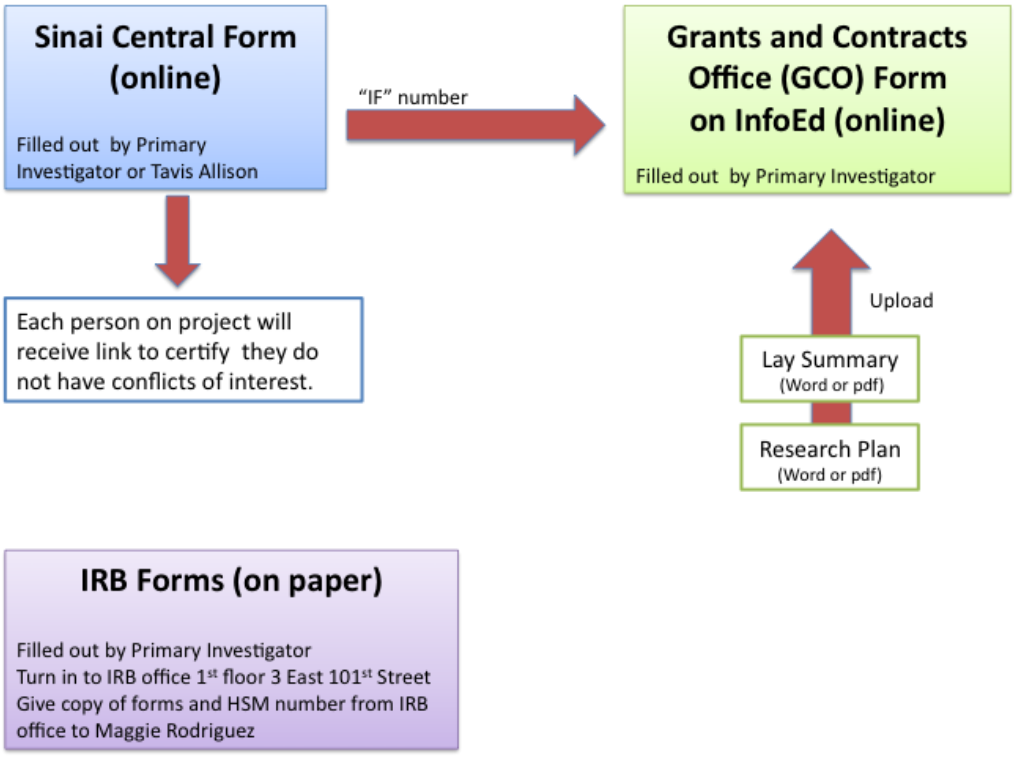
IRB Approval in 3 Easy Steps

(Well, ok, 37.5 Steps of Varying Levels of Frustration)

SUMMARY OF PROCESS:



WALK-THROUGH OF PROCESS AND STRATEGY FOR FILLING OUT FORMS:

First, if you have not already met our grantwriter, Tavis Allison, you should find him on the 2nd floor of 3 East 101st street and introduce yourself. He is an invaluable resource for all of this stuff and is frequently referenced below. He's also a very nice guy.

There are 3 main parts to getting IRB approval under the new process:

1. The Sinai Central form (online, best to have Tavis Allison fill it out for you)
2. The InfoEd GCO form (online)
3. The IRB forms (on paper)

Before you start the forms:

- Make sure that someone on the project has a login for the InfoEd system.
    - This will usually be an attending
    - If no one has one, see "Getting an InfoEd Login" below.
- Make sure **everyone** working on the project has done the Human Subjects Research training.
    - There is a new one (CITI training) as of a few months ago that you need to do if you originally did the old version. See "Doing the Human Subjects Research Training" below for information.
- Have a list of everyone involved in the project including RAs
- Decide whether the project will likely be exempt from IRB review, qualify for expedited review, or will need to undergo the regular review.
    - For help, see "How to Know if your Project will be Exempt from IRB Review, Expidited or Neither" below

1. The Sinai Central Form

The purpose of this form is to figure out if anyone involved in the project has any financial conflicts of interest.

This form generates an "IF" number that you will need for another form.

It's usually best to have Tavis Allison fill out this form for you so he can help you track your submission. To allow him to do this, email him (Tavis.Allison@gmail.com) with:

1. The title of the project
2. Whether there is any funding for it, and if so, the source
3. The names of everyone involved and their roles
    a. One Principal Investigator
    b. Any number of Investigators (usually anyone with post-college degrees)
    c. Non-Key Personnel (RAs, etc)

After the form is filled out,

- Tavis will email you the IF number for your project
- Everyone listed on the project will receive an email with a link to 3 questions they need to answer verifying that they do not have conflicts of interest.
- If you have not filled out your annual hospital conflict of interest form you may be prompted to do this first.

To do the Sinai Central form by yourself, go here: http://sinaicentral.mssm.edu/ and log in. (This is the same system you use to look at pay stubs.)

Click on "COI" > "Investigator Forms" > "New Investigator Form"

Fill out the form. Choose "MSSM" for both "funding agency" and "funding agency type" if the project is unfunded. Note that this form is hard to edit once saved.

2. The GCO (Grants and Contracts Office) form on InfoEd

The purpose of this form is to make sure that Sinai gets its cut of any funding related to the project, but you have to fill it out even for unfunded projects.

To get into the InfoEd system, someone on the project needs a login. See "Getting an InfoEd Login" below if no one has one.

Before you start this form, you should prepare the **two short "essay" sections** as Word or pdf files:

- The Layperson Summary : describes what you are doing and why in language appropriate for someone without a scientific or medical background.

- The Research Plan: similar to a methods section of a paper, explaining the study design and how you will collect and analyze data.

Each section only needs to be few paragraphs long. In both sections, as everywhere else in the application, you should emphasize wherever possible that subjects will not be hurt (personally, professionally, financially), identifying data will not be collected, data will be stored securely, and the results that are ultimately reported will be aggregated (e.g. the average test score rather than each subject's score) so it will not be possible to determine anything about specific subjects.

To fill out the form, go to InfoEd and log in: https://eresearch.mssm.edu/

Click on My proposals > Create New Proposals

You will see a screen with a series of tabs on the left as described below. **After you complete the information in each tab, click "Completed" in the upper right corner.**

Under Setup Questions Tab:

Step 0: Confirm PI (click to confirm)

Step 1: select Create New Proposal

Step1 continued: select "Neither of the above" for unfunded proposals

Step 2: select "New Competing"

Step 3, Select a Sponsor: Select the default, MSSM, for unfunded proposals

(Step 4: automatic)

Step 5: put in title

Step 6, Project Start and End dates: you have to renew every year, and there's no advantage to putting in less than a year, so pick a start date at least a week or two in the future and an end date a year after that.

Step 7: confirm timing

"Yes create proposal"

You will now have a PD number in the upper right hand corner. Write this down.

It will tell you that you are creating a Final Report, but change the pulldown menu to "New (non-S2S, no budget".

Cover letter: no

Under Brief Lay Summary and Research Plan Tabs: Upload your word or .pdf documents then check "Completed" in the upper right corner

Under the Personnel Tab:

Click on "Personnel Wizard" to add people other than the PI. For each person:

- Search for them alphabetically
- If they do not appear, and most residents won't, click on the first choice in the pull-down menu, "not found"
- Enter the info for the new person
- Search for them alphabetically again and select them

People will automatically be listed as "0% effort". Leave this as is unless the project is funded. You don't need to upload CVs or current support info for unfunded projects.

Under the Classifcation Codes Tab: Click something relevant or "other"

Under the Approvals Tab:

Select "Add"

Choose "Human Subjects" from pulldown

"Protocol not attached"

Choose exempt/expedited, etc

Don't worry about the items starting with exemption number

Under the Internal Documents Tab:

"Add Institutional Forms"

check "New/competitive renewals"

click on the icon of the paper to open the form and fill it out

- put the IF number from the Sinai Central form in "Sinai Central Project ID"
- put Tavis Allison as the primary contact person, phone 5-8083 (212-824-8083)

Under the Finalize Tab:

Click “build” to create a pdf file.

The PI of the proposal will then need to click the “thumbs up” symbol to submit your project. The PI will need to re-enter their InfoEd username and password to make this happen. It will then go to the department heads for electronic signatures, then on to the GCO.

3. The IRB Paperwork

These forms are done on paper now.

1. Fill out the forms
2. Get the necessary people to sign them (usually the PI and Dr. Lynne Richardson)
3. Make one copy for the IRB, one for yourself and one for Maggi Rodriguez, who sits in front of office 206 at 3 East 101st Street
4. Turn in one copy to the IRB office on the 1st Floor of 3 East 101st Street
5. Keep a copy of the HSM Number they give you, and give the slip with this number plus one copy of the entire paperwork to Maggi Rodriguez

The links to the 2 forms you need, HRP 211 and HRP 503, are here:

http://www.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/application-information/forms

However, for HRP 503, Tavis has helpfully pre-populated some of the fields if you use this one:

HRP-503 Template Protocol with INSTRUCTIONS

Just replace the directions for each section with your text (keep the subjects headings.) Note than many things, like specimen banking, likely don’t apply to your project.

General Strategy for filling out an Institutional Review Board (IRB) application: First do no harm

The goal of IRB review is to ensure that no one is harmed, physically, emotionally, financially or professionally in the process of a study. If there is a chance that anyone might be harmed, you need to prove that the possible benefits of the study outweigh the risks. Keep this in mind as you fill out the application. Unlike when you write a research proposal, grant application, etc, your goal is not to prove that you have the best-designed, most interesting or most necessary study. They only care about the science in order to determine that a) this is a research activity,

not a non-science thing that's not human subjects research and b) the likely scientific benefits outweigh the costs. You can help convince them of a) by talking about how you'll analyze the data and present them for publication. b) is less of a concern for minimal risk studies; making the science clear so that they understand what you're doing is more important than giving all the technical details.

You just want to convince them that you can do the study without hurting anyone, or at least that it's worth doing even if you might. (The first is the easier approach to take for most studies.)

To this end, you need to convince the IRB either that you are not collecting any data that could be used against people, or that any sensitive data you collect will be rigorously protected. "Sensitive data" includes most personal health information but it is not limited to this. For example, if you conduct a survey of what EM attendings think of the quality of their hospital leadership, the attendings' responses could be used against them by their employers (the hospital leadership). Or, if you are testing resident knowledge of something and they do poorly on the test, this could affect their reputation and standing in the residency if their score becomes known. So, to get IRB approval you have to demonstrate that either 1. You will not collect any identifying information, i.e. information that will allow someone to figure out who gave which response or who has which health issue, or if you need identifying information for your study, that 2. You are protecting this data very well. **Protecting electronic data** well usually means password protecting any computers on which the data is stored, encrypting the data and having as few people as possible know the password. For encryption, you can download the Truecrypt software for free. For **data on pape**r, you need to keep it in a locked container in a locked office to which few people have access.

Note **that identifying information** doesn't just mean name and social security number. For example, if you ask residents to report age, level of residency training, gender, and the name of their residency, and if there are only 1 or 2 28-year old men training at Maimonides, this would be considered identifying data. On the other hand, if you are counting how many people are in the Emergency Department on a given day, or surveying people about their favorite ice cream flavor and not asking them anything else about themselves, this is not identifying information. Asking people for gender, age and level of training on a national survey would not be considered identifying, but doing the same if you are only surveying your department probably would be.

Getting an InfoEd Login:

At least one person on the project needs an InfoEd login. This is usually one of the attendings on the project but it doesn't have to be. Getting a login requires attending a 3-hour course, and the schedule for the courses can be found here:

http://eolas.mssm.edu/e-learn/

Once you have a login and password, forward them to our department's grantwriter, Tavis Allison (tavis.allison@mountsinai.org) so he can help you track submissions.

Doing the Human Subjects Research Training:

Here are instructions Tavis Allison created for doing the CITI training…

To do the training, you'll need to log onto www.citiprogram.org and click the link **New Users** **Register Here** - you may be able to save a step by clicking that link here. In Step 1, where it asks for **Participating Institutions** you'll use the pull-down menu to select **Mount Sinai School of Medicine NYC** - you can click in the pull-down box and type 'mou' to get there a little sooner. (Don't choose Mount Sinai School of Medicine - Graduate School of Biological Sciences.) Then fill out the rest of the information requested.

Once you have registered, choose **Investigators/ Research Staff** as your learner group. You probably don't need to select the Good Clinical Practice box, or to affiliate with another institution on the next page.

On the Main Menu page, you'll see a heading called **My Courses**. Below that, Investigators/ Research Staff, Basic Course should be listed. Click the Enter link next to that to take the course; it looks like this: Not Started - Enter. There are 13 required modules, and seven elective modules. You have to do two of the electives, but it doesn't matter which ones - choose the two that are most relevant to your research. You have to do the required modules in order, starting with the statement of principles. Each module requires you to read the section, and then click a link to take a quiz on that section. You may find it helpful to open the section in a second window (right-click on the link that takes you to that section) so that you can refer to it while taking the quiz.

After you complete the training, under My Courses you'll see a link that says Print under the heading **Completion Reports**. Click this link to get to a dialog box asking you to choose a printer. If you select **Adobe PDF** as the printer, you can save your certificate as a PDF file that you can upload here. You can also choose a regular printer to make a paper copy, which you can scan and upload.

How to know if your project will be exempt from IRB review, expedited or neither:

You can't. You can only guess, and the IRB will agree or disagree based on some general principals, on how well you fill out the forms and on the mood of the person reading the application on a given day and possibly on the results from a Magic 8-ball. But for the sake of filling out the forms, all you have to do is take your best guess.

Exemptions are nice because you can usually get them within a week. Expidited reviews will take longer, but should still be faster than the months and months it can take for a regular review.

In general:

Exemption

Projects generally only qualify for **exemption** if they do not involve any type of intervention (extra blood draws, new medications, etc) and do not involve collection of any identifying information (see first section).

Examples of exempt projects might include:

-analysis of IBEX data to see whether the number of patients per day in the ED corresponds to weather pattern

-a *national* survey you distribute at a booth at ACEP about emergency physician perception of ultrasound's usefulness where you ask for the state in which they practice, whether they trained in ultrasound, their gender and how many years of experience they have. *(Note that doing the same survey only at Sinai would make it not exempt because you could identify individuals from the information you're collecting*.)

-a survey of the general public where you are testing knowledge of stroke symptoms but do not ask the respondents anything about themselves

-an analysis of whether an educational model you designed improves understanding of something, when the study subjects cannot be identified from their responses.

Expidited Review

The distinction between what qualifies for expedited review and what does not is foggier. Generally if you are collecting information about individuals but it's fairly harmless information (hair color, opinion of the new carpets in the waiting room, etc), or if you are collecting more sensitive information but protecting it well it will be expediting. Anything that involves interventions (drawing blood, administering medications) will usually require regular review, **unless** they are interventions that are being done anyway in the process of caring for patients. Also, if you can argue that your intervention does not carry any risk of harm (performing an ultrasound on patients when it will not delay their care otherwise and will not change the plan for their care) you may be able to obtain expedited review.