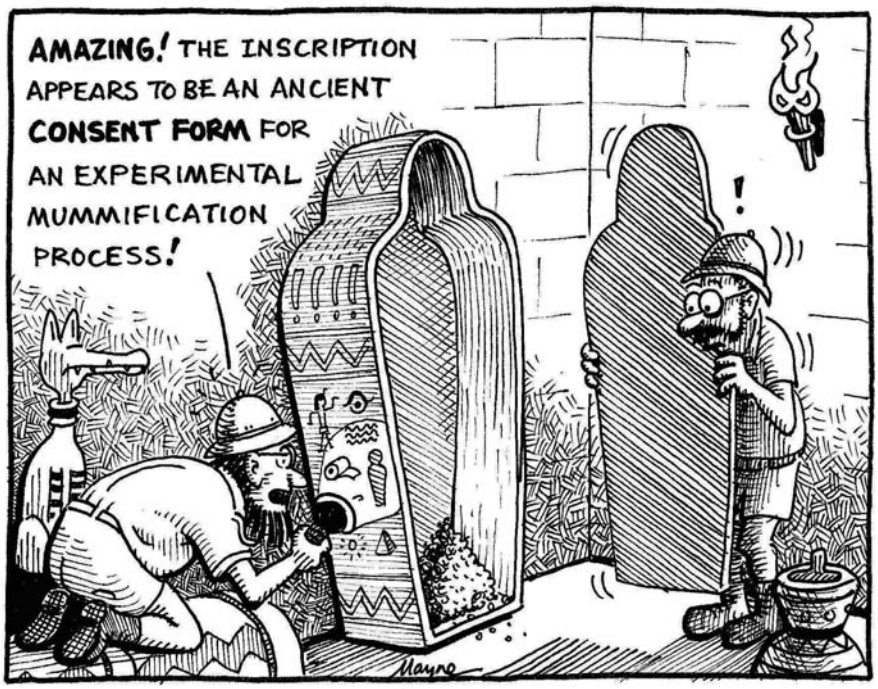
JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Navigating the JHSPH Institutional Review Board (IRB):

A Primer for Students and Postdoctoral Fellows



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Navigating the JHSPH Institutional Review Board (IRB)
A Primer for Students and Postdoctoral Fellows

The JHSPH IRB Office is charged with assuring that human subject research studies conducted in the school comply with internal school policies and external regulations designed to protect human subjects. The IRB application submission and review process can seem overwhelming to individuals new to it; the goal of this document is to help students and post-doctoral fellows understand and navigate the system.

Most of this process, which can often seem arbitrary and excessively time-consuming, is a direct result of the School's obligation to comply with the regulations implemented by the federal Office for Human Research Protections (OHRP) in the Department of Health & Human Services (DHHS). Masters and doctoral students who plan to do human subjects research must have IRB approval **before** working with human data or samples and/or **before** contacting human subjects. "Human subjects research" is broadly defined to include any activity involving identifiable living humans, including their existing data and biospecimens, that seeks to test a hypothesis or answer a scientific question. This can include both secondary data analysis as well as research involving direct contact with subjects.

It is important to isolate your research activities from the activities of the overall project. The IRB will help you determine whether or not your activity is or is not "human subjects research", and even if the overall project is "human subjects research", whether or not you are actually doing an activity that makes you "engaged" in human subjects research. For example, if you are obtaining de-identified data generated by a human subjects research study at another institution, the originating project is "human subjects research", but your activity doesn't involve use of identifiable personal information. So you, and JHSPH, are not "engaged" in human subjects research; only the originating institution is. In that case, no JHSPH IRB oversight is required. But there may be Data Use Agreement concerns, etc., so it is best to submit your proposed activity to the IRB using the Student Determination Forms posted on the IRB website.

If your proposed activity is human subjects research, and you will be "engaged", then you will need IRB oversight for the activity. As a student, you cannot submit your own IRB research application; instead, your advisor or other faculty member must agree to serve as the Principal Investigator (PI) on the research application you submit to the IRB. This means that they accept the full responsibility for compliance with IRB requirements. Since you can prepare the application yourself, it's to your advantage to understand as much about the process and issues that you can so that your research application can move smoothly and quickly through the system. The best way to ensure a rapid review is to prepare your research application so that it answers all of the questions the JHSPH IRB Office is required to ask.

If you are listed as a study team member on a human subjects research application at a different institution, the JHSPH IRB must also oversee your role in that study.

Types of review:

There are three main categories of review for a research application: Exempt, Expedited, and Convened. Much of the research done in the JHSPH fall into the first two categories. Underlined words reflect key elements of the definitions:

1. **Exempt.** Research may be designated as "exempt" if it falls within the DHHS categories of human subjects research that are considered to be so minimal risk that an IRB is not required to review the study to ensure compliance with the human subjects regulations. You may find the categories listed in 45 CFR 46.104 on the OHRP website (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML). Exempt studies are reviewed by an IRB X member and are likely discussed in a Group Discussion setting with other IRB X members. **You cannot make the determination that a project is exempt. Instead you must have a primary faculty member submit an application for your project and await a communication from the IRB that will inform you of its decision.**

2. **Expedited, or Single IRB Member Review.** Research that fall into the 9 categories of human subjects research (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) that qualify for expedited review and are "minimal risk" may by law be reviewed by a single IRB member. The practice at JHSPH is to assign such studies to a member of our IRB X for review and for presentation at a Group Discussion with other IRB X members. The study is discussed, and the Group votes on the outcome. The discussion is recorded in Group Discussion Notes. This procedure ensures that the research meets institutional standards for sound science and ethical conduct. Minimal risk is defined by federal guidelines as:

   > "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

   The list of research activities considered to be minimal risk include such procedures as blood draws, collection of anthropometric or physiological data such as height and weight or electrocardiogram, behavioral assessments, interviews and psychological questionnaires.

3. **Convened Review. "**Convened" review involves review by IRB FC (Full Committee), with a meeting agenda and meeting minutes documenting the discussion and determinations. In general, research that involves greater than minimal risk (physical, medical, psychological, social, or legal/economic), or focuses on particular vulnerable populations (e.g., prisoners) requires convened review. Research in this category includes clinical trials involving therapeutic or behavioral interventions as well as other types of studies with elevated risk. Interview, focus group, or questionnaire studies which ask about sensitive topics (domestic abuse, sexual or drug use behavior, etc.) may qualify for this category of risk. The JHSPH IRB reviews in a convened session many studies that other institutions might assign to expedited review because of our work in international settings. The addition of "cultural context" as a consideration when weighing the risk or discomfort of a study requires careful thought and we believe a convened review is appropriate in many cases even when the study procedures might meet the definition of "minimal risk".

How the JHSPH IRB operates

Research application reviews are conducted by JHSPH faculty or representatives of the local community who serve as members of one of two JHSPH IRBs. IRB-X reviews protocols that are determined to qualify for as minimal risk studies; IRB-FC reