



Icahn School of Medicine at Mount Sinai

**Policies and Procedures
Governing Research and Sponsored Projects**

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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), the COI Office, Human Embryonic Stem Cell Research (ESCRO) 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 Projects Finance (SPF) 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

Review the [introduction](#) for information regarding the organization of Part I.

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. You can access their services by opening a ticket with the [Research 411 Portal](#).

Options include:

- [Research 411](#)
Contact ORS with any question about navigation of the MSHS research processes, resources and services
 - [Clinical Research Orientation](#)
Offered to both new and existing research coordinators, managers, and non-faculty staff.
 - [Clinical trials.gov Registration & Assistance](#)
 - [Research Subject Recruitment Support](#) - including [ResearchMatch.Org](#) support
 - [Spanish Translations](#)
[ORS offers Spanish translation services for study documents on NIH funded studies.](#)
 - [OnCore CTMS \(Clinical Trials Management System\)](#)
ORS provides the non-cancer research community dedicated support and centralized services through its OnCore Central Team.
 - All interventional, industry-funded clinical trials are centrally built within OnCore.
 - Research teams may opt to have any non-interventional and/or non-Industry funded studies built in OnCore by request
 - ORS provides centralized OnCore services and support for non-cancer research teams
 - [Department specific education & training research infrastructure, processes & procedures](#)
 - [Communication Support](#) - Research Listserv Assistance
- B. Resources**
- [Research Roadmap](#)
Central hub for navigation of the Mount Sinai Health System research enterprise. Below are some of the resources to help investigators navigate the first steps in conducting research.
 - [Fundamentals of Research at ISMMS](#)
Provides reference information about the research infrastructure, policies, training requirements, and systems throughout the Mount Sinai Health System.
 - Research specific guidance is located in the following sections of the Research Roadmap:
 - [Industry Initiated Clinical Research](#)
 - [Investigator Initiated Clinical Research](#)
 - [Basic Science](#)
 - [The Center for Nursing Research and Innovation \(CNRI\)](#)
 - [ISMMS Clinical Research Coordinator Vault \(sharepoint.com\)](#)
SharePoint environment for research teams to access regulatory documents, PPHS Clinical Research Forum presentations, and other information vital to the conduct of clinical research.
 - [Grant Application Resource Center \(GARC\)](#)

Provides Mount Sinai investigators with the standardized language describing a wide variety of Mount Sinai programs and resources that can be used for grant applications.

- [Research Listserv](#)

The research administration email messaging service enables you to receive important Icahn School of Medicine news and information targeted to researchers and their staff.

C. Contact Information

For further information, please open a ticket with the [ORS Research 411 Portal](#).

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

- [Health System Resources | Icahn School of Medicine \(mssm.edu\)](#)
- [Institutes | Icahn School of Medicine \(mssm.edu\)](#)
- [Centers | Icahn School of Medicine \(mssm.edu\)](#)
- [Research | Icahn School of Medicine \(mssm.edu\)](#)
- [Education | Icahn School of Medicine \(mssm.edu\)](#)

C. Contact Information

To provide feedback, submit a [Research 411](#) ticket.

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 sponsored project applications and a subset of research applications are prepared in [InfoEd](#) and routed for approval through the department(s) in which there are key personnel each year of the project. For an understanding of the terms used in the sponsored project and research application 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.

All sponsored 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 GCO's [Submission, Review, and Approval Process Pictorial](#), [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](#).

a. Sponsored Project Applications

All sponsored project applications are submitted to the GCO. A sponsored project is defined as an externally-funded activity in which a formal written agreement, i.e., a grant, contract, or cooperative agreement, is entered into by Mount Sinai and the extramural funding agency generally after a competitive peer review process.

Other types of projects that are submitted to the GCO are industry sponsored projects in which there typically is no competitive peer review process. However, please note effective January 1, 2024 new industry sponsored clinical trials are no longer submitted in InfoEd. Re: industry sponsored clinical trials with no competitive review process that have already been submitted to the GCO, please do continue submitting the non-competitive applications to the GCO through close out. Industry funding where MSIP signs the agreement and all industry funding that is peer reviewed, including but not limited to SBIR/STTR subawards, continues to require GCO submission and review.

All BRANY clinical trials, both new and continuing studies do not require submission to GCO.

Exception to InfoEd Submission:

Do not submit the project to the GCO if this is a Cooperative Research Group project. Cooperative research group projects are studies where the overall funding is provided by the NIH either directly or through a subaward and then the Institution is asked to carry out multiple individual clinical studies, which do not have separate applications or budgets. The overall funding continues to go through GCO, but the *individual clinical studies* do not require GCO submissions.

b. ISMMS Projects

These are research projects in which the Icahn School of Medicine at Mount Sinai (ISMMS) is not receiving external sponsored project funding to carry out the associated activities. 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.

All ISMMS projects that do not involve human subjects or vertebrate animals must be submitted to the GCO.

Exception to InfoEd Submission:

Do not submit the project to the GCO if this is an ISMMS project involving human subject or vertebrate animal research. However, if an ISMMS project requires an endorsement by the GCO (e.g., Data Use Agreement, Study Drug Donation, Confidentiality Disclosure Agreement, etc.), do submit the project to the GCO.

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 updated eDMS project specific conflict of interest disclosures (i.e., answering research trigger questions) for each investigator.

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, Associate Director, and Assistant 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 updated conflict of interest disclosure profiles for each investigator, the deadline schedule applies below.

Application Type	Deadline	Other
Federal Applications	5 Business days prior to extramural funding agency deadline by 11 am	See note below.
All Other Applications	1 Business Day prior to extramural funding agency deadline	See note below.
<p>Note: Please contact your assigned Grants Specialist in advance regarding any additional time the GCO may need in the review and approval process if you are applying for a sponsored project with complex budgetary and/or administrative requirements (e.g., program projects, application with many subawards, international extramural funding agency application with nonstandard budget forms).</p>		
<p>Note: Only a small subset of ISMMS projects must be submitted to the GCO. Click here for more information.</p>		

5. Compliance Application (PPHS/IACUC) Requirement

This section is applicable to studies that involve human subjects and/or animals.

a. Requirement

i. Competitive Sponsored Projects

For NIH competitive sponsored projects, submission of the compliance application (PPHS/IACUC) is not required at the time of GCO submission nor is a compliance waiver at this time. For non-NIH competitive sponsored projects, submission of the compliance application (PPHS/IACUC) to the appropriate compliance office or completing a [compliance](#)

[waiver](#) is required. Please see the following section 5.b for more information about Just in Time policy and use of the compliance waiver form.

ii. ISMMS Supported Projects and All Transfer, Non-Competitive, and No Cost Extension Projects

For all ISMMS projects in which a GCO submission is required and for all transfer, non-competitive, no cost extension projects, the corresponding compliance application to the appropriate compliance office is required. GCO requires the submission of the compliance application for other types of non-peer reviewed research projects such as those supported by industry and federal cooperative trials.

Regarding non-competitive and no cost extension projects, check with the PPHS and/or IACUC whether the compliance submission is every year or every three years. If the project requires PPHS/IRB or IACUC approval for the upcoming year, please submit the application to these respective offices prior to InfoEd submission. Many projects share the same yearly start and end dates as the GCO / InfoEd submission. In other cases, the PPHS yearly start and end dates are different from the GCO / InfoEd yearly submission dates. In the case that they are not in sync, submission of an upcoming year's PPHS application may be premature. Please check when your IRB approval ends. IRB submissions are submitted generally 8 weeks prior to expiration.

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 Finance's [Policies and Procedures for Charging Indirect Costs to Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts \(170\)](#). Also, please refer to this guidance document for more information. [Facilities and Administrative Costs: Determination of On and Off Campus Activity](#). Announcements of revised fringe benefit and F&A cost rates are periodically issued by the Sponsored Projects Finance (SPF).

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? Sponsored Projects](#)
- [Application Submission Process: Which Applications and Forms do I Work on First? ISMMS](#)
- [Budgeting for an ISMMS Faculty Member with a VA Appointment](#)
- [Budgeting - Facilities and Administrative Costs: Determination of On and Off Campus Activity](#)
- [Budgeting: Updated DHHS Rate Agreement and Federal Split Rate Sponsored Projects](#)
- [Communications from the GCO and InfoEd](#)
- [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](#)
- [GCO Submissions Workflow Diagram](#)
- [Gift vs Sponsored Project \(includes checklist\)](#)
- [Glossary of Common Terms](#)
- [InfoEd Proposal Status Definitions - Terms to assist you in navigating the submission and funding processes.](#)
- [No-Cost Extensions](#)
- [Preferred Name Use on Sponsored Project Applications](#)
- [Students and Post Graduates on Federal Research and Training Guidance – A Compendium of Budgetary, Administrative, Application Submission, and Post Award Information](#)
- [Subawards: ISMMS as the Prime Institution](#)
- [Subawards: ISMMS as the Subawardee](#)
- [Submission, Review and Approval Process Pictorial](#)
- [Supervision of a Related Party on a Sponsored Program](#)
- [VA Appointments: Budgeting for Faculty Members with a VA Appointment](#)
- [VA Appointments: GCO Procedure for Oversight of VA Memorandum of Understanding \(MOU\)](#)

National Institutes of Health Related Policies

- [NIH Biosketch and MyNCBI FAQs](#)
- [NIH Confidentiality Reminder for Reviewers](#)
- [NIH and Foreign Influences on Research Integrity: A Guide to Navigating Through NIH Policy and Procedure](#)
- [NIH Genomic Data Sharing \(GDS\) Policy: Grant Application Instructions](#)
- [NIH Individual Development Plan \(IDP\) Information Requirement for all Annual Progress Reports](#)
- [NIH/AHRQ Multiple PI Guidance and Template](#)
- [NIH Multi-Project and Single-Project with Complicated Structure RPPR Applications](#)
- [NIH and Foreign Influences on Research Integrity: A Guide to Navigating Through NIH Policy and Procedure](#)

- [NIH Prior Approval Requirements](#)
- [NIH Prior Approval: Guidance for Grants that Do Not Allow for Automatic Carryover of Funds](#)
- [NIH Small Business Innovation Research \(SBIR\) / Small Business Technology Transfer \(STTR\): Guidance for Employee Participation](#)
- [NIH Training Grants: Certification Letter for Harassment and Discrimination Protections](#)
- [NIH Training Grants: Human Subjects and Vertebrate Animals Section Boilerplate Language for Competitive Applications](#)

NIH Other Support Guidance

- [Informing the NIH When Applying to Multiple Funding Agencies](#)
- [Biosketch: Who Must Submit](#)
- [Biosketch and Other Support Changes: GCO's Response and Instructions](#)
- [Biosketch and Other Support FAQs](#)
- [Other Support: Adobe Signature Certification Instructions](#)
- [Other Support: List of Most Common Errors](#)
- [Other Support Instructions](#)
- [Other Support: Overlap Guidance \(Dean's Office/GCO\)](#)
- [Other Support: Overlap Guidance Clarification](#)

NIH Data Management and Sharing Plan

Consult the Data Management and Sharing Plan section of GCO's [Application Information](#) for additional Mount Sinai resources including data storage options and preparation tools.

- [1: Preparing and Budgeting to Meet NIH's Jan. 25 2023 Data Management and Sharing Plan Requirement](#)
- [2: Strengthen your Proposal by Discussing Data Management and Sharing in These Areas](#)
- [3: Budget for Data Management and Sharing](#)
- [4: Advice for Element 1 Data Type, Element 2: Related Tools, Software and/or Code: and Element 3: Standards in Your NIH DMSP](#)
- [5: Advice for Element 4: Data Preservation, Access, and Associated Timelines](#)
- [6: Advice for Element 5: Access, Distribution, or Reuse Considerations and Element 6: Oversight of Data Management and Sharing](#)
- [7: Prior Approval Requirement for Changes to DMSP](#)

b. Checklists

- [Application Submission Checklist](#)
- [Gift vs Sponsored Project \(includes checklist\)](#)
- [NIH ASSIST](#)
- [NIH Competitive Subaward Checklist: ISMMS as the Prime Institution](#)
- [NIH Competitive Subaward Checklist: ISMMS as the Subawardee](#)
- NIH Single Project, Competitive Grant Application Checklist
[PDF](#) | [Excel](#)

- NIH RPPR SNAP & Single Project Non-SNAP Checklist
[PDF](#) | [Excel](#)
not for use in K and F grants
- [NIH Other Support Checklist](#)
- [Subawardee, Consultant, and Vendor Determination Checklist](#)

c. Forms

See the following section for information on “Software Systems” re: 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 \(Recommended\)](#)
- [Budget Template \(Use with Caution\)](#)
- [Budget Calculator: Prorating Federal Indirect Costs](#)
- [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](#)
- [Grants Management Tool](#)
- [NIH Foreign Component Prior Approval Request 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](#)
- NIH Salary Cap: Effort and Salary Source Transaction Forms
 - o [Training Video](#) (approx 12.5 minutes)
 - o [P-T Employees Above the NIH Salary Cap \(Required beg 4/1/22\)](#)
 - o [F-T Employees Above the NIH Salary Cap \(Required beg 4/1/22\)](#)
 - o [P-T Employees Below the NIH Salary Cap \(Optional\)](#)
- [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](#)
- NIH Other Support Related Forms
 - [InfoEd Eform for New and Competitive Sponsored Projects: Entering Major Goals for Other Support](#)
 - [NIH Other Support Checklist](#)
 - [NIH Other Support RPPR Changes Form](#)

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. electronic Disclosure Management System (eDMS)

eDMS is a Mount Sinai electronic system in which investigators complete Conflict of Interest Disclosures. The PI or his/her delegate must create a Triggering Event in eDMS 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 updating the disclosure profile is to generate project specific COI questions from the Triggering Event for the investigators to answer. Refer to the [eDMS instructions](#) for complete information.

3. CITI

CITI is the software program investigators use to complete mandatory Financial Conflict of Interest training. The certification must be renewed every four years.

Logon to [CITI](#) > Log in through my Institution > View Courses > Add a Course > Choose FCOI > Submit > Start Now

Additional CITI instructions from the COI Office are [here](#).

As of 5/18/20, this training course has transitioned from PEAK to CITI Program. In the CITI Program site, investigators need to add their Mount Sinai email address and life number to their institutional profiles so that the training certification date appears in eDMS. If the investigator's COI training module in PEAK has not expired, completing the COI training in CITI is not required. For any questions or concerns, please contact the Office of Industry Engagement and Conflicts of Interest at Conflicts.of.Interest@mssm.edu or (212) 241-0845.

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 through 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 Dean's [Committee on Special Awards \(CoSA\)](#) is responsible for the dissemination, solicitation and selection of proposals for limited submission funding opportunities and awards for which new investigators, newly recruited faculty, postdoctoral fellows and senior faculty are eligible.

CoSA is composed of senior faculty who have the appropriate scientific expertise for critically evaluating research applications to determine the candidates who most likely will compete successfully for awards. CoSA assists faculty in the preparation of applications and letters of support required from the Dean. In addition, CoSA helps facilitate processing and mailing the application to the award 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 (DCCF)

A. Overview

Dedicated to helping researchers and clinicians obtain philanthropic support from independent foundations, corporate foundations, and health-related organizations, Corporate and Foundation Relations is strategically situated within the Mount Sinai Health System's Department of Development.

How the Department of Corporate and Foundation Relations Work

Several effective approaches are employed in fundraising:

- The DCCF matches foundation interests with Mount Sinai Health System lab, clinic, medical school, and community-based programs. Through this work, we provide

strategic assistance to our researchers from concept to proposals, including writing and editorial services, as well as proposals and report-writing cycles management.

- The DCCF fosters relationships with donors, faculty, and the wider Mount Sinai Health System community. This includes informative outreach to funders, with news from throughout the Health System and Icahn School of Medicine, as well as site visits for faculty and grant makers to engage in substantive conversations about mutual interests.
- The DCCF fosters relationships with donors, faculty, and the wider Mount Sinai Health System community. This includes informative outreach to funders, with news from throughout the Health System and Icahn School of Medicine, as well as site visits for faculty and grant makers to engage in substantive conversations about mutual interests.
- Finally, DCCF continually monitors and reports on national trends in corporate and foundation giving, and provide efficient communication between faculty and the Mount Sinai Health System.

B. Policies and Procedures

Principal 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

Email Devcorpfound@mountsinai.org to contact a member of the Corporation and Foundation Relations team.

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 V](#) 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 Medicaid 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.
2. Investigators complete the “Ancillary Review Form” on RUTH system.

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 delegated to maintain 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 drug interventions administered within the Hospital must be reviewed and approved by PPHS/IDS. The review occurs concurrently with PPHS review and is initiated at the time of the protocol submission.

Review and 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 RUTH. If the protocol is not submitted to the PPHS through RUTH, then researchers must complete the IDS' Authorization Form and submit it the Pharmacy for review.

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](#)

Additional Department of Pharmacy policies 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 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:

- The research protocol is IRB-approved
- FDA and Institutional regulations are met for shipment and receipt of drugs,

a. Formulary Drugs

Hospital supply of FDA approved, commercially available, formulary drugs are not to be used to support research. As such, the agent 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.

b. Non-Formulary Drugs

Non-formulary drugs must 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.

4. Controlled Substances Used in Research

a. Schedule II – IV Agents

Each institution's Department of Pharmacy maintains a Drug Enforcement Administration (DEA) registration and NYS Class IV Research license from the DOH to support research involving schedule II-V agents.

These research projects must be approved by both the IDS and the IRB.

A subcommittee comprised of members of ISMMS research administration will review projects using controlled substances to determine if the project will be covered Department of Pharmacy's DEA registration and license.

If approved, the IDS will purchase, control and dispense all controlled substances to be used in human trials at the institution.

b. Schedule I Agents

Each investigator must obtain a DEA registration and NYS DOH license in order to conduct trials using Schedule I agents.

Each individual investigator and trial must be approved by the regulatory agencies .

The investigator must be in control of agent and thus the IDS cannot directly support the trial in terms of drug ordering, storage, dispensing and disposition of the product.

The IDS will be available to consult and collaborate with the investigator on a protocol by protocol basis to develop a secure plan for the control and distribution of these agents.

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 RUTH.

D. Contact Information

A Clinical Pharmacy Manager of the Investigational Drug Service is available to answer questions at #IDSAnnenberg@mountsinai.org. Alternatively, researchers can contact the PPHs or the Office of Research Services (ORS). For general information, please see the [Contact Info](#) 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 of the Manual](#) 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. Policy, Procedures, and Forms

[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 Your Representative](#) or email us at MSIPinfo@mssm.edu.

Section IX. Research Information Technology Department (RAIT)

A. Overview

Mount Sinai's [Research Technologies department](#) provides services and resources to support the school's research mission. Services include:

- [Electronic Research Administration \(i.e., InfoEd\)](#)
- [Data Storage](#)
- [Data Classification](#)
- [Research Administration 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](#)

For information about RUTH, the software system used to submit human subject proposals to the [PPHS](#) office and information about eIACUC, the software system used to submit animal proposals to the [IACUC](#) office, please visit those office websites for information.

C. Approval/Requirement

All research and sponsored project applications excluding cooperative clinical trials and BRANY projects must be prepared in InfoEd.

D. Contact Information

For technical assistance with InfoEd (i.e., How Do I...”) please use this [ServiceNow Form](#). You must be connected to the VPN to access if off campus. 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:

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.

- Academic Research Organization (ARO)
- Confidentiality/Confidential Disclosure/Non-Disclosure Agreements
- Consulting Agreements, including Foundations
- Data Use Agreements
- Gift Agreements, including Foundations
- Grant Agreements, including foundations
- Industry Funded Research Agreements
- Material Transfer Agreements
- Outgoing Licensing Agreements - Including Licensing of Tangible Materials
- Publishing Agreements
- Purchasing Agreements
- Data Use Agreements
- Service Agreements
- 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.

PART II. Regulatory Requirements and Services

Review the [introduction](#) for information regarding the organization of Part II.

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 main [IACUC](#) and [IACUC Applications](#) webpages for complete information.

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 Office of Animal Care, Use and Welfare (OACUW) at (212) 241-0153 or by [e-mail](#). Complete information can be found on the [staff](#) page.

Sections II. - V. Biosafety

Section II. Institutional Biosafety Committee (IBC)

The Icahn School of Medicine at Mount Sinai, as an institution receiving research funds from the National Institutes of Health (NIH), is subject to the NIH "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules." As mandated by the guidelines, the Institutional Official has appointed an [Institutional Biosafety Committee \(IBC\)](#) to ensure that the research that Mount Sinai conducts or sponsors complies with the NIH Guidelines, regardless of the source of funding. The IBC provides additional evaluation of protocols involving human subjects or animals. The IBC also serves as a resource for obtaining information on how to conduct research activities in a safe manner.

The IBC also monitors these critical areas of biomedical research:

- Dual Use Research of Concern (DURC)
- [Select Agents and Toxins](#)

Please visit the links above and refer to the next three sections in the Manual, Part II Section III for the IBP, Part II Section IV for IDUCC, and Part II Section V for Select Agents and Toxins.

B. Policy, Procedures, and Forms

The IBC monitors all activities as required by the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules." The IBC ensures that the research that the institution conducts or sponsors complies with the NIH Guidelines irrespective of the source of funding. Please visit the [IBC Policies](#) webpage for more information. The PI or designated proxy should describe research involving use of biohazards and risk mitigation measures in an [eSafety research registration](#).

Additional guidance is provided by Biosafety in Microbiological and Biomedical Laboratories (BMBL), Sixth Edition, which outlines biosafety practice and policy in the United States.

C. Approval/Requirement

The PI or designated proxy should submit an [eSafety research registration](#) three full weeks before the scheduled [IBC meeting date](#).

D. Contact Information

Contact the Institutional Biosafety Committee (IBC) at 212-241-0704 or biosafety.ibc@mssm.edu. Complete contact information can be found on the IBC [staff](#) page.

Section III. Institutional Biosafety Program (IBP)

A. Overview

The Institutional Biological Safety Program identifies biological safety practices, procedures, facility construction, and operational standards for the safe handling and use of biohazardous materials for research, clinical, and teaching activities at the Icahn School of Medicine at Mount Sinai (ISMMS). The Institutional Biological Safety Program applies to all academic faculty, staff, visiting scientists, students, public visitors, volunteers, and contract personnel located on the campus or any locations where ISMMS has management control of specific biohazardous materials.

B. Policy, Procedures, and Forms

IBP guidelines, forms, and policies can be found on the [IBP webpage](#).

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 eSafety research registration. General biosafety training for researchers is available through the [CITI training](#) program.

D. Contact Information

The Biological Safety Officer (BSO) may be contacted by [e-mail](#).

Section IV. 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 following 15 agents of concern.

- 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
- 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. The CITI training program provides specific biosafety training for researchers working on DURC projects.

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

Completed DURC Evaluation questionnaires must be submitted as part of your eSafety research registration. Inquiries about Dual Use Research of Concern (DURC) or Pathogens with Pademic Potential Care and Use (P3CO) may be submitted to biosafety.abc@mssm.edu or you may contact the [Biosafety Program by e-mail.](#) Complete contact information for the BSO is provided on the Institutional Biosafety Program staff page.

Section V. Select Agents and Toxins

A. Overview

The Federal Select Agent Program (FSAP) is jointly comprised of the Centers for Disease Control and Prevention/Division of Regulatory Science and Compliance and the Animal and Plant Health Inspection Service/Division of Agricultural Select Agents and Toxins.. The FSAP regulates the possession, use, and transfer of [biological select agents and toxins](#) (BSAT) that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.

Research involving BSAT falls under the oversight by the Institutional Biosafety Committee (IBC). For more information about the IBC, please see [Part II section I.](#)

B. Policy, Procedures, and Forms

For any research involving BSAT, the PI should submit an [eSafety research registration](#) and DURC Evaluation questionnaire.

The Select Agent Regulations require the Principal Investigator use “due diligence” when transferring an amount of a HHS select toxin otherwise [excluded from the Select Agent Regulations](#). This provision requires the Principal Investigator to take reasonable actions to ensure that the recipient:

1. Is eligible to receive the select toxin (Principal Investigator, treating physician or veterinarian, or commercial manufacturer or distributor).
2. Has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such select toxins.

C. Approval/Requirement

Every individual or entity that possesses, uses, or transfers these agents or toxins must be registered with the FSAP. Please see additional information on the [Select Agents and Toxins](#) webpage.

D. Contact Information

For information regarding select agents or toxins, contact the [Responsible Official](#).

Section VI. Conflict of Interest in Research - Office of Industry Engagement and Conflicts of Interest (“COI Office”)

A. Overview

The [Office of Industry Engagement and Conflicts of Interest Office \(“COI Office”\)](#) is responsible for institutional compliance with regulatory requirements relating to conflicts of interest. The COI Office 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, 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 interest in research requirements. Each project year investigators must answer conflict of interest trigger questions specific to the sponsored project in [eDMS](#) software system. [Instructions](#) are available for completing the trigger questions as well as for creating the triggering event. The Financial Conflicts of Interest in Research policy applies to all projects submitted to the Grants and Contracts Office and to the PPHS, 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 [CITI](#) > Log in through my Institution > View Courses > Add a Course > Choose FCOI > Submit > Start Now

Additional CITI instructions from the COI Office are [here](#).

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 VII. Export Controls

A. Overview

ISMMS is committed to providing researchers, faculty, trainees, staff, and students with the tools and support needed to adhere to all laws and regulations applicable to research standards. The [Export Control Website](#) was created to help you understand how you or your research may be affected by

applicable Export Control Laws. The [ISMMS Export Control Oversight Policy](#) (the “Export Control Policy”) provides descriptive information and guidance regarding how to comply with these laws. Export Control Laws cover a broad range of activities, including the sharing of information (written or spoken), technology or research, as well as the shipment of biological specimens or equipment. Everyone at ISMMS is responsible for ensuring their research, education, and other business activities are conducted in compliance with applicable Export Control Laws.

B. Policies and Procedures

[ISMMS’s Export Control Oversight Policy](#) (the “Export Control Policy”) is noted above. Other policy and procedure information as well as guidance and training can be found on [Mount Sinai’s Export Control Website](#).

C. Approval/Requirement

If an Icahn School of Medicine at Mount Sinai Party is not sure if a proposed activity is restricted, it is their responsibility to contact the Export Control Officer for assistance. ISMMS Parties are encouraged to contact the Export Control Officer as soon as possible when contemplating research that would involve interactions with or creation of an export-controlled item, a publication restriction in the terms, material derived from a sanctioned country or an entity or individual located in a sanctioned country.

If an ISMMS Party becomes aware of a potential violation of Export Control Laws, the ISMMS Party must immediately contact the Export Control Officer and immediately cease all related activities until further guidance is provided by the Export Control Officer.

Prior approval is required for all business travel. See ISMMS’s [Travel Policy ACS-A.2021a](#). Additionally GCO prior approval is required on all foreign travel paid for by federal awards. See GCO’s [Foreign Travel Request Reminder Memorandum](#).

D. Contact Information

Please contact the Export Control Officer, Reginald W. Miller, DVM, DAACLAM, by email at reginald.miller@mssm.edu / ExportControl@mssm.edu or by phone at 212-241-3006.

Sections VIII-IX. Human Subjects Research

Section VIII. 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 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 identifiable biospecimens 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

1. PPHS's [Investigator Manual \(available in the RUTH Library > General Tab\)](#) 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](#).
2. The Icahn School of Medicine may cede IRB review to other 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. See the [Request to Rely \(R2R\) page on the PPHS](#) website for more information.
3. The ISMMS IRB may be willing to serve as the single IRB (sIRB) for certain federally-funded studies, at the discretion of the PPHS Executive Director, after consideration of the protocol complexity, the role of ISMMS in the research, and the PPHS resources required to facilitate this review. See the [Request for ISMMS to Serve \(R2S\) as the Reviewing IRB page](#) of the PPHS website.

Requests for the ISMMS IRB to serve as the sIRB for all domestic sites under the federal sIRB mandate must be made well in advance of your grant submission.

Prior to your grant submission deadline, you must submit a Request to Serve (R2S) inquiry to the IRB inbox (irb@mssm.edu) by providing the [HRP-230 form](#).

C. Approval/Requirement

IRB approval must be secured prior to the start of human 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. 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 [Meet the Team](#) page for a staff listing.

Section IX. 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.committee@mssm.edu.

Section X. 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 175.102(c)(1)(i)(B) of the New York City Health Code.

B. Policies and Procedures

[Radiation Safety Office](#) (intranet) maintains a comprehensive website. All application materials for authorization, 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 Procedure 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:

1. Complete the [Authorization Application](#) (intranet).
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 XI. 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.

The [Research Integrity Officers \(RIOs\)](#) are responsible for (1) Receipt and Assessment of Allegations of Research Misconduct (i.e., [Fabrication](#), [Falsification](#) or [Plagiarism](#)); (2) Overseeing the review process (i.e., Assessments, Inquiries and Investigations) related to ethical practices in research; and (3) Other responsibilities as described in the [Faculty Handbook](#).

Every institution that receives DHHS support must have an assurance on file with the [DHHS Office of Research Integrity \(ORI\)](#). In addition, any allegation of Research Misconduct involving PHS-funded research must be reviewed in accordance with [42 CFR Part 93](#) and [Mount Sinai's Policies and Procedures on Ethical Practices in Research](#).

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
- [Postdoc Handbook](#) – Section 10: Responsible Conduct in Research (RCR)
- [Graduate School Handbook](#) – Chapter 1: Academic Policies

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 Office website](#) or by contacting the Senior RIO for the Mount Sinai Health System, Dr. Reginald Miller, at reginald.miller@mssm.edu or (212) 241-3006 (Direct Line). After-hours reporting: 1-800-853-9212. All concerns are considered confidential and can be reported anonymously.

Section XII. - 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

Review the [introduction](#) for information regarding the organization of Part III.

Section I. Department of Finance

A. Overview

The ISMMS [Department of Finance](#) oversees and provides core support and guidance to school personnel for financial operations and business practices. This includes assistance with budgets, payroll, research grant fiscal stewardship, asset management, and travel reimbursement.

The Department is comprised of the following divisions:

- Accounts Payable (A/P)
- Cash Operations (Main Cashier)
- Faculty Practice Accounting
- Financial Administration of Clinical Trials Services (FACTS)
- General Accounting
- Payroll Services
- Purchasing
- Sponsored Projects Finance (SPF)

B. Policies and Procedures

Please visit each [Division of Finance webpage](#) for information as well as the relevant sections of this manual.

C. On Line Transaction System

[Sinai Central](#) is the on line transaction system that investigators and staff use to process Purchase Requisitions, Travel Requests, Check Requests, Vouchers, and Petty Cash and to access ledger reports.

Sinai Cloud includes the PaaS which is used to process personnel actions. Within Sinai Central is "[Sinai Knowledge: The User Guide to Sinai Central.](#)" The "Finance" within Sinai Knowledge include the technical instructions for using the system, processing transactions, and viewing reports.

D. Contact Information

Please refer to the "resources" section of [Research Grant Compliance Guide](#) for contact information as well as the [Finance Staff Listing](#).

Section II. Sponsored Projects Finance (SPF)

A. Overview

SPF's mission is to provide consistent and high-quality financial stewardship of sponsored projects, interpret policy for our researchers, and ensure compliance with institutional and sponsoring agencies' policies. SPF serves its customers through a department-wide commitment to quality and excellence, striving to attain high standards of performance and proficiency.

SPF is responsible for the post-award administration of grants and contracts received by the Icahn School of Medicine at Mount Sinai (ISMMS). It includes account setup, billing, receivables analysis, financial reporting, and account closeout activities. The department is also responsible for compliance

activities relating to grants as well and serves as the primary liaison for all audits, including the annual audit under the Uniform Guidance.

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.

B. Services

SPF is responsible for the post-award administration of sponsored projects which include the following activities:

- Account Set Up
- Account Monitoring
- Financial reporting to funding agencies and investigators Billing
- Receivables analysis
- Cash management
- Account Close Out
- Fringe benefit rate and Facilities and Administrative (F&A) cost rates calculation and negotiation
- Compliance activity
- Annual Uniform Guidance (UG) audit.

C. Policies and Procedures

1. 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 Finance 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 Finance 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.

2. 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 Finance 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.

3. 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 available on the School Finance Website under Sponsored Projects Finance. Generally, these guidelines link PHS grant management requirements to Icahn School of Medicine's transaction approval and processing requirements.

4. 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) Uniform Guidance, 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 Uniform Guidance, 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.

5. Rebudgeting

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 funding agency'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 funding agency's funds and ensure that all charges to the awards are allowable, allocable, and reasonable.

Rebudgeting Federal funds may require prior approval. Please review [GCO's NIH Prior Approval Requirements and Rebudgeting Policy](#) for more information regarding NIH awards.

6. 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 and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. In such instances, the principal investigator must notify the GCO. Please refer to GCO's [No-Cost Extension Application and Procedures Memo](#) for complete information.

7. Reporting

Most grants and contracts (PHS awards in particular) require both financial and programmatic performance reporting. In such cases the Sponsored Projects Finance Department prepares the financial report according to the funding agency'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 Federal financial report must be submitted within 120 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.

8. Closeout

Generally, it is both the policy of the funding agency and Icahn School of Medicine 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.

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

10. Fringe Benefit Rate and Facilities and Administrative (F&A) Rate Negotiation

The Department of Health and Human Services (DHHS) Division of Cost Allocation reviews and approves ISMMS' F&A cost and fringe benefit rates as per the provisions of the [Uniform Guidance](#) (UG). More information regarding rates can be found in SPF's [Policy 157](#).

All expenses included in either administrative or facilities F&A cost pools are screened according to UG requirements to ensure that unallowable expenses are eliminated from the F&A rate calculation. The cost pools subject to screening include:

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

11. Responsibility for Financial Compliance

Refer to the [Research Grant Pocket Compliance Guide](#) for information on roles and responsibilities. In addition, see below.

a. Principal Investigator (PI)

The PI is responsible for review and approval of all direct cost charges according to the award budget and for ensuring that they are allowable, allocable and reasonable according to the policies and procedures of the extramural funding agency and ISMMS.

The PI or the PI's designee must review and approve all sponsored project direct cost transactions 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 sponsored 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. See policy entitled "[Grant and Contract Cost Transfers \(176\)](#)" for complete information and a sample listing of correct and incorrect justifications.

- b. The Sponsored Projects Finance 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.

Table I: Table of Responsibility for Expenditure or Activity Requiring Approval

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 I: Expenditure or Activity Requiring Approval	
Expenditure or Activity	Approval Required from . . .
Supplies, salary adjustments, equipment	PI or designee authorized by the PI
Time and effort reporting	Faculty member/employee <i>and</i> supervisor (or designee) with firsthand knowledge of faculty member/employee’s activities
Cost transfers	PI or designee authorized by the PI
Budget transfers >\$25,000 (prior institutional approval required)	Extramural funding agency, PI, Chair, GCO, and SPF
Travel (domestic)	PI
Travel (foreign)	PI, Chair, GCO, and Dean’s Office
Patient care billing	PI
Financial reporting to extramural funding agencies	SPF, PI
Cash management	SPF
Fringe benefit rate calculation and negotiation	SPF

12. Internal Controls/Financial Compliance Issues on Common Revenue and Expenditures

Table II: Internal Controls/Financial Compliance Issues on Common Revenue and Expenditures

Table II below is designed to minimize the chance of disallowing common revenue and expenditures in an audit by outlining the compliance issue and the internal control in place. The PI must 1) submit complete, accurate additional supporting documentation when applicable and 2) the expenditure must be approved by the appropriate party or parties.

SPF policies are generally included in the “Compliance Program” column below and may be supplemented by additional Grants and Contracts Office (GCO) and Finance policies and procedures. Please see the next section II.C.13 entitled “Policies and Procedures on Website” for additional guidance including the [Transaction Approval For Expenditures \(179\)](#) and [Unallowable Expenses \(173\)](#) policies.

SPF follows federal grant management principles for all sponsored projects unless specified by the extramural funding agency.

Table II: Internal Controls on Common Revenue and Expenditures			
	Documentation	Internal Control/Compliance Issue	Compliance Program
	Time & Effort Report	<ul style="list-style-type: none"> - Does the effort report accurately reflect effort (within 5%) spent on extramurally supported activities? - Overlapping funding sources. - Are changes to personnel actions to reflect changes in effort processed in a timely fashion? 	<ul style="list-style-type: none"> - SPF distribution of Time and Effort Reports for all employees charged to sponsored projects. - Effort reporting package contains instructions for employee. - Effort reports are approved by both employee and supervisor. - Responsibility of employee and his/her supervisor to ensure that the time and effort report is accurate. - Changes to the effort should be made on the report and returned to SPF as a basis for retroactive changes to the salaries charged on the sponsored project. - Periodic review of effort reporting requirements at Administrators' Forum. - Applicable Policies/Procedures <ul style="list-style-type: none"> o Administrative and Clerical Salaries to Federal Grants and Contracts (171) o Time and Effort Reporting Policies and Procedures (174) o Faculty Effort on Sponsored Projects (185)
	<ul style="list-style-type: none"> - A full explanation of the reason for the transfer - Certification of the correctness of the new charge by the principal investigator 	<ul style="list-style-type: none"> - Frequent errors in recording costs may indicate weaknesses in the PI review and approval process. - Transfers from one budget period to the next may be an indication of cost overruns. 	<ul style="list-style-type: none"> -Cost transfers are not processed by Sponsored Projects Finance unless accompanied by the required documentation. -Internal review by SPF of PI's review and approval procedures when an excessive number of cost transfers are required to close out an award. - Applicable Policies/Procedures <ul style="list-style-type: none"> o Grant and Contract Cost Transfer 176

	<ul style="list-style-type: none"> - PI sends a memo to the laboratory or special services area identifying the patient(s) and/or unit number. - Laboratory or special services area then sends bills for services against that patient or unit number. 	<ul style="list-style-type: none"> - 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. - PI responsible for directing the billing to the correct payer. 	<ul style="list-style-type: none"> - Every patient on a research protocol signs a research consent form which is included in the patient file. - Department administrator and PI are responsible for directing the bill for services to the correct payer.
	Rate agreement negotiated with DHHS annually	No exceptions are made for charging the Federally approved fringe benefit rate to all extramurally sponsored salaries and wages.	<ul style="list-style-type: none"> - Prepare comprehensive fringe proposal with support documentation for review by DHHS. - Applicable Policies/Procedures “Fringe and F&A Negotiation” section II.B.10.
	<ul style="list-style-type: none"> - Evidence of bidding - Evidence of sole source procurement - Voucher package - Institutional prior approval - PHS approval if over \$25,000 and involves a change in scope 	-Are documentation and approvals for equipment purchases complete, accurate and authorized?	<ul style="list-style-type: none"> - Purchasing Dept enforces bidding requirements. - SPF reviews requisitions. - Applicable Policies/Procedures <ul style="list-style-type: none"> o Asset Management Policies and Procedures (100A) o Interinstitutional Transfer of Assets Purchased Through Grants (101A) o Government Furnished Property (186) o Purchasing Policy User’s Guide (intranet) o Capitalization Guidelines – Section 9 of Financial Policies and Procedures User Guide o See GCO’s NIH Prior Approval Requirements

	<ul style="list-style-type: none"> - Travel request - Travel voucher 	<ul style="list-style-type: none"> -Is documentation submitted for travel reimbursement complete, accurate and authorized according to both Federal and Mount Sinai Policy? 	<ul style="list-style-type: none"> - SPF reviews and approves travel requests and vouchers - Applicable Policies/Procedures <ul style="list-style-type: none"> o Travel Policy ACS-A.2021a o Fly America Act
	Purchase order	<ul style="list-style-type: none"> -Is adequate documentation submitted to support payment? 	<ul style="list-style-type: none"> - All transactions above the threshold as described in Financial Memorandum No. 179 require prior SPF review and approval. - Accounts Payable ensures voucher package is complete before bill is paid.
	<ul style="list-style-type: none"> -Statement of Appointment - No debt delinquencies in Federally sponsored projects - Pay-back agreement - Termination notice - Green card 	<ul style="list-style-type: none"> -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. 	<ul style="list-style-type: none"> - SPF ensures that all information verifying compliance with trainee requirements is submitted to the funding agency. - SPF confirms that Statement of Appointment has been filed on xTRAIN before processing HR transaction. - Applicable Policies/Procedures <ul style="list-style-type: none"> o GCO’s Budgeting Students and Post Graduates on Federal Research, Training and Fellowship Grants
	F&A Cost Rate Agreement or rate stipulated by funding agency	Use of wrong rate in sponsored project application	<ul style="list-style-type: none"> - GCO and SPF checks applications for appropriate F&A cost rate. - SPF responsible for preparation of F&A cost proposal. - SPF screens all indirect F&A pools to ensure unallowable expenses are eliminated. - Applicable Policies/Procedures <ul style="list-style-type: none"> o Charging Indirect Costs to Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts (157)
	Federal Cash Transactions Report	Draw downs in excess of immediate cash requirements	Quarterly cash reconciliation for all Payment Management System (PMS) and other Federal accounts

<p>Cost reimbursement: Federal contracts,</p>		<p>-Reimbursement request may not agree with actual expenditures. - Funding agency may disallow expenses if not included in original award.</p>	<p>- SPF ensures that all reimbursement requests are reconciled to the general ledger by individual award. - All expenditures in excess of \$1,000 are compared by SPF against the approved budget. - Expense compliance risks are discussed periodically with departmental administrators at the Administrators’ Forum. - Financial reporting to funding agencies is controlled by SPF. Expense activity is reviewed by SPF in relation to the approved budget as part of the financial reporting process</p>
	<p>Award Letter</p>	<p>-Are the funds gift or grant? - Are there financial reporting requirements? - Should a separate account be established?</p>	<p>- Communication by SPF with PI, funding agency and Development Office to ensure funds are recorded properly. - Applicable Policies/Procedures</p> <ul style="list-style-type: none"> o Charging Indirect Costs to Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts (157) o Accounting Policies and Procedures for Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts (170) o Gifts and Classification of Net Assets – Section 12 of Financial Policies and Procedures User Guide o Opening New Gift Fund and Endowments – Section 12.2 of Financial Policies and Procedures User Guide

13. Policies and Procedures on Website

Please refer to the SPF website for the most up to date listing of the following [Policies and Procedures](#):

a. General

- [Research Grant Compliance Guide](#)
- [Financial Policies and Procedures User Guide \(Table of Contents\)](#)
- [Commonly Asked Questions](#)
- [SPF Alerts](#)
- [Monthly Expenditure Review Checklist](#)

- b. Award Management: Allowable Expenses, Program Income, and Reporting
- [Accounting Policies and Procedures for Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts \(170\)](#)
 - [Active Account Documents \(177\)](#)
 - [Administrative Charges to Endowment and Similar Funds \(158\)](#)
 - [Administrative and Clerical Salaries to Federal Grants and Contracts \(171\)](#)
 - [Charging Office Supplies and Other Administrative Expenses \(Other than Salaries\) to Federal Awards \(172\)](#)
 - [Charging Indirect Costs to Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts \(157\)](#)
 - [Consultant Services Provided By A Related Party \(155A\)](#)
 - [Consultant Services - Purchase Orders and Invoices \(155\)](#)
 - [Grant and Contract Cost Transfers \(176\)](#)
 - [Research Subject Payments \(184\)](#)
 - [Service/Recharge Centers Policy and Procedures Manual \(187\)](#)
 - [Shared Resources Facilities Policy and Procedures Manual \(183\)](#)
 - [Subawards \(182\)](#)
 - [Transaction Approval For Expenditures \(179\)](#)
 - [Travel Policy ACS-A.2021a](#)
 - [Unallowable Expenses \(173\)](#)
- c. Time and Effort
- [Time and Effort Reporting Policies and Procedures \(174\)](#)
 - [Faculty Effort on Sponsored Projects \(185\)](#)
- d. Reporting and Close Out
- [Sponsored Projects Financial Reporting and Financial Closeout \(181\)](#)
- e. Asset Management
- [Asset Management Policies and Procedures \(100A\)](#)
 - [Interinstitutional Transfer of Assets Purchased Through Grants \(101A\)](#)
 - [Government Furnished Property \(186\)](#)
- f. Small Business Subcontracting
- [Small Business Subcontracting Plan \(177A\)](#)
- g. Other Documentation
- [Joint Appointments - Memorandum of Understanding \(175\)](#)
 - [Guidelines for Allocation and Uses of 'R' Dollars \(180\)](#)
- h. Forms
- The below forms in excel/word formats are available under Alerts to investigators and staff for use as required.
- [Consent Letter to Transfer Multiple PI Grant to Another Institution](#)
 - [Cost Sharing](#)

- [Cost Transfer](#)
- [Faculty Research Effort Disclosure](#)
- [Fly America Waiver Checklist](#)
- [Grant Financial Report Authorization](#)
- [NIH Prior Approval Request Form for Rebudgeting Activity at High Risk of Indicating a Change in Scope](#)
- NIH Salary Cap: Effort and Salary Source Transaction Forms
 - o [Training Video](#)
 - o [P-T Employees Above the NIH Salary Cap \(Required beg 4/1/22\)](#)
 - o [F-T Employees Above the NIH Salary Cap \(Required beg 4/1/22\)](#)
 - o [P-T Employees Below the NIH Salary Cap \(Optional\)](#)
- [PI Exit Document](#)
- [Prior Approval Request Form for Establishment of a Fund Number Prior to Award](#)
- [Subject Fee Payment](#)

D. Contact Information

[Staff Listing](#)

All questions relating to post-award compliance issues should be directed (646) 605-4023.

Section III. Accounts Payable

A. Services

The Accounts Payable Division assists faculty and administrative staff in meeting their operational needs by disbursing payments to vendors and reimbursements to employees in a responsible and timely manner. The Accounts Payable team recognizes the importance of and strives to build and maintain positive relationships. The Division also seeks to maximize effective cash management and comply satisfactorily with all applicable rules and regulations.

B. Policies and Procedures

- [Section 5 - Travel](#)
- [Axiom FAQs](#)
- [Amex Policy](#)
- [Section 7 - Check Requests](#)
- [Accounts Payable Guide](#)

For a complete list of policies and procedures, please visit the [General Accounting](#) website.

C. Contact Information

[Staff](#)

Section IV. Cash Operations

A. Services

The Cash Operations/Main Cashier's Office is charged with the responsibility to collect and deposit all Icahn School of Medicine's funds in accordance with its policies and procedures. The Main Cashier's

Office develops and implements standardized cash receipting and cash handling procedures, along with managing the petty cash fund.

B. Policies and Procedures

- [Section 6 - Petty Cash](#)

C. Contact Information

Cash Operations/Main Cashier Tel: 212-241-6745 or 212-241-6329

Section V. 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 the [Patient Care Billing section in Table II of the SPF section](#). 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 VI. General Accounting

A. Services

The General Accounting Division oversees and provides support to school personnel regarding financial reporting and management and related business services. The primary responsibilities of the General Accounting Division are:

- Accounting, reporting and preparing the School's monthly internal financial statements.
- Primary liaison for the year-end audit, including preparation of the audited financial statements and all other finance related surveys.
- Integrity of the financial accounting systems data.
- Maintenance of the School's Chart of Accounts.
- Customer support to all areas throughout ISMMS.
- Coordinating the ISMMS budget process.
- Accounting and reporting on the Health System's Investment Portfolio.

- Maintenance and modification of School’s online procurement system (Sinai Central), including monthly financial reports/ledgers and online transaction processing.

B. Policies and Procedures

Financial Policies and Procedures User Guide

- [Section 1 - Introduction](#)
- [Section 2 - Account Structure](#)
- [Section 3 - Ledger Groups](#)
- [Section 4 - Account Subcodes](#)
- [Section 5 - Travel](#)
 - [Section 5.1 - Axiom FAQs](#)
 - [Section 5.2 - Amex Policy](#)
- [Section 6 - Petty Cash](#)
 - [Section 6.1 - Employee Reimbursement](#)
- [Section 7 - Check Requests](#)
- [Section 8 - Payroll and Human Resources](#)
- [Section 9 - Capitalization Guidelines](#)
- [Section 10 - Departmental Financial Performance](#)
- [Section 11 - Capital Project Management System](#)
 - [Attachment to Section 11 - Project Set-Up Form](#)
- [Section 12 - Gifts and Classification of Net Assets](#)
 - [Section 12.2 Opening new gift fund and endowments](#)
- [Section 13 - Annual Budget Process](#)
 - [Section 13.1- School Budget System \(SBS\)](#)
- [Section 14 - Fund Account Deficits](#)
- [Section 15 - Fixed Asset Control](#)
 - [Section 15.1 - Change of Property Status Form](#)
- [Section 16 - Purchasing Policy](#)
- [Section 17 - Records Retention Policy](#)
- [Section 18 - Accounts Payable Guide](#)
- [Section 19 - Unclaimed Property Policy & Procedures](#)

C. Contact Information

[Staff Listing](#)

Section VII. Payroll

A. Services

The Payroll Division is responsible for ensuring that all Icahn School of Medicine employees are paid accurately and in a timely manner. This Division also promotes and monitors compliance with appropriate State and Federal financial and tax laws and regulations along with confirming that all payroll transactions are properly recorded in the School’s accounting system and that all accounts are reconciled on a routine and timely basis.

B. Policies and Procedures

- [Section 8 - Payroll and Human Resources](#)

C. Contact Information

[Staff Listing](#)

Section VIII. Purchasing

A. Services

Mount Sinai requires that all suppliers doing business with our organization register their company information within the Vendormate system. Appropriately managing our supplier relationships is an essential part of providing world-class care to Mount Sinai's patients and our community.

B. Policies and Procedures

Vendors who wish to do business with the Mount Sinai Health System, please visit our [Vendor Portal](#). Members of the Mount Sinai Health System may visit the [Supply Chain intranet page](#) for the most up-to-date Purchasing policy and contact information.

C. Contact Information

[Staff Listing](#) (intranet)

Section IX. Mount Sinai Innovations Partners (MSIP)

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 VIII](#) 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

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 [Contact Your Representative](#) or contact us at MSIPinfo@mssm.edu.

Section X. Sponsored Project Regulations

A. Overview

ISMMS uses the same guiding principles across all sponsored awards as set forth in the Uniform Guidance (UG) [200.403](#) to determine the cost allowableness based on these criteria: 1) necessary, 2) reasonable, 3) authorized/not prohibited under applicable laws and regulations, 4) conforming to any limitations or exclusions, 5) necessary, and 6) consistently treated. The UG, in addition, guides ISMMS' pre and post award requirements. See the policies and procedures sections of this manual set forth by the GCO, the Department of Finance and the Office of Compliance for internal policies, procedures and controls.

B. Uniform Guidance

2 CFR 200, Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, known as the "Uniform Guidance (UG)" issued by Office of Management and Budget (OMB) is a set of Federal regulations that consolidates several OMB Circulars, including A21, A110, and A133. The UG is available in [html](#), [pdf](#) and [e-CFR](#).

C. Other Regulations

Below is a listing of other federal and extramural funding agency policies.

[Federal Acquisition Regulation \(FAR\)](#) – Federal Contracts

[Department of Defense \(DOD\)](#)

[Health and Human Services \(HHS\)](#)

[NIH Grants Policy Statement](#)

[National Science Foundation \(NSF\)](#)

[United States Army Medical Research Acquisition Activity \(USAMRAA\)](#)

Foundations and Non-Profits: Agency specific

State contracts: Agency specific

Industry and pharmaceutical company awards: Company specific

For Mount Sinai Health System hospitals, we adhere to the existing principles located at [45 CFR Part 74 Appendix E](#), entitled "Principles for Determining Cost Applicable to Research and Development Under Grants and Contracts with Hospitals."