How to Submit a Research Study

Sinai Central → Financial Conflict of Interest (FCOI) → Gives IF #

Info Ed → Grants and Contracts Office (GCO) → Gives GCO #

Ideate or Email → Institutional Review Board (IRB) → Gives HS #

NEW SUBMISSION

- **Research Registration Form**

  Ensure you are using the most updated version

  Fill out all appropriate areas

  Have the department chair sign

  Submit the form to Joyce Preisinger at joyce.preisinger@mssm.edu

- **Sinai Central**

  Log into Sinai Central: https://sinaicentral.mssm.edu/

  Go to 'COI' on left hand side

  Click Annual Report of outside Relationships (tab must be completed yearly)

  Click 'Investigator Form'

  Complete New Investigator Form

  Add all personnel as well as their role and ensure they complete their FCOI in a timely fashion, hit the save button, once this is done, all personnel listed will receive an email with a link to complete the form on Sinai Central.

  Make sure educational requirements are up to date CITI and FCOIR

  Once everyone has signed their conflict of interest, it will be submitted to the GCO department.

  Contact person in GCO is Claribel Santos and Arlene Reisman. They could be reached at Claribel.santos@mssm.edu and Arlene.Reisman@mssm.edu

  The new investigator form will be give you a new IF or investigator form # (make sure to use this on all submissions)

- **InfoEd**

  This is how you communicate with grants and contracts

  Log onto InfoEd: https://eresearch.mssm.edu/ (use chrome)

  On left hand side click 'Create New'

  Complete all steps for a NEW submission, hit finalize button, build pdf

  The PI needs to sign off on this not anybody else!, PI hits submit for internal review, the PI will enter username and password and click thumbs up, (it will take a few minutes to route, be patient! the PI will

- **Ideate**

  This is how you communicate to the Institutional Review Board

  Log onto Ideate via https://www.ideate.mssm.edu (use fire fox)

  Fill out all appropriate fields

  The PI needs to sign off on this, not anybody else!

  All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

RENEWALS

- **Research Registration Form**

  Ensure you are using the most updated version

  Fill out all appropriate areas

  Have the department chair sign

  Scan and save a copy on the J drive

  Submit the form to Joyce Presinger at joyce.preisinger@mssm.edu

- **Sinai Central**

  Log into Sinai Central: https://sinaicentral.mssm.edu/

  Go to 'COI' on left hand side

  Click 'Investigator Form'

  Complete New Investigator Form

Add all personnel as well as their role and ensure they complete their FCOI in a timely fashion

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- **InfoEd**

  This is how you communicate with grants and contracts

  Log onto InfoEd: https://eresearch.mssm.edu/

  On left hand side click 'Create New'

  Complete all steps for a CONTINUATION study

  Progress report with updates will need to be included

  Ensure research personnel are updated

  The PI needs to sign off on this, not anybody else!

- **Ideate (if study was submitted using this system)**

  This is how you communicate to the Institutional Review Board

  Log onto Ideate via https://www.ideate.mssm.edu

  Fill out all appropriate fields

  The PI needs to sign off on this, not anybody else!

  All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

- **Email IRB (if study was submitted in email format - pre-IDEATE)**

  For renewals, you could find blank documents of all IRB forms at:

  (http://icahn.mssm.edu/research/pphs/researcher/forms)

  HRP 211 application for human research, update as necessary

  HRP-212 continuation/final report, update as necessary

HRP 503 protocol, update as necessary (clean and tracked copy if applicable)

If any modifications have occurred in the last year, include an HRP 213 form

Add CV's of any new research personnel

Updated consent form (clean and tracked if applicable) or waiver of consent signed by PI

CLOSING OUT A STUDY

- **InfoEd**

  This is how you communicate with grants and contracts

  Log onto InfoEd: https://eresearch.mssm.edu/

  On left hand side click 'Create New'

  Complete all steps for a FINAL REVIEW study

  Progress report with updates will need to be included

  The PI needs to sign off on this, not anybody else!

- **Ideate if study was submitted using this system**

  This is how you communicate to the Institutional Review Board

  Log onto Ideate via https://www.ideate.mssm.edu

  Fill out all appropriate fields final closing out the study

  The PI needs to sign off on this, not anybody else!

  All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

- **Email the IRB if study was submitted in email format**

  HRP- 212 final report form

GENERAL HELPFUL TIPS

InfoEd HELP – click top left hand icon SUPPORT located on the main page– this will take you to a helpful page with links to user guides, classes and how to open a research ticket.

IRB analyst assigned to your project will send you comments/suggestions during pre-review of project items – You must respond to the email addressing the comments within 1 week (normally 1 week turnaround)

Save approval forms and all approved items (i.e. consent forms) in the shared drive.

Online Resources

Important/Key Websites

Add to "Bookmarks" list in Firefox the following web addresses for quick and easy access to the Grants and Contracts website, the Program for the Protection of Human Subjects website, the Institutional Animal Care and Use Committee, etc.:

Grants & Contracts (GCO) website:

http://icahn.mssm.edu/research/resources/grants-and-contract-office

Sinai Central website:

http://sinaicental.mssm.edu/

InfoEd website:

Log-in http://eresearch.mssm.edu/

Program for the Protection of Human Subjects (PPHS) website:

http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects

IDEATE website:

http://ideate.mssm.edu/home/

Institutional Animal Care and Use Committee (IACUC) website:

http://icahn.mssm.edu/education/postdoctoral-training/postdoc-resources/institutional-services/iacuc

Office of Research Services (ORS) website:

http://ica hn.mssm.edu/research/resources/office-of-clinical-research

Research Web Portal website:

http://icahn.mssm.edu/research-portal

Supplemental Resource Information

Grants and Contracts (GCO)

https://icahn.mssm.edu/research/portal/resources/gco/application

Getting Started:

GCO Application Submission Process

GCO application Submission Process for Unfunded Human Subject Studies

Grants and Contracts Office Application Submission Checklist

ISMMS Grants and Contracts Office Application Submission Checklist Instructions

Submission, Review,and approval Process Pictorial

InfoEd:

Instructions→ Instructions for Creating an InfoEd Application

Ideate:

InfoEd→ Policy: Training Request→Support Center Home→ Ideate Human Subjects for Researchers →Ideate Human Subjects User Guide

Program for the Protection of Human Subjects (PPHS)

http://icahn.mssm.edu/research/pphs

Guidance and Policies:

Investigator Manual

For Researchers:

Forms and Documents--> E-Submission Checklist

Information for Sponsored Research--> ISMMS IRB Review Fees

ISMMS IRB Review Deadlines & Board Meeting Dates

Office of Research Services

http:ljicahn.mssm.edu/research/portal/resources/office-research-services

Research Orientation for New Faculty and Staff --> Principal Investigator--> Principal

Investigator/Co-Investigator- Research Startup Tool

Clinical Trials

http://icahn.mssm.edu/about/finance/clinical-trials

Financial Administration of Clinical Trials Services (FACTS)

http://www. mountsinai.org/health-professionals/pharmacy-services/investigation1-drug-service

Investigational Drug Service (IDS) --> IDS Review Form

Investigational Drug Service (IDS)--> IDS Review Form Guidance

Investigational Drug Service (IDS) --> IDS Usage Fees

Compliance/Quality Improvement

http://icahn.mssm.edu/research/pphs

For Researchers:

Forms and Documents --> E-Submission Checklist --> HRP-430 Checklist: Investigator Quality Improvement Assessment

Icahn School of Medicine at Mount Sinai
Department of Obstetrics, Gynecology, and Reproductive Science
Research Registration Form

Project Approved by Division Director:

NAME: _____

SIGNATURE: _____

DATE: _____

Principal Investigator/Department:

Co-Investigator(s)/Department(s): All co-investigators and their departmental affiliations should be listed

Is this a Fellow's Project?
☐ Yes
☐ No

Is this a Resident's Project?
☐ Yes
☐ No

Sponsor: This section must be completed. *If the research project has received extramural funding or there is a request for extramural funding, please list the funding source. Otherwise, list the Sponsor as the Icahn School of Medicine at Mount Sinai (ISMMS).*

Brief Title:

GCO #: If known, please include.

I. New submission or resubmission
☐ **New submission**
☐ **Continuation, changes made to original submission. Check all that apply**
- ☐ **Change in investigators**
- ☐ **Change in protocol**
- ☐ **Change in funding source**
- ☐ **Other**

☐ **Continuation, no changes made**
All projects, including continuation projects, must have a complete PPHS/IRB packet submitted

II. Brief Description of Project [Maximum 300 words; For all prospective human subject research - please include in the study description all proposed study sites (FPA, D&TC practice, labor floor, other inpatient units, off-campus practices, etc.) as well as targeted enrollments (if known) for each site. Also, please include number of proposed study visits over what period of time. For research involving human tissue/specimens, please include type of tissue/specimens, number of tissue/specimens to be evaluated and which laboratory will be responsible for proposed analyses. If archived specimens will be studied, please list where material is currently archived.] Submit IRB paperwork in addition to the brief description.

III. Type of Research: (check all that apply)

☐ Human Subject Research
☐ Research on Human Data/Specimens Collected During Previous Research/Clinical Care
☐ Vertebrate Animal Research
☐ Basic Science Research
☐ Resident/Fellow Research Project
☐ Pilot Data for Grant Submission
☐ Other – please explain

IV. Location of Study (Check all that apply and provide address(s) where enrollment will take place)

☐ MSH (Mount Sinai Hospital) _____
☐ MSW (Mount Sinai West) _____
☐ BI (Beth Israel) _____
☐ Other _____

V. Is this a retrospective chart review?

☐ Yes
☐ No

VI. Is this a Global Health study?

☐ Yes
☐ No

If yes, respond to the following:

Is this an existing Sinai site overseas? ☐ Yes ☐ No

Do you have plans for a foreign IRB approval? ☐ Yes ☐ No

Do you have a partnership with a University at the site? ☐ Yes ☐ No

Are there any potential conflicts of interest? ☐ Yes ☐ No

VII. Is this a prospective research study?

☐ Yes
☐ No

If yes, respond to the following:

Include a description of study methods including selection criteria, Interventions, procedures to be performed, and timeline.

_____
_____

VIII. Enrollment information:

Will subjects be enrolled in E-Level Clinic? ☐ Yes ☐ No

Will subjects be enrolled on Labor & Delivery? ☐ Yes ☐ No

Other enrollment locations: _____

Total number to be enrolled _____

Who will recruit subjects? _____

Are Residents involved with recruiting? _____

Total number enrolled to date _____

IX. Will this study include the collection of maternal/fetal specimens (swabs, blood, urine, amniotic fluid, umbilical cord blood placenta, etc.) on Labor and Delivery?

If cord blood is to be collected, how many samples are planned? _____

If cord blood is to be collected, are Residents doing the collection? _____
If tissue samples are to be collected, how many are planned? _____

If tissue samples are to be collected, are Residents doing the collection? _____

If you are collecting blood samples, tissue samples, or any other specimens who is paying for the tests? _____

X. Will this study include the collection of newborn specimens (urine, cheek swabs, merconium, etc.) after delivery?

If specimens are to be collected, what type? _____
How many samples are planned? _____

If you are collecting blood samples, tissue samples, or any other specimens who is paying for the tests? _____

XI. Is this an industry sponsored trial?

☐ Yes
☐ No

If yes, answer the following:

Number of enrollment sites _____
Number to be enrolled across all sites _____
Estimated date enrollment to be completed across all sites _____
Total number enrolled to date across all sites _____
Duration of Study _____

Number plan to enroll at Mount Sinai Hospital _____
Number plan to enroll at Mount Sinai West _____
Number plan to enroll at Mount Sinai Beth Israel _____

Number enrolled at Mount Sinai to date _____

XII. Status of Current Proposal

☐ GCO/IRB submission in progress, no extramural grant being prepared
☐ GCO/IRB submission in progress, extramural grant also being prepared for submission

If an NIH application (or other extramural grant) is being prepared, the extramural budget must be submitted for review at least 4 weeks before project is due at Icahn School of Medicine at Mount Sinai GCO

XIII. Is there/will there be a FDA IND or IDE associated with this project?

☐ Yes
☐ No

XVI. Do you or a related party have any financial interests related to the conduct of this research?

☐ Yes
☐ No

XV. Are there any individual-investigator and/or institutional financial interests related to the conduct of this research?

If this is a project being conducted by a PI in another department and you are asked as an obs-gyn co-investigator to recruit obs-gyn subjects, don't answer "no" without confirming in writing with the PI

☐ Yes
☐ No

XIVI. Is this project/will this project be registered in clinicaltrials.gov? All intervention studies must be registered at clinicaltrials.gov.

☐ Yes
☐ No

XVII. Do you need help with any of the following?

☐ Yes ☐ No Preparation of an extramural grant application
☐ Yes ☐ No Budget preparation for an extramural grant application
☐ Yes ☐ No Other, please specify

XVIII. Will bio-statistical support be required to assist with either study design or data analyses?

☐ **Yes**
If yes, who will you utilize for this service? _____
☐ **No**

XIX. Other Financial Support

Other than statistical support, will financial support be requested from the department for this project?

☐ Yes [If yes, please provide itemized budget. Examples of items in this category include but are not limited to items such as (, (1) $ for lab reagents, (2) $ for shipping/handling specimens, and (3) $ for travel expenses.]

☐ No

XX. For Fellow Projects

☐ Proposed budget and budget justification are attached

☐ No financial support requested

XXI. For Resident Projects

☐ Proposed budget and budget justification are attached

☐ No financial support requested

XXII. Please list all abstracts, presentations, and publications related to this research project

Failure to provide this information could jeopardize ongoing departmental approval. Scholarly activity related to research will be used as a metric to judge project merit as well as ongoing departmental approval and financial support.

Approved:

_____	_____	_____
Elizabeth Howell, M.D.	Denise Berdebes	Michael Brodman, M.D. .
Date: _____	Date: _____	Date: _____

DEPT OB-GYN RESEARCH PROJECT CHECKLIST FOR STATISTICAL ANALYSIS

(Key overall thinking: What is your hypothesis or research question and how are you going to prove it?)

1) Date:

2) Researcher Name:

3) Mentor Name (if applicable):

4) Topic:

5) Description (including number of groups and what you are measuring):

Examples: *(1) Retrospective chart review from November 2014 to 2015 of patients induced with cytotec vs cervedil to look at various outcomes such as… (2) Prospective study.…… (3) Randomized controlled trial involving.……*

6) Hypothesis (stating a succinct quantitative hypothesis):

Primary:

Secondary:

7) Number of patients planned:

8) Statistics planned (if known):

9) IRB proposal type planned:

10) IRB status submitted?

11) When do you expect to have all your data?

12) What's your rationale for that timeframe?

13) Number of patients' data collected to date:

14) Your deadline? Presentation date, abstract deadline, manuscript submission date, grant deadline etc.

Department of OB/GYN Research Submission Process Overview

Departmental Requirement:

• Departmental Research Registration Form

- A completed Research Registration Form (RRF) is required for every New and Continuation submission.
- The completed RRF should be submitted to the Research Office and reviewed before the InfoEd submission is Finalized.

Institutional Requirements:

• A Grants and Contracts section for each submission that is prepared in InfoEd

- An InfoEd submission is required for every New and Continuation submission.
- A FCOI section is required for every New and Continuation submission and it is set-up on Sinai Central.

• A regulatory section for each Human Subjects study that will be reviewed by the Internal Review Board (IRB)

- New studies and Continuations that were previously set-up in Ideate are submitted in Ideate
- Continuation studies not previously set-up in Ideate are sent by email to IRB@mssm.edu

» PPHS (Program for the Protection of Human Subjects) works from a Friday submission deadline. This means that all submissions received Monday thru Friday of a given week will have met the Friday deadline of that particular week.

» Pre-review is a 5-day process beginning the Monday after the Friday deadline.

» If questions arise regarding this process, call the PPHS Office at 212-824-8200.

• A regulator section for each animal study that will be reviewed by Institutional Animal Care and Use Committee (IACUC)

- New and Continuation animal study submissions are prepared in Ideate.

Annual Renewals and Closure

• Every research study must be renewed on an annual basis. The same basic submission process is required for study renewals. This includes: a completed Research Registration Form; setting- up the FCOI requirement on Sinai Central; preparing a Continuation submission in InfoEd; and preparing the IRB Continuation submission in IDEATE or on forms posted to the PPHS website and sent by email to IRB@mssm.edu as appropriate.

• For studies that are completed, close-out is required. A Final Report has to be prepared in InfoEd for the GCO and IRB close-out requirements must also be satisfied.

Regulatory Binder Tabs for Clinical Research Studies

The original version of this document was prepared by the

Department of Emergency Medicine at the

Icahn School of Medicine at Mount Sinai

*Denotes documentation that is required only for certain types of studies (for e.g. FDA-governed studies)

Table or Regulatory Binder Tabs

Tab 1: Study Protocol and Supporting Documents

Tab 2: Case Report Forms/Research Data Capture Forms

Tab 3: Informed Consent and Supporting Documents

Tab 4: Correspondence

Tab 5: IRB Information/Protocol Review Correspondence

Tab 6: Study Participants

Tab 7: Adverse Events & Unanticipated Problems

Tab 8: Study Personnel

Tab 9: Laboratory*

Tab 10: Drug Device Accountability*

Tab 11: Pharmaceutical Submissions: FDA 1571 and 1572 Forms*