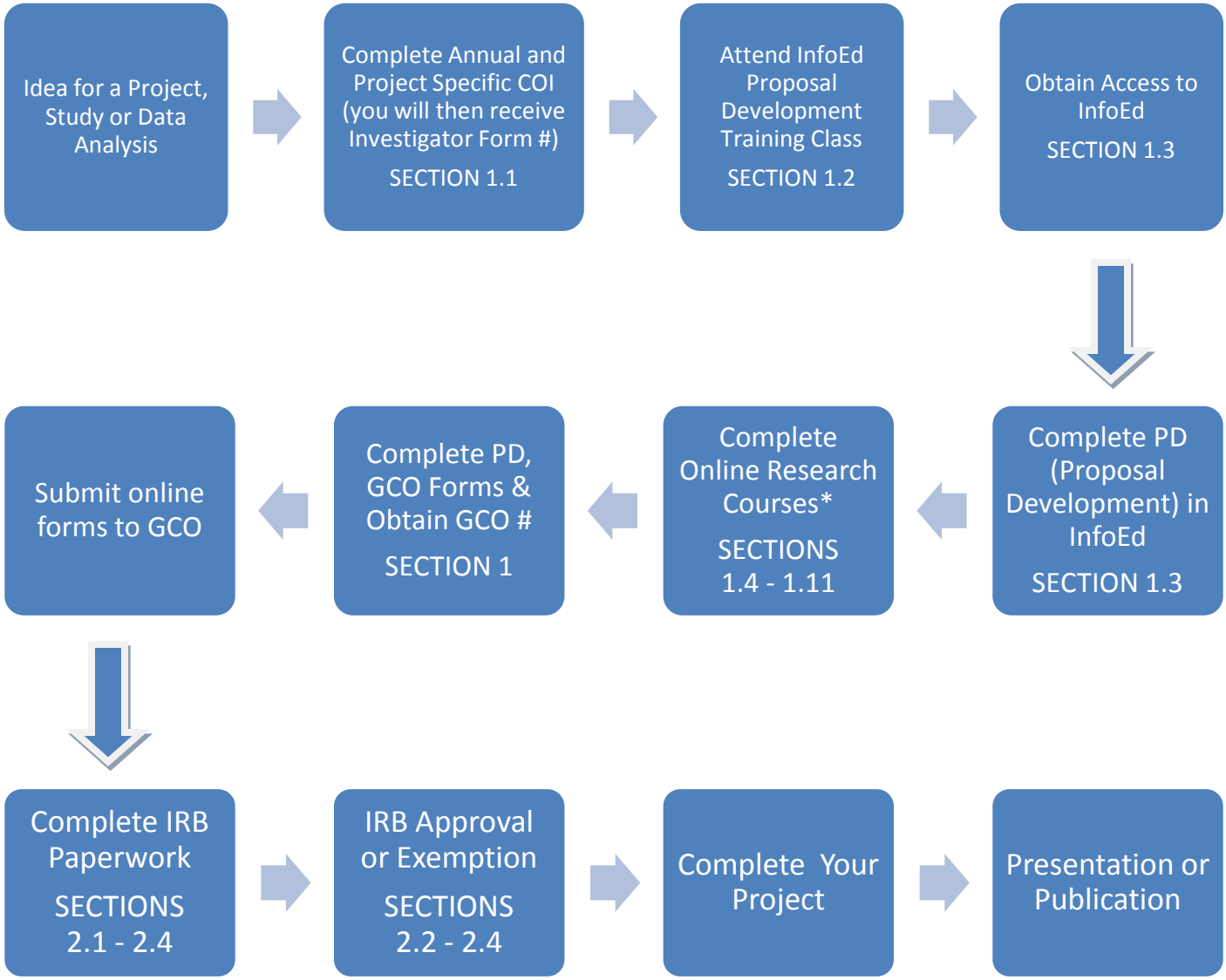
Flow Chart for Obtaining IRB Approval or Exemption



**Note: The Proposal Development Module and the Online Research Courses can be done concomitantly, but the courses must be complete prior to submitting your proposal.

