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 Financial Conflict of Interest (FCOI) section is required for every New and Continuation submission; set-up on Sinai Central

- A Regulatory section for each Human Subjects study that will be reviewed by the Institutional 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
    - » Program for the Protection of Human Subjects (PPHS) 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 Closures

- 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 Grants and Contracts Office (GCO), and IRB close-out requirements must also be satisfied.

How to Submit a Research Study

Sinai Central → Financial Conflict of Interest (FCOI) → Gives IF #
InfoEd → 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 financial conflict of interest (FCOI) form in a timely fashion. Click 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 training and annual report of outside relationships)
    - Once everyone has submitted their conflict of interest form, it will be submitted to the Grants and Contracts Office (GCO)
    - Contacts in GCO are Claribel Santos and Arlene Reisman. They may be reached at Claribel.santos@mssm.edu and Arlene.Reisman@mssm.edu
    - The new investigator form will give you a new investigator form (IF) number. Save this number, as you will use it again in InfoEd.

  - **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, click finalize button, build pdf
    - Only the Principal Investigator (PI) is permitted to sign off on this; no one else!
    - The PI will log into InfoEd
    - On the left hand side they should click 'My Proposals' then 'Show List' to view all of their InfoEd submissions
    - The most recent proposal will be listed last
    - When the PI identifies the proposal requiring a signature, they should hover over the folder icon and click 'Edit' under PD. This will open up the proposal.
    - Now the PI should click 'finalize'
    - On the finalize tab the PI will see a 'thumbs up' icon. He/she should click this icon, which will then prompt the PI to enter his/her username and password. (The system is rather slow, and it will take a few minutes to load; be patient!)

- **Ideate**
  - This is how you communicate to the Institutional Review Board (IRB)
  - Log onto Ideate via https://www.ideate.mssm.edu (use Firefox)
  - Fill out all appropriate fields
  - Only the PI is permitted to sign off on this; no one else!
  - All communication with the IRB will be submitted through Ideate. Only the PI will receive 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
    - 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 '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 financial conflict of interest (FCOI) form in a timely fashion. Click 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 training and annual report of outside relationships)
    - Once everyone has submitted their conflict of interest form, it will be submitted to the GCO department.
    - Contacts in GCO are Claribel Santos and Arlene Reisman. They may be reached at Claribel.santos@mssm.edu and Arlene.Reisman@mssm.edu
    - The new investigator form will give you a new IF (investigator form) number. Save this number, as well as the previous IF numbers, as you will use it again in InfoEd.

  - **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
    - Only the PI is permitted to sign off on this; no one else!
    - The PI will log into InfoEd
    - On the left hand side they should click 'My Proposals' then 'Show List' to view all of their InfoEd submissions
    - The most recent proposal will be listed last
    - When the PI identifies the proposal requiring a signature, they should hover over the folder icon and click 'Edit' under PD. This will open up the proposal.
    - Now the PI should click 'finalize'

        - On the finalize tab the PI will see a 'thumbs up' icon. He/she should click this icon, which will then prompt the PI to enter his/her username and password. (The system is rather slow, and it will take a few minutes to load; be patient!)

    - **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
        - Only the PI is permitted to sign off on this; no one else!
        - All communication with the IRB will be submitted through Ideate. Only the PI will receive email notifications informing him/her that revisions are required

    - **Email the IRB if study was submitted in email format – Generally older studies, pre-Ideate**
        - For renewals, you can 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 CVs of any new research personnel
            - Updated consent form (clean and tracked, if applicable) or waiver of consent signed by PI

- **GENERAL HELPFUL TIPS**
    - InfoEd HELP – click top left hand SUPPORT icon 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
    - An 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 **one week** (normally one week turnaround.)
    - Save approval forms and all approved items (i.e. consent forms) in the shared drive

- **CLOSING OUT A STUDY**
    - **Sinai Central**
        - Nothing to do

    - **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
        - Only the PI is permitted to sign off on this; no one 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
  - Only the PI is permitted to sign off on this; no one else!
  - All communication with the IRB will be submitted through Ideate. Only the PI will receive email notifications informing him/her that revisions are required.

- **Email the IRB if study was submitted in email format**
  - For closures, submit:
    - HRP- 212 final report form

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

What is the study location? _____

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)

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

V. Is this a retrospective chart review?

☐ Yes
☐ No

VI. Is this a Global Health study?

☐ Yes
☐ No

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

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 _____

VIII. 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 Health System _____
Number plan to enroll at Mount Sinai West _____
Number plan to enroll at Mount Sinai Beth Israel _____

IX. 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

X. Is there/will there be an FDA IND or IDE associated with this project?

☐ Yes
☐ No

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

☐ Yes
☐ No

XII. 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

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

☐ Yes
☐ No

XIV. 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 yes, please detail the number and type of specimens to be collected on an annual basis.* ***All projects requiring collection of specimens on Labor and Delivery must be registered with Dr. Raymond Sandler****.*

☐ Yes
☐ No

XV. Will this study include the collection of newborn specimens (urine, cheek swabs, meconium, etc.) after delivery*?* *If yes, please detail the number and type of specimens to be collected on an annual basis.*

☐ Yes
☐ No

XVI. 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

XVII. 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

XVIII. 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

XIX. For Fellow Projects

☐ Proposed budget and budget justification are attached
☐ No financial support requested

XX. For Resident Projects

☐ Proposed budget and budget justification are attached
☐ No financial support requested

XXI. 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 of 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 patient data collected to date:

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

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*

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 and Contracts (GCO) website:
http://icahn.mssm.edu/research/resources/grants-and-contract-office

Sinai Central
http://sinaicental.mssm.edu/

InfoEd 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 Log-in
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)
http://icahn.mssm.edu/research/resources/office-of-clinical-research

Research Web Portal
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 and 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/investigational-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