This document has some information to help you navigate the Institutional Review Board (IRB) process at Mount Sinai (MSH/BI/MSSL/MSW). For the nuts and bolts of dealing with the actual online programs (Sinai Central, Ideate, InfoED) please see the IRB Checklist. For approval for a project at Elmhurst Hospital, complete this process and then do the additional forms required by Elmhurst, available from the administrative folks there.

Note that protocols change frequently for this. The information here is up to date as of 5/1/17.

Which projects need IRB approval?

- Any project which you would like to publish or present. Conferences and journals will generally require that you testify to IRB approval or exemption.
- Any study for which you might use sensitive health or other information. QI projects which are not meant for presentation or publication are generally not included in this.

What do I need to submit for a project that needs IRB approval?

Again, see the IRB checklist for details, but regardless of whether your project is exempt, expedited or requires standard review, all of the following are required:

- **Sinai Central** (Conflict of Interest)
- **InfoEd** (Grants and Contracts paperwork—making sure Sinai gets it's cut of your funding)
- **Ideate** (IRB paperwork)

Exempt, Expedited or Standard Review?

Is your project exempt from review? Is it eligible for expedited review? Or must it go through the standard IRB process?

The answer depends on the risks your project poses to the study subjects. The main goal of the IRB process is the protection of human subjects. Studies posing more risk to the subjects must undergo more thorough full board IRB review.

Risks can be physical, such as pain or side effects from administered treatments, but they can also be less tangible. Also considered is whether the study design risks exposing subjects' personal health information, academic deficits, or otherwise harming them emotionally, professionally or financially.

Why does it matter?

The process tends to change pretty frequently, but as of this writing, you have to do the same paperwork and computer system entry regardless of the expected status of your project. However, you will hear a decision most quickly for exempt projects, then expedited, then standardly-reviewed.

Which projects are Exempt?

If a study poses no risk to the study participants it may be exempt from IRB review.

The exact language specifying what is and is not exempt is listed below. In general, if at no time the investigators need to access or store both **sensitive** and **identifying information** to perform a study, it *may* be exempt.

"Sensitive information" includes personal health information, test scores, salaries, responses to opinion questions that a subject may not want made public, etc.

Note that name and medical record numbers are not the only information considered "identifying". Date of birth, medical conditions, date of visit, etc also can be identifying information. (How many 103 year olds with Crohn's disease visit the ED on a given day?)

Studies that require access to medical charts are less likely to be exempt because the investigators have access to both identifying and sensitive information while they are accessing the chart.

Specific examples of exempt projects might include:

- An analysis of EPIC data to see whether the number of patients per day in the ED corresponds to weather pattern—note that no individual patient's chart needs to be accessed for this, only summary reports.
- 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 might 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.
- A structured literature review or meta-analysis of existing studies.

The following passage regarding exemption criteria was taken from the Mount Sinai Institutional Review Board's Guidelines and Policies Manual,[1] page 15, and cites federal guidelines on exemption. Though the IRB no longer requires an exemption letter citing the exact regulation under which your project is exempt, if you are requesting exemption you should know which regulation applies in case it comes up later.

"Some very specific forms of research may be exempt from IRB review and may not require a subject's consent. It is important to note that the study of existing data (retrospective chart reviews) or the use of existing discards of tissue taken for clinical reasons can ONLY be exempted from IRB review IF the investigator records the information in such a manner that the subjects can not be identified, either directly or through a code linked to the subject. It is also important to note that the types of research that can be exempted must pose NO risks to the subjects.

Research protocols that may be eligible for exemption must be submitted for registration and approval through the GCO and must contain a statement that justifies the request for exemption.

NOTE: NONE OF THE EXEMPTIONS APPLY TO RESEARCH IN PRISONERS, FETUSES, PREGNANT WOMEN OR HUMAN IN VITRO FERTILIZATION.

NOTE: EXEMPTION (2), see below, CANNOT BE USED FOR RESEARCH IN MINORS IF IT INVOLVES SURVEYS OR INTERVIEW PROCEDURES OR OBSERVATION OF PUBLIC BEHAVIOR (except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed).

Categories of research that may be exempt from IRB review [as written in 45 CFR 46.101(b)(1-6), 21 CFR 56.104 and 38 CFR 16.101(b)(1-6)]:

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior
UNLESS:

[1] Downloaded 4/12/17 from http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/application-information/preparing-application/exempt-projects

(a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(b) 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.

(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 (b)(2) of this section, IF:

(a) the human subjects are elected or appointed public officials or candidates for public office; or

(b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of EXISTING data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or 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.

(5) Research and demonstration projects which are conducted by or subject to the approval of U.S. Government Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(a) public benefit or service programs;

(b) procedures for obtaining benefits or services under those programs;

(c) possible changes in or alternatives to those programs or procedures; or

(d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(a) if wholesome foods without additives are consumed or

(b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture."

Which projects are expedited?:

If your project is not exempt, it is therefore a “standard or expedited submission” that needs to be reviewed by an IRB analyst. Both mechanisms require you to complete the same processes as an exemption (Sinai Central, Infoed, Ideate). Studies may be eligible for expedited review if they pose relatively little to no risk to subjects. For example, a study that requires chart extraction but in which the data is stored carefully and

identifiers are removed as soon as the chart extraction is done may qualify for expedited review.

Anything that involves interventions (drawing blood, administering medications) will usually require full board review, unless they are interventions that are being done as part of routine care for those patients. Also, if you can argue that your intervention does not carry any risk of harm (e.g. 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.

General Tips for writing an IRB Application: First do no harm

The goal of IRB review is to protect the well-being of all human subjects physically, emotionally, financially and 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 don't really care about that. 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 there is potential for harm (unintentionally of course).

To this end, you need to convince the IRB that you are going to be scrupulously careful about collecting, storing, and reporting any sensitive data that could identify study subjects. As noted above, "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) if they became public. 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
2. If you need identifying information for your study, that you are protecting this data very well. To do this, you should specify that you will
    a. Create a de-identified dataset as soon as it is feasible to do so, and discard the original dataset.

b. Password protect any computers on which the data is stored
c. Encrypt the data (For encryption, you can download the Truecrypt software for free.)
d. Have as few people as possible know the password (only members of study team).

When true, it can be helpful to mention that the people conducting the study do not need more access to personal information than they already posess for the purpose of performing clinical work.

For data on paper, you need to keep it in a locked cabinet in a locked office to which few people have access (the study team only).

Regarding reporting of data, it's good to emphasize when results will be reported in aggregate (e.g. average blood pressure of a group, average wait time, etc). Reporting results in aggregate guarantees that no one subject's information is identifiable from them.