Guidelines for Submitting an Educational Research Proposal for IRB Review developed by Erica Friedman, MD with additional support from Anna Horton, Keelie Jones and Elizabeth Carroll

Guidelines for Submitting an Educational Research Proposal for IRB Review
May 2011

General Information

If a project meets the regulatory definition of research – a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, and further meets, or may meet, the definition of research involving human subjects – about a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual; or identifiable private information, review and approval from the Institutional Review Board (IRB) is required in advance of the conduct of said project. Generally, if a project is expected to be submitted for presentation or publication, all institutions, organizations and publications require Institutional Review Board (IRB) approval (either through review and approval of the project or exemption from IRB review) in advance. IRB approval cannot be given retroactively. Therefore, you must obtain approval or exemption for your research project prior to beginning your data collection, analysis or project. Any results or analyses from a human research project that are presented or published (educational or otherwise), in any format (abstract, poster, article, online submission) must be supported by documentation of either IRB exemption or approval of the research (see SECTION 2 for details).

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. All sponsored programs and/or research proposals 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. Even if your project is not sponsored and does not have a budget, it must be registered and approved by the GCO. You should submit your GCO forms online (see SECTION 1 for details), and deliver your complete IRB paperwork (see SECTION 2 for details) at the same time.

SECTION 1: Instructions on Completing GCO Forms

Conflict of Interest Forms

1. In order to complete the required forms (both GCO and IRB) you must first complete a project financial Conflict of Interest (COI) form. To do this, sign into Sinai Central (https://sinaicentral.mssm.edu) and on the homepage click on COI then click on Investigator Forms and then New Investigator Form (at this point a new Investigator Form will appear onscreen). For every research project, you must complete a separate project COI form. In order to complete the project COI, you must first complete your annual COI, which can also be done on Sinai Central. When you enter the title for your project, the form will assign you an ID, which is the Investigator Form (IF) number. You will need this number when you submit your forms to IRB and you must place this number on your GCO eform in InfoEd. Also, the IRB will not accept your paperwork without an IF number. In addition, the GCO assigns your project a unique reference number that you will refer to in all communications with the GCO and IRB.

InfoEd Training

2. You submit your project to the GCO via InfoEd, which is the electronic program that houses proposal development, tracking, compliance and project management. The InfoEd website provides instructions on how to develop and submit a proposal. However, you must first attend a training course prior to becoming an InfoEd user. Register to attend a 3 hour instructional class at the following link (provides class schedules): http://eolas.mssm.edu/e-learn/. There are usually 4-5 PD (Proposal Development) classes each month and the class times vary.

InfoEd Access

3. Once you have taken the InfoEd PD module, go to http://eolas.mssm.edu/e-learn and complete the form requesting access to InfoEd (new use form). Once you have obtained access to InfoEd, you will need to create a new proposal through the proposal development tab. There are instructions you can download on how to complete proposal development at http://eolas.mssm.edu/e-learn/. Your log in is your Mount Sinai network username and password. Remember that you need to complete online courses (see #4) before submitting your proposal. Because it takes some time to complete these, you may want to take these courses before you even create your proposal.

Mandatory Online Coursework

4. Before any involvement in a human subject research project or processing of any research projects that involve human subjects (even anonymously), you must complete the following online courses. All courses are available through www.CITIprogram.org:

    1. Human Research Protection Education (HRPE)
    2. Data Security for Human Research
    3. HIPAA for Human Research
    4. HIPAA for Research Update

5. **How To Complete Courses**

- Go to www.citiprogram.org
- Click on "New Users Register Here"
- Under "Select your institution or organization" select "Mount Sinai School of Medicine NYC" in the "Participating Institutions" drop down box
- Create your own username and password and select the Learner group (Researcher) and the courses you wish to complete.
- Make sure to keep a copy of your CITI certificate for your records

How to Complete the HRPE Certification Course - Course 1

6. The Human Research Protection Education (HRPE) course is comprised of multiple modules and takes about 4 hours to complete. It can be accessed through http://www.citiprogram.org/ which has the Collaborative Institutional Training Initiative (CITI) human subjects' protection online training program where this course is located. You can save the information and complete the modules at different times. Make sure to keep a copy of your CITI certification for your records. The HRPE course is valid for 3 years, after which a refresher course is required

How to Complete the Data Security and HIPAA Training Courses - Courses 2-4

7. You must complete the Data Security in Human Subjects Research course (course 1) which is a 42 min video, accessed through the same website. You must then complete the 4 item test. If you do not pass the test, you are told which answer is incorrect and can immediately retake the test until you pass.

8. To complete the HIPAA and Research course (course 2), you must view a 73 minute video and complete the test. When viewing the video, you can fast forward or click on each slide to advance the video to your pace. If you do not pass the test, you are told which answer is incorrect and can immediately retake the test until you pass.

9. In order to complete the HIPAA Update course, you must return to your main menu page in www.citiprogram.org and click the link to "Add a course or update your learner groups". On the next page, under Question 3, select "HIPAA Update" and click "Continue". Now you will have an active link under My Courses to the HIPAA Research Update. Click the Enter link and complete the module as you did courses 2 and 3.

10. There is an additional training course for Good Clinical Practice (GCP) available through the CITI program or conducted by the Office of Research Compliance entitled "Clinical Research: Are You Doing It Right?" which is required of any investigator conducting clinical trials under FDA jurisdiction.

11. After course completion you will create and complete the forms for a proposal development through InfoEd. If you have other individuals doing the project with you, they must also complete all the course requirements. If they are faculty, they also need their Department Chairs approval. When you add faculty to a proposal in InfoEd, you should always designate that faculty as "Key Personnel." No matter what the faculty's role on the project, in your InfoEd proposal, designate the person as Key.

    When InfoEd sends your proposal to the signatories, it routes the proposal according to the Key personnel. If a faculty is designated as Key, the proposal will be routed to the signatories in that person's department. If a faculty is not designated as Key, the proposal will not be routed to the faculty's department for signing. The GCO will then decline approval because of the missing signatures.

SECTION 2: IRB Information and Instructions

1. Once you have completed the COI, received an IF number and completed the GCO online forms, you can access the IRB forms and submit for IRB approval (review or exemption from review) at http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palette/pphs-form-and-document-kiosk. All documents to the IRB are printed and submitted as one paper copy to the IRB office. If this is a new submission, your department chair must always sign the form. The IRB approval is provided for up to one year, the approval period will be stated in your approval letter and paperwork to continue or close out your project must be submitted in advance of the end of the approval period.

2. To request IRB exemption from review, you must deliver a printed cover letter to the IRB requesting exemption based upon one of several exemption codes below. Even if requesting exemption, you must complete the IRB FORM HRP-211: Application for Human Research and HRP 503-a Protocol Template. HRP-211 also requires completing the informed consent form or asking for a waiver of informed consent.

Information on what might qualify for IRB exemption and specific categories of research that are exempt

3. Exemption: Certain categories of Human Research may be exempt from regulation applicability but still require PPHS review and approval. It is the responsibility of the PPHS, not the investigator, to determine whether Human Research is exempt. Review the PPHS's "CHECKLIST HRP-412: Exemption Determination" at http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palette/pphs-form-and-document-kiosk for reference on the categories of research that may be exempt.

4. These are the most common categories that education research falls under that may make a proposal exempt from IRB review:

   Category (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, a classroom management methods

Category (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In addition: If the research involves children, the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("N/A" if the research does not involve children)**

Category (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category (4)[i] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **("existing" means existing at the time the research is proposed.)**

[i] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.

Note:
Excluding completion of InfoEd training and the courses mentioned above, the entire process of submitting a project to the GCO and IRB can take as long as 3 months to complete if your proposal requires IRB approval. If it is determined that your project is exempt, the process may be faster.

If the project continues beyond one year, you must resubmit forms to the GCO and IRB each year, using the same GCO number. You must submit the usual forms and you must also complete an additional form HRP 212. If the IRB previously exempted the project, and your project continuation is identical (for instance, if you survey students or residents annually, the survey content must be identical from year to year- otherwise you will need to submit the amended survey), you only need to resubmit your cover letter requesting exemption from IRB review again. You do not need to resubmit any other IRB forms.

You must also submit a final report to the GCO and IRB to close out the project once all research activities are completed. HRP-212 is used for both continuing your project and for closing out your project.

For additional questions refer to:

IRB Website at http://www.mssm.edu/pphs
Program for the Protection of Human Subjects (PPHS) Office
3 East 101st Street, 1st Floor
New York, NY 10029
Tel: 212-824-8200

GCO Website at http://www.mssm.edu/research/resources/grants-and-contract-office
Grants and Contracts Office
3 East 101st Street, 1st Floor
New York, NY 10029
Tel: 212-824-8300
Fax: 212-241-3294
Email: grants@mssm.edu

Erica Friedman, MD
Associate Professor of Medicine
Mount Sinai School of Medicine
One Gustave Levy Place Box 1127
New York, NY 10029
Tel: 212-241-8572
Erica.friedman@mssm.edu