

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

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TABLE OF CONTENTS

FOREWORD iv

PART I. RESEARCH

GRANT AWARD PROCESS 1

Introduction 1

SECTION I.

RESEARCH PROPOSAL DEVELOPMENT, INTERNAL REVIEW, AND SUBMISSION

1

Definition of Research 1

Eligibility for Principal Investigator Status 1

Application Forms 1

Sponsor Forms 1

GCO Forms 1

Budget Preparation 2

Fringe Benefits and Indirect Facilities and administrative Cost Rates 2

Required Signatures 2

GCO Review 2

GCO Research Development Services 2

Notices of Funding Opportunities 3

Database Tracking System 3

Clinical Trials 3

Investigational Drugs 3

Department of Pharmacy 3

Purchase and Use of Investigational Drugs 3

Non-Formulary Drugs 3

Formulary Drugs 3

Controlled Substances Used in Research 4

Materials Transfer Agreements,
Inventions, and Patents 4

Office of Industrial Liaison 4

Invention Reports 4

SECTION II. REGULATORY AND INSTITUTIONAL REQUIREMENTS5

Institutional Review Board (IRB) 5

Institutional Animal Care and Use Committee (IACUC) 5

Misconduct in Research 6

Policy on Conflict of Interest in Research6

NIH Guidelines for Research Involving Recombinant DNA Molecules 6

Biosafety Program 7

Radioisotopes in Research 7

Assurances and Certifications 8

PART II. POST-AWARD 9

Introduction	9
SECTION I. OVERVIEW OF POST-AWARD REQUIREMENTS AND PROCEDURES	9
Grant and Contract Awards	9
Administration of Awards	9
No-cost Extension	10
Financial Management	10
Monitoring of Awards	10
Reporting	11
Closeout	11
SECTION II. RESPONSIBILITY FOR FINANCIAL COMPLIANCE	11
SECTION III. HIGHLIGHTS OF INTERNAL CONTROL/ FINANCIAL COMPLIANCE ISSUES	12
Salaries and Wages	13
Cost Transfers	13
Patient Care Costs	13
Allocation of Costs When Work is Closely Related	13
Disposition of Unexpended Balances on Non-Federal Awards	14
Indirect Facilities and Administrative Cost Screening	14
SECTION IV. MEDICAL CENTER RESOURCES FOR COMPLIANCE QUESTIONS AND OBTAINING ADDITIONAL INFORMATION	15
SECTION V. GRANT MANAGEMENT GUIDELINES	15
Federal and Non-Federal Sponsors	15
State and Non-Federal Grant Management Guidelines	16
Mount Sinai Specific Guidelines	16

ABBREVIATIONS USED IN THIS MANUAL 21

FREQUENTLY USED TELEPHONE NUMBERS 21

APPENDICES 22

- I. GRANTS AND CONTRACTS OFFICE COMPUTERIZED RESEARCH APPLICATION
- II. CONTROLLED SUBSTANCES

FOREWORD

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

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

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

PART I. RESEARCH GRANT AWARD PROCESS

Introduction

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

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

SECTION I.

RESEARCH PROPOSAL DEVELOPMENT, INTERNAL REVIEW, AND SUBMISSION

Definition of Research

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

Eligibility for Principal Investigator Status

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

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

All project directors and/or investigators must have the approval of their Chairs indicated by the Chair's signature on the GCO application form. ¹

If there is a question of eligibility, please contact the GCO, (212) 659-8970.

¹The term "Chair" includes Department Chairs, Center Directors and Institute Directors.

Application Forms

Sponsor Forms

Application Forms for the National Institutes of Health (NIH), and most other agencies are available on the web. Many sponsors still require paper applications, but an increasing number of agencies have gone to an electronic submission process. Mount Sinai School of Medicine utilizes a system-to-system provider, InfoEd, for federal applications utilizing the SF 424 R&R packet. The mode of application does not change the internal Mount Sinai process except for the length of review required. Contact the GCO for information (212) 659-8970 if you are unsure how to obtain or submit a particular sponsor's application forms

Agencies and foundations that do not provide application forms generally specify a format in their guidelines. These instructions should be carefully followed. Contact the GCO, (212) 659-8970.

GCO Forms

Mount Sinai School of Medicine Research Applications (*Appendix I*) are available in the GCO in hard copy or on our website. The GCO plans to go to an electronic submission process soon and will make announcements as to the new program's availability.

The principal investigator must submit one original packet of GCO forms plus three copies of each paper extramural (NIH, ACS, etc.) or one copy of an electronic extramural application/proposal to the GCO.

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

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

Budget Preparation

All budgets must follow the specific instructions of the sponsor, and each expenditure must be carefully justified. The GCO will assist faculty in budget preparation. The GCO Budget Form available on the web-site is programmed to calculate fringe benefits and facilities and administrative cost rates based on the selection of the appropriate rate. Questions regarding patient care expenses should be directed to the Compliance office.

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

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

The Federal fringe benefits and F&A cost rates are approved by the Department of Health and Human Services (DHHS) following negotiation with the Department of Finance of the Mount Sinai School of Medicine. Federally negotiated rates apply to all agreements between the Mount Sinai School of Medicine and the Federal Government unless appropriation restrictions have been placed on the funding or other mandatory stipulations apply. Announcements of revised fringe benefit and F&A cost rates are periodically distributed by the Department of Finance and reported in various publications issued by the Finance Department and the GCO.

Required Signatures

The Department Chair(s) of the involved clinical or basic science department(s) must review, approve and endorse the research application on the

appropriate GCO Forms. This is an attestation that the project is consistent with the mission of the Department and the School, and that departmental resources will be available consistent with the intent of the proposal.

The respective Chair must sign for each key professional identified in the proposal.

See Faculty Handbook, *Chapter IV-15*.

GCO Review

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

The Grants and Contracts Officer, has been designated by the Office of the Dean and the Board of Trustees as the institutional official who provides institutional endorsement of each extramural research proposal. This individual will provide the needed institutional endorsement within one business day of the receipt of paper proposals. Turn-around times for electronic submissions vary by agency, please contact the GCO if you are unsure of the internal dead-line. Applications must be *complete* to receive endorsement. Pre-application consultation is readily available and recommended.

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

GCO Research Development Services

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

Notices of Funding Opportunities

The GCO prepares comprehensive monthly announcements regarding funding using information from the Sponsored Program Information Network (SPIN) Database, the NIH, the NSF, and other sponsoring agencies. This includes a calendar identifying major research sponsors by deadline date. These are available on the web-site...

InfoEd International, Inc. is now available on our website (www.mssm.edu/grants). Enrollment will provide on-line, personalized funding opportunities and permit you and your colleagues access to the latest biomedical research being conducted at Mount Sinai School of Medicine and other academic health centers.

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

Individual consultations concerning funding can be arranged by calling the GCO at (212) 659-8976.

Database Tracking System

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

Clinical Trials

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

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

Investigational Drugs

Department of Pharmacy

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

A schedule of charges for investigational pharmacy services has been developed by Pharmacy and approved by the School Administration. It is intended as a guide to the Pharmacy Research Coordinator in calculating appropriate charges for

each research protocol. Charges will be assessed on an individual project basis with an opportunity for discussion with the Pharmacy Research Coordinator.

All budgets must include the cost of drugs and services as established by the Pharmacy. Protocols not funded for these products and services will be reviewed by the Department of Pharmacy to determine feasibility of support. In order to make these assessments, researchers must complete the IRB's Drug Information Sheet (Form 3) and submit it to the Pharmacy for review and approval prior to submission of a research project to the GCO and IRB. In the case of emergency use, researchers can contact the IRB or the Pharmacy; rfurther information is also available on the IRB Guidelines and Policies Manual which is also on the IRB web-site.

Purchase and Use of Investigational Drugs

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

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

Non-Formulary Drugs

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

Formulary Drugs

Drugs used according to the FDA approved dose, route and method of administration, but not supplied by the study sponsor, will be covered by

Mount Sinai. Drugs used in a non-FDA-recommended fashion must be supplied by the study sponsor at no charge or funds must be designated/budgeted by the principal investigator's Department prior to purchase.

Controlled Substances Used in Research

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

A research protocol proposing the use of controlled substances must include that information on GCO Page 1 and IRB Form 3 (Drug Information Sheet_) and elect one of the following options:

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

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

Pharmacy Director: (212) 241-6171.

Materials Transfer Agreements, Inventions, and Patents

Office of Industrial Liaison

The Mount Sinai Office of Industrial Liaison (OIL)

oversees and assists in the commercial development of selected technology. The Director is appointed by the President and the Dean to negotiate contracts relating to intellectual property.

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

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

Invention Reports

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

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

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

Refer to the Mount Sinai School of Medicine Faculty

Handbook - Policies on Intellectual Property: Ownership and Commercial Development, *Chapter VIII-13*.

SECTION II. REGULATORY AND INSTITUTIONAL REQUIREMENTS

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

Institutional Review Board (IRB)

The Mount Sinai School of Medicine Institutional Review Board is the official oversight committee for the protection of human subjects in research. It functions under a Federal Wide Assurance (FWA00005656) granted by the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS), which indicates that all research conducted at Mount Sinai will be guided by ethical principles and be in compliance federal policy. Without the Assurance, PHS support may not be provided for research involving human subjects. It is negotiated and approved for three-year periods.

The IRB reviews each applicable research proposal and related materials, including informed consent documents. Approval must be secured prior to the start of research activity. It is the responsibility of researchers to meet established deadlines in order to secure IRB review of their research.

The IRB has the responsibility and authority to approve, require modification of, or disapprove any research activity involving human subjects or tissue derived from human subjects. It employs Full Board and Expedited review methodologies. The IRB meets four times each month, and employs a pre-

review process to assist in timely review and approval. Research protocols must be reviewed by the IRB at intervals appropriate to the degree of risk, but not less than every 12 months. Researchers must submit applications for continuing review in a timely fashion to avoid gaps in IRB approval.

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

The Chair, Vice-Chair, Director, and support staff of the IRB are available to provide assistance regarding IRB matters.

Further information on IRB compliance issues can be obtained from the IRB Guidelines and Policies Manual, the IRB Procedures Manual, and the IRB's website.

Institutional Animal Care and Use Committee (IACUC)

In accordance with Public Health Service (PHS) policy on humane care and use of laboratory animals and Animal Welfare Act Regulations (AWAR), the Mount Sinai School of Medicine's Institutional Animal Care and Use Committee (IACUC) is charged with overseeing the institution's animal care and use program and to ensure compliance with AWA, AWAR, PHS policies and the NRC Guide for the Care and Use of Animals. It functions under an approved Animal Welfare Assurance (A3111-01) granted every five years by the Office of Laboratory Animal Welfare (OLAW) of the PHS/National Institutes of Health without which PHS support may not be provided for research involving laboratory animals.

The IACUC of the Mount Sinai School of Medicine is responsible for approving, requiring modification of, or disapproving any research or teaching activity

using live vertebrate animals. As required by federal regulations, its membership includes a chair, the attending veterinarian, several practicing scientists and one unaffiliated lay member. Full Board review is mandated for all protocols involving species protected by the AWA, when procedures/methods with potential to pain or distress are used, or at the request of any IACUC member. In general, protocol review and approval require four weeks.

The Center for Comparative Medicine and Surgery (CCMS) of the Mount Sinai School of Medicine is accredited every three years by the Council on Accreditation of the American Association of Laboratory Animal Care (AAALAC). While AAALAC Accreditation is not required for conducting PHS-sponsored research, AAALAC is the only non-profit, independent organization recognized by the PHS to accredit organizations with active animal care and use programs. All animals used in the conduct of research must be purchased by CCMS.

Further information regarding IACUC compliance can be obtained from the Instructions for Completing Veterinary Sheets and Selected Policies of IACUC available in the Center for Comparative Medicine and Surgery and the GCO.

Ethical Practices in Research

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

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

and Procedures on Ethical Practices in Research. (http://www.mssm.edu/forfaculty/handbook/cha_p6h.shtml)

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

Policy on Conflict of Interest in Research

A conflict of interest in research may arise when an investigator or any other person at the Medical School who is responsible for, or involved in, the design, conduct or reporting of research, or a spouse, domestic partner or dependent child or Institutional Official has a financial interest which could directly and significantly affect the design, conduct and reporting of the research.

The Mount Sinai **Policy on Financial Conflicts of Interest in Research** (http://www.mssm.edu/forfaculty/handbook/cha_p7n.shtml) 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.

The Mount Sinai Policy on Financial Conflicts of Interest in Research applies to all research projects, whether federally funded, funded by other public and private sources, or supported by the institution. Principal investigators and project directors must ensure that all persons covered by the policy on conflicts of interest comply fully with its disclosure requirements.

NIH Guidelines for Research

Involving Recombinant DNA Molecules

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

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

Biosafety Program

The Mount Sinai School of Medicine Biosafety Program monitors all laboratory activities involving biohazards and potentially infectious materials to ensure that proper precautions are observed. Biohazards, infectious agents or biologically derived infectious materials that present a risk or potential risk to the health of humans or animals, either directly through infection, or indirectly through damage to the environment. Infectious agents can replicate and give rise to large populations in nature when small numbers are released from a controlled situation. Special duties include the design and improvement of disposal procedures for biological, chemical, and radiological waste and the preparation, submission, and maintenance of records, reports, and documents as may be required by government regulations.

Radioisotopes in Research

Research involving radioisotopes falls under the

purview of the Radioisotopes Utilization and Radiation Safety Committee (RURSC), which establishes policy and oversees the use of radioisotopes. The Radiation Safety Office (RSO), under the leadership of the Radiation Safety Officer, implements the policies and requirements established by RURSC.

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

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

Assurances and Certifications

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

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

PART II. POST-AWARD REQUIREMENTS

REQUIREMENTS AND PROCEDURES

Introduction

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

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

SECTION I. OVERVIEW OF POST-AWARD

Grant and Contract Awards

Post-award grant and contract requirements apply when an extramural sponsor issues a grant or contract award letter to a Mount Sinai principal investigator. The award letter and related budget enable the Fund Sponsored Projects Accounting Department to create an account that can accept revenue and expense transactions related to the award. Each account receives a unique number and is active for the time span of the award.

Facilities and Administrative (F&A) costsSponsored Projects F&A

F&A 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 indirect costs, which reimburses the 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 School of Medicine Fund Accounting Department is responsible for reviewing the adequacy of documentation supporting certain direct cost transactions, maintaining support documentation that justifies the indirect costs and fringe benefit costs charged to the award, and assisting investigators and administrators with questions of compliance with financial policies and regulations.

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

Administration of Awards

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

Federal grant management guidelines allow some flexibility in making post-award programmatic changes and budget revisions in Public Health Service (PHS) non-construction grants awarded on the basis of an approved grant budget broken down by object class (personnel, travel, supplies, etc.) and specifying funds that are available to carry out approved activities. Unless otherwise restricted by the terms of the Notice of Award, the grantee may rebudget within and between budget categories in the approved total budget of the project to meet unanticipated needs or to accomplish certain programmatic changes. Investigators must exercise proper stewardship over the sponsor's funds and ensure that all charges to the awards are allowable, allocable, and

reasonable.

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

No-cost Extension

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

Financial Management

To assist investigators in controlling receipts and disbursements according to Federal,

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

Monitoring of Awards

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

- X Financial operations are properly conducted.
- X Financial reports are presented fairly and

accurately.

- X Applicable laws, regulations, and other grant terms have been complied with.
- X Resources are managed economically and efficiently.
- X Desired results and objectives are being achieved efficiently.

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

Reporting

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

Closeout

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

SECTION II. RESPONSIBILITY FOR FINANCIAL COMPLIANCE

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

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

carry out the grant agreement.

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

All grant and contract direct cost transactions must be reviewed and approved by the principal investigator or a designee before being charged to the award. Time and effort reports require the approval of the faculty member/employee as well as the supervisor or designee with first hand knowledge of the faculty member/employee's activities. Transfers of costs to or from grant-supported projects may be necessary to correct bookkeeping or clerical errors. When an error is discovered, the investigator must promptly provide support documentation, a full explanation of how an error occurred, and certification of the correctness of the new charge. An explanation which states merely that the transfer was made "to correct error" or "to transfer to correct projects" is not sufficient.

Transactions in excess of \$25,000 charged to a Federal award require the sponsoring agency's approval.

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

Table I.

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

SECTION III. HIGHLIGHTS OF INTERNAL CONTROL/ FINANCIAL COMPLIANCE ISSUES

To assist departmental administrators and principal investigators in meeting the requirements associated with common

revenue and expenses charged to sponsored awards, the Fund Sponsored Projects Accounting Department has prepared a summary of the documentation, internal control/compliance issues, and Mount Sinai's program to minimize the chance that these categories of revenue and expense may be disallowed in an audit. The summary included in Table II is for common receipts and charges to sponsored awards. Questions about appropriate

approvals and documentation relating to categories of receipts and expenses that may not be listed in Table II should be directed to the Fund Sponsored Projects Accounting Department.

Salaries and Wages

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

Cost Transfers

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

the grant as compared to the approved budget.

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

Patient Care Costs

Investigators should ensure that the proper payer (either third party or the grant award) is billed when a patient receives routine care while registered as a research patient.

When the patient's medical record contains a research consent form and funds are available on a sponsored project to cover patient care, it is the investigator's responsibility to direct the bill for services to the correct payer. Significant unrestricted funds remaining in the patient care component of the budget when a sponsored award is closed indicate that billing errors may have occurred. In such cases, School Finance will request the Internal Audit Department to review the accuracy of patient care billing on the award.

When using second generation investigational devices, compliance with Medicare billing regulations is essential. Under these regulations, Medicare will reimburse for Category B devices and related services provided the use is part of an FDA-approved clinical trial and other conditions are met. Medicare will not reimburse for Category A experimental/investigational devices and related services. For further information on these requirements, contact the Office of the General Counsel (241-8105).

Allocation of Costs When Work is Closely Related

When salaries and/or other activities are

supported by two or more sources, issues arise as to how these costs should be allocated among the sources of support. It is Federal policy that if a cost benefits two or more projects or activities in proportions that can be determined, the cost should be allocated according to the proportional benefit. If a cost benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved, the cost can be allocated to benefitted projects on any reasonable basis.

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

- X The projects are scientifically and technically related.
- X The projects are under the direction of the same principal investigator.
- X The projects have been funded by the same PHS awarding office.
- X There is no change in the scope of the individual grants involved.
- X The relating of costs will not be detrimental to the conduct of work approved under each individual award.
- X The relatedness will not be used to circumvent the terms and conditions of an individual award.

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

Disposition of Unexpended Balances on Non-Federal Awards

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

- X To continue use of the unexpended balance according to the project objectives, the principal investigator must submit a request to the Grants and Contracts Office for an extension of the project work.
- X The sponsor must provide a letter stating that all contractual requirements have been fulfilled and that no refunds are due the sponsor.
- X A final report must be submitted to the Grants and Contracts Office.
- X The principal investigator must submit a memorandum to Fund Sponsored projects Accounting stating that there are no outstanding obligations to the School of Medicine for special services or laboratory analysis.

Indirect Cost Screening

F & A All expenses included in either administrative or facilities indirect F & A cost pools are screened according to OMB Circular A-21 requirements to ensure that unallowable expenses are eliminated from the indirect cost rate calculation. The cost pools subject to screening include:

- X Building Depreciation
- X Equipment Depreciation
- XX Operations & Maintenance
- X InterestX General Administration
- X Departmental Administration
- X Sponsored Programs Administration
- X Library
- X Student Services

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

- X An annual audit is conducted by the School's external auditors, Ernst & Young, according to the audit requirements of OMB Circular A-133.
- X All faculty members are required to sign conflict of interest disclosures on a periodic basis (monitored by Internal Auditthe Medical Center's Compliance Office).
- X School Finance holds quarterly meetings with Departmental Administrators to discuss grant management

compliance issues that may arise.

- X Detailed ledger reports that include a listing of expenditures for each grant or contract are provided to the investigators monthly.
- X The institution has its own policies and procedures that supplement and help ensure compliance with the sponsor's grant and contract requirements
- X User-friendly grant and contract policies and procedures are included in the *Finance at a Glance* on the School Finance website under Grant and Restricted Funds including other grant management references and tools. This section of the website also includes Sponsored Project Accounting Alerts manual.
- X A training webcast of Pre and Post Award Grant Finance and Compliance issues is mandatory for all School of Medicine research investigators and administrators (website_____.)

Services provided by the Fund Sponsored Projects Accounting Department include:

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

administrators.

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

All questions relating to post-award compliance issues should be directed to the Mount Sinai School of Medicine Fund Sponsored Projects Accounting Department at (212) 731-3174 3338 (extension 8715983338)

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

Sponsored Projects A webcast pre and Grants and Contracts and Sponsored Projects AccountingT at (website____)An orientation and training session for post-award administration is offered by the Fund Accounting Department to new investigators and departmental administrators.

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

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

- X Salary and wages (personnel action forms/time and effort reports).
- X Domestic and foreign travel (100% review).
- X All Equipment purchases. in excess of \$500.
- X All Consultant and professional services. (all contracts in excess of \$1,000).
- X All Blanket and other individual orders over \$1,000 for supplies and other items.
- X All Hospitalization and ancillary charges (100% review).
- X Lease agreements for equipment (100% review).
- X Institutional recharges for service and merchandise (review of all journal entries).

SECTION V. GRANT MANAGEMENT GUIDELINES

Federal and Non-Federal Sponsors

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

- X OMB A-110. *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-*

Profit Organizations.

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

Mount Sinai Specific Guidelines (See School Finance website under Grants and Restricted Funds/Policies X Asset

- Management Policies and Procedures (100A)
- X Inter-institutional Transfer of Assets Purchased Through Grants (101A)
- X Travel Policy (115E)
- X Rebudgeting of Grant Funds DHHS Public Health Service and National Science Foundation (137D)
- X Consultation Services - Purchase Orders and Invoices(155)
- X Policies and Procedures for charging F&A Costs to Sponsored Projects Received from Extramural Sponsors, Gifts, Donations, and Other Receipts (170)
- X Charging Administrative and Clerical Salaries to Federal Grants and Contracts (171)
- Charging Office Supplies and Other Administrative Expenses (other than Salaries) to Federal Awards (172)
- X "Unallowable Expenses" (173)
- X Time and Effort Reporting Policies and Procedures (174)

X Faculty Joint Appointments -
Memorandum of Understanding (175)
Grant and Contract Cost Transfers (176)

#170. Accounting Policies and
Procedures for Sponsored Projects
Received from Extramural Sponsors,
Gifts, Donations and Other Receipts

X Other Grant Management References
and Tools.

- PI Exit Checklist
- Research Grant Pocket Compliance
Guide
- GCO/Sponsored Projects Policies
and Procedures Governing
Sponsored Programs
- MSSM Monthly Expenditure Review
Checklist.

X OMB A-110. *Uniform Administrative
Requirements for Grants and
Agreements with Institutions of Higher
Education, Hospitals and Other Non-
Profit Organizations.*

X OMB A-133. *Audits of Institutions of
Higher Education and Other Non-Profit*

Mount Sinai Specific Guidelines

Financial Memoranda:

#137-D. Rebudgeting of Federal Grant
Funds

#155. Consultant Services

#101-A. Interinstitutional Transfer of
Assets Purchased Through Grants

#115-E. Institutional Travel Policy

#157. Policies and Procedures for
Charging Indirect Costs to Sponsored

Institutions.

X Title 45 Part 74. *Administration of Grants.*

X *PHS Grants Policy Statement.*

X OMB Circular A-21. *Principles for
Determining Costs Applicable to Grants,
Contracts and Other Agreements with
Educational Institutions.*

X Agency Specific Regulations.

State and Non-Federal Grant Management Guidelines

X Foundations: Agency specific.

X Voluntary health agencies: Agency
specific.

X State contracts: Agency specific.

X Industry and pharmaceutical company
awards: Company specific.

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

Projects Received from Extramural
Sponsor, Gifts, Donations and other
Receipts

#170. Accounting Policies and
Procedures for Sponsored Projects
Received from Extramural Sponsors,
Gifts, Donations and Other Receipts

Finance at a Glance provides other policies
and procedures for expenditure processing

specific to grants and contracts.

TABLE II: GRANTS AND CONTRACTS SERVICES

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

Equipment	<p>X Evidence of bidding</p> <p>X Evidence of sole source procurement</p> <p>X Voucher package</p> <p>X Institutional prior approval</p> <p>X PHS approval if over \$25,000</p>	<p>X Are documentation and approvals for equipment purchases complete, accurate and authorized?</p>	<p>X Purchasing Department enforces bidding requirements</p> <p>X Fund Sponsored Projects Accounting reviews voucher packages</p> <p>X Institutional prior approval system administered according to Federal guidelines.</p> <p>X Policies and procedures included in <i>Finance at a Glance</i>.on the <i>School Finance website</i></p>
Travel	<p>X Travel request</p> <p>X Submission of travel voucher with documentation in accordance with travel policy. (115E and <i>Finance at a Glance</i>)</p>	<p>X Is documentation submitted for travel reimbursement complete, accurate and authorized according to both Federal and Mount Sinai Policy?</p>	<p>X All travel requests and travel vouchers for grants and contracts are reviewed and approved by Fund Sponsored Projects Accounting</p> <p>X Policies and procedures included in <i>Finance at a Glance</i>on the <i>School Finance website</i>.</p>
Supplies, subscriptions, other miscellaneous expenses	<p>X Purchase order</p> <p>X Purchase Express (\$500) Check Requestonline Purchasing System</p>	<p>X Is adequate documentation submitted to support payment?</p>	<p>X All transactions over \$500 require prior review and approval by Fund Sponsored Projects Accounting</p> <p>X Accounts Payable ensures voucher package is complete before bill is paid</p> <p>X Policies and procedures included in <i>Finance at a Glance</i>on <i>School Finance website</i></p>

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

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

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

ABBREVIATIONS USED IN THIS MANUAL

AALAC	American Association for Laboratory Animal Care
CLASCCMS	Center for Laboratory Animal Sciences (Mount Sinai)Comparative Medicine and Surgery.
CTA	Clinical Trial Agreement
DHHS	Department of Health and Human Resources
FDA	Food and Drug Administration
FEDIX	Federal Information Exchange
GCO	Grants and Contracts Office (Mount Sinai)
IACUC	Institutional Animal Care and Use Committee (Mount Sinai)
IRB	Institutional Review Board (Mount Sinai)
NIH	National Institutes of Health
NSF	National Science Foundation
OMB	Office of Management and Budget
OPRROHRP	Office for of Human Research Protection from Research Risks
ORI	Office of Research Integrity
OIL	Office of Industrial Liaison (Mount Sinai)
PHS	Public Health Service
RSO	Radiation Safety Office (Mount Sinai)
RURSC	Radioisotopes Utilization and Radiation Safety Committee (Mount Sinai)
SPIN	Sponsored Program Information Network
SPA	Sponsored Projects Accounting
F & A Cost	Facilities and Administrative Costs

FREQUENTLY USED TELEPHONE NUMBERS

Center for Laboratory Animal ScienceComparative Medicine and Surgery (212) 241-6685

Fund Sponsored Projects Accounting Department (212) 731-31743338

Grants and Contracts Office (212) 659-8970

Office of the General Counsel (212) 241-8105

Office of Industrial Liaison (212) 659-9680

Pharmacy Director (212) 241-6171

