigators with risk evaluation / estimation for a given organism, the practices and equipment needed by which the organism can be safely manipulated, and considerations for handling a given pathogen in a new procedure.

The IBC has developed forms to assist the Principal Investigator with the submissions and filings required by federal regulatory agencies.

C. Approval/Requirement
Investigators must indicate during the pre-award process to the GCO (i.e., answering the appropriate questions in the InfoEd application) when infectious pathogens, chemical hazards, biohazards, recombinant DNA, and Dual Use Research of Concern (DURC) is involved. With regards to recombinant DNA, investigators must identify the biosafety level for physical containment in the Institutional Biosafety Committee Risk Assessment. The Institutional Biosafety Committee will determine whether the research described falls within NIH guidelines and if further evaluation is required. General biosafety training for researchers is available through the CITI training program.

D. Contact Information
Inquiries, completed Institutional Biosafety Committee Risk Assessment, or completed Dual Use Research of Concern (DURC) Evaluation questionnaires may be submitted to biosafety.ibc@mssm.edu. The Biological Safety Officer (BSO) may be contacted at 212-241-5169 or by e-mail. Complete contact information for the BSO is provided on the Institutional Biosafety Program staff page.

Section III. Conflict of Interest - Conflict of Interest (COI) Office
A. Overview
The Conflict of Interest (COI) Office is responsible for institutional compliance with regulatory requirements relating to conflicts of interest. The COI oversees Mount Sinai's efforts to identify and manage potential conflicts of interest. ISMMS encourages collaborative relationships with industry that could lead to breakthroughs in research and clinical care, and it is essential that these relationships are free of real or perceived conflicts.

Mount Sinai’s Conflict of Interest in Research policy is based on the standards set forth in the federal regulations governing research funded by the Public Health Service (PHS) or the National Science Foundation (NSF) and the recommendations promulgated by the Association of Academic Medical Centers.

B. Policies and Procedures
To safeguard the academic integrity of Icahn School of Medicine and its investigators, the institution has a rigorous conflict 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. Please refer to the Faculty Handbook: Policy on Financial Conflicts of Interest in Research. Please review the appropriate pages of the COI website for other COI policies including consulting, advisory board participation and, vendor interaction. See following section for conflict of interest in research disclosure requirements.

C. Approval/Requirement
Principal Investigators and Project Directors must ensure that all investigators comply fully with conflict of interested in research requirements. Each project year, investigators must complete and sign the COI form on Sinai Central. Instructions are available for completing the COI form as well as for its initiation via the Investigator Form. The Financial Conflicts of Interest in Research policy applies to all projects submitted to the Grants and Contracts Office, whether federally funded, funded by other public and private sources, or supported by the institution.

All Investigators are also required to complete a COI education module every four years on PEAK Online Courses > Research > Financial Conflict of Interest in Research.

D. Contact Information
Contact the COI Office at 212-241-0845 or by e-mail. Complete contact information can be found on COI Contact Us section of the website.

Section IV. Human Embryonic Stem Cell Research (ESCRO) – ESCRO Committee
A. Overview
The goal of the Embryonic Stem Cell Research Oversight (ESCRO) committee is to provide oversight of all issues related to derivation and use of hESC lines and to facilitate education of investigators involved in hESC research.

NIH has developed guidelines to establish policy and procedures under which NIH will fund research in the area of human stem cells, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

B. Policies and Procedures
Visit the Human Embryonic Stem Cell website for further information.

C. Approval/Requirement
Investigators must indicate during the pre-award process to the GCO (i.e., answering the appropriate questions in the eForm of the InfoEd application) whether human embryonic stem cells are used.

D. Contact Information
Contact ESCRO Committee at 212-824-8200 or by e-mail at escro@mssm.edu.

Section V. Human Subject Research - Program for the Protection of Human Subjects (PPHS)
A. Overview
The Program for the Protection of Human Subjects (PPHS) ensures the protection of the rights and welfare of subjects in human research. It supports Mount Sinai’s researchers in assuring the ethical conduct of research and compliance with federal, state and institutional regulations, and provides a professional office staff to assist both investigators and participants. PPHS’s five Institutional Review
Boards (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.

PPHS is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). PPHS maintains federally mandated assurances of compliance, called Federal Wide Assurances (FWA) with the Office for Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS). FWA and IRB Registration information is posted on the PPHS website.

B. Policies and Procedures
The Icahn School of Medicine accepts IRB review from the Biomedical Research Alliance of New York (BRANY) IRB and other commercial IRBs 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.

PPHS’s Investigator Manual is designed to guide the research community through the policies and procedures related to the conduct of human research specific to Mount Sinai. Please visit the Program for the Protection of Human Subjects website for complete information, including the For Researchers page and Guidance and Policies.

C. Approval/Requirement
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.

See GCO’s Compliance Requirement (i.e., submission of IRB application) for additional information on GCO’s process.

D. Contact Information
For further information, please contact the PPHS at irb@mssm.edu or at 212-824-8200. Refer to the About Us page for a staff listing.

Section VI. Institutional Dual Use Research of Concern Committee (IDUCC)
A. Overview
Dual Use Research of Concern (DURC) is research that is reasonably anticipated to provide knowledge, information, products, or technologies that could positively benefit public health and safety, agriculture, or the environment. At the same time, this research could be misapplied to pose a significant risk of threat to individual and/or public health and safety, agriculture, or the environment. The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern defines research that falls under the definition of Dual Use Research of Concern and articulates the practices and procedures required to ensure that Dual Use Research of Concern is identified at the institutional level and risk mitigation measures are implemented as necessary. Implementation of this Policy is intended to instill a culture of responsibility for research conducted at our Institution.

The Institutional Dual Use Research of Concern Committee (IDUCC) is tasked with implementation of the requirements specified by the Policy including providing institutional oversight of the conduct and
communication of research that may fall under the definition of Dual Use Research of Concern at the Icahn School of Medicine at Mount Sinai.

For information on the Institutional Biosafety Committee (IBC), please see Part II section II.

B. Policies and Procedures
The Principal Investigator must evaluate the proposed research to determine if the research involves one of 15 agents of concern (i.e. highly pathogenic avian influenza virus, Bacillus anthracis, botulinum neurotoxin (any amount-no exemptions), Burkholderia mallei, Burkholderia pseudomallei, Ebola virus, foot-and-mouth disease virus, Francisella tularensis, Marburg virus, reconstructed 1918 Influenza virus, Rinderpest virus, toxin-producing strains of Clostridium botulinum, Variola major virus, Variola minor virus, or Yersinia pestis). The PI then needs to evaluate if the proposed research will produce one or more anticipated outcomes of concern (i.e., increase virulence, overcome immunity, develop resistance to drugs, increase transmission, change tropism, increase host susceptibility, and/or regenerate extinct pathogens). If the proposed research satisfies one of these criteria, then the PI must complete the Dual Use Research of Concern Evaluation, and submit the completed form to the Institutional Dual Use Research of Concern Committee. Specific biosafety training for researchers working on DURC projects is available through the CITI training program.

C. Approval/Requirement
The Institutional Dual Use Research of Concern Committee (IDUCC) will review the completed Evaluation and any additional relevant information that the committee may request of the PI. Within 30 calendar days of determining that the proposed research meets the definitions of DURC, the IDUCC will notify the appropriate United States Government agency of whether the proposed research is determined to meet the definition of DURC and submit a draft risk mitigation plan. The Committee and the PI will then cooperate with the relevant agency to complete the risk mitigation plan. The IDUCC will provide continuing oversight of the approved DURC project, and ensure that the PI implements the approved risk mitigation plan.

D. Contact Information
Inquiries and/or completed DURC Evaluation questionnaires may be submitted to biosafety.ibc@mssm.edu. The Biological Safety Officer (BSO) may be contacted at 212-241-5169 or by e-mail. Complete contact information for the BSO is provided on the Institutional Biosafety Program staff page.

Section VII. Radioisotopes in Research - Radiation Safety Office (RSO)
A. Overview
Research involving radioisotopes falls under the purview of the Radiation Safety Committee (RSC) (intranet), which establishes policies and oversees the use of radioisotopes. Policies address both human subject and animal research. The Radiation Safety Office (RSO), under the guide of the Radiation Safety Officer, implements the policies and requirements established by RSC.

The Mount Sinai Medical Center's Radiation Safety Committee (RSC) functions according to Article 175.103(b)(3) of the New York City Health Code.

B. Policies and Procedures
Radiation Safety Office (intranet) maintains a comprehensive website. All application materials for authorization, radiation safety trainings, the radiation safety manual, etc. are available at this website.
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.

The Radiation Safety Office Policy and Procures Manual (intranet) is a compilation of policies, procedures and regulations governing the use of ionizing radiation.

C. Approval/Requirement
In order to become an authorized user to acquire radioactive material (RAM) for research, the user must:

2. Complete the Initial Radiation Safety for Researchers – RAM Users training course, available on the PEAK training system.
3. Complete the Radiation Badge Application (intranet) if required. Depending on the radioisotope used, the user may be required to wear a radiation monitoring badge. Isotopes that require a badge include but are not limited to the following: P-32, Cr-51, Rb-86, Co-57, I-131, and Na-22. Isotopes that do not require a badge include C-14, S-35, I-125, and H-3 (tritium).

IACUC: In order to get approval for research involving animals and radioactivity, the user must submit the protocol to the IACUC for approval. The Radiation Safety Officer will review these protocols for radiation safety compliance.

IRB: In order to get approval for research involving humans and radioactivity, the user must submit the protocol to the IRB for approval. The Radiation Safety Committee will review the protocol and evaluate the risks and determine the consent language that must be signed by the individuals involved in the study.

D. Contact Information
If you have any questions the Radiation Safety Office can be reached at (212) 241-2269 or by e-mail at RSO@mssm.edu.

Section VIII. Research Integrity - Research Integrity Officer (RIO)
A. Overview
Mount Sinai affirms its commitment to the highest ethical standards in the conduct of scientific research, the promotion of original research of high quality, and the importance of academic freedom. It also acknowledges that unethical conduct in research is extremely serious and threatens these principles. Mount Sinai, therefore, is committed to preventing unethical conduct in research from occurring and, should it occur, to dealing with it swiftly, fairly and thoroughly.

Research Integrity Officer (RIO) is responsible for (1) Receipt and Assessment of Allegations of Research Misconduct; (2) Overseeing the review process (Inquiries) and (Investigations) related to ethical
practices in research. (3) Other responsibilities as described in the Faculty Handbook.

Every institution that receives DHHS support must have an assurance on file with the NIH Office of Research Integrity (ORI).

B. Policies and Procedures
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:
- Faculty Handbook – Policies and Procedures on Ethical Practices in Research section

C. Approval/Requirement
n/a

D. Contact Information
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 (Direct Line). After hours reporting: 1-800-853-9212. All concerns are considered confidential and can be reported anonymously.

Section IX. - Research Compliance and Education Program
A. Overview
Research Compliance is part of the Mount Sinai Health System robust compliance program whose role is to provide oversight, education and monitoring of the research activities. Activities include:
- Providing regulatory guidance on clinical trial management and provide example based-education regarding clinical trial conduct and regulatory compliance.
- Conducting internal audits to ensure that the human subject research conducted at ISMMS meets federal as well as institutional regulations and to ensure that trial data is accurate, complete and verifiable.
- Monitoring conflicts of interest in research program, which includes proper disclosure and auditing of the management plans of the FCOIR committee.
- Partnering with the investigative team to provide the necessary tools to assist with their research efforts.

B. Form Templates and Education
Information regarding template documents related to regulatory requirements can be found here (intranet).

There is a monthly education session regarding on how to conduct clinical research, we provide interactive example based scenarios. We can also provide education for your division/research team on request.

C. Contact Information
For further information, please contact: Vivian Mitropoulou MA,CHRC by e-mail or by phone at (646) 605-7120. For anonymous reporting of a research compliance concern, please call 1.800.853.9212.
PART III.
POST-AWARD REQUIREMENTS

(rev. 3/25/14)

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>
</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
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
- Library
- Student Services
- Equipment Depreciation
- Interest
- Departmental Administration
- Sponsored Programs 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.

- Title 45 Part 74. Administration of Grants.
- PHS Grants Policy Statement.
- 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.
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>Expenditures</td>
</tr>
<tr>
<td>--------------</td>
</tr>
</tbody>
</table>

40
<table>
<thead>
<tr>
<th>Salaries &amp; wages</th>
<th>Time &amp; Effort Report</th>
<th>Does the effort report accurately reflect effort (within 5%) spent on extramurally supported activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Overlapping funding sources.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are changes to personnel actions to reflect changes in effort processed in a timely fashion?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time and Effort reports for all employees charged to grants and contracts are distributed by Sponsored Projects Accounting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effort reporting package contains instructions for employee.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effort reports are approved by both employee and supervisor.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is the responsibility of the employee and his/her supervisor to ensure that the timecard effort report is accurate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effort reporting requirements are reviewed periodically at Administrators’ Forum.</td>
</tr>
<tr>
<td>Fringe benefits</td>
<td>Rate agreement negotiated with DHHS annually</td>
<td>No exceptions are made for charging the Federally approved fringe benefit rate to all extramurally sponsored salaries and wages.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prepare comprehensive fringe proposal with support documentation for review by DHHS.</td>
</tr>
<tr>
<td>Equipment</td>
<td>□ Evidence of bidding</td>
<td>□ Are documentation and approvals for equipment purchases complete, accurate and authorized?</td>
</tr>
<tr>
<td></td>
<td>□ Evidence of sole source procurement</td>
<td>□ Purchasing Department enforces bidding requirements</td>
</tr>
<tr>
<td></td>
<td>□ Voucher package</td>
<td>□ Sponsored Projects Accounting reviews requisitions</td>
</tr>
<tr>
<td></td>
<td>□ Institutional prior approval</td>
<td>□ Institutional prior approval system administered according to Federal guidelines.</td>
</tr>
<tr>
<td></td>
<td>□ PHS approval if over $25,000 and involves a change in scope</td>
<td>□ Policies and procedures included in <em>Finance at a Glance on the School Finance website</em></td>
</tr>
<tr>
<td>Travel</td>
<td>□ Travel request</td>
<td>□ Is documentation submitted for travel reimbursement complete, accurate and authorized according to both Federal and Mount Sinai Policy?</td>
</tr>
<tr>
<td></td>
<td>□ Submission of travel voucher with documentation in accordance with travel policy. No.115E</td>
<td>□ All travel requests and travel vouchers for grants and contracts are reviewed and approved by Sponsored Projects Accounting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Policies and procedures included in the School Finance website.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Fly America Act</td>
</tr>
<tr>
<td>Supplies, subscriptions, other miscellaneous expenses</td>
<td>Purchase order</td>
<td>Is adequate documentation submitted to support payment?</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Patient care costs</td>
<td>Investigator will send a memorandum identifying the patient(s) and/or unit number. Laboratorv 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>
</tr>
<tr>
<td>Cost transfers</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>
</tr>
<tr>
<td>Trainee stipend</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>
</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>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></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>
</tr>
<tr>
<td></td>
<td></td>
<td>Sponsor may disallow expenses as not being included in original award.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All expenditures in excess of $1,000 are compared by Sponsored Projects Accounting to the approved budget</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expense compliance risks are discussed periodically with departmental administrators at the Administrators’ Forum</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Checks received from donors</td>
<td>Award Letter</td>
<td>Are the funds gift or grant?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Should a separate account be established?</td>
</tr>
</tbody>
</table>

**Section VI. Financial Administration of Clinical Trials Services (FACTS)**

A. Services

The **Financial Administration of Clinical Trials Services (FACTS)** office is the center for coordinating pre and post financial aspects of clinical trials. 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. This section of the manual includes FACTS post award services. In addition, see SPA section II.B.10 for information regarding Patient Care Billing. See Part I section VI for FACTS pre-award services and Part I section X for its role in agreement negotiation.

FACTS offers a range of services that assist investigators and research personnel with post-award management of industry funded clinical trials including:

- Submission of CMS letters for device trials
- Monitoring of clinical trial fund accounts
- Approval of financial transactions, including fund close-out

B. Policies and Procedures

- Financial Close Out of Industry-Sponsored Projects

Forms

- Sample Close Out Letter

C. Contact Information

Staff Listing

Section VII. Mount Sinai Innovations Partners (MSIP) (rev. 8/21/17)

A. Services

Mount Sinai Innovation Partners (MSIP) oversees and assists in the commercial development of technology researched and developed at Mount Sinai. As a recipient of Public Health Service (PHS) funding (e.g., NIH grants and contracts), ISMMS is governed by PHS regulations for patents and inventions arising out of activities supported by a PHS grant. MSIP must ensure compliance with the intellectual property, transfer, and development policies of sponsoring agencies.

See Part I section VII for information about MSIP’s pre-award services and Part I section X for information about MSIP’s role in agreement negotiation.

B. Policies and Procedures

1. Policies and Procedures on Website

- Intellectual Property: Ownership and Commercial Development
- Technology Disclosure

2. Invention Reporting MSIP

PIs must disclose all inventions to MSIP, including any applicable federal grant numbers. MSIP must promptly and fully report those inventions funded by federal agencies in compliance with the Bayh-Dole act.

The federal awarding office provides MSIP instructions for these reports, which must be filed prior to the publication of any description of the invention. In addition to immediate invention reports, in both the competing and non-competing continuation PHS applications, as well as during award closeout, PIs must include either a list of all inventions made during the preceding budget period or a certify that no inventions were made during the applicable period.
C. Contact Information
Refer to the Find Your Representative or Contact Us webpages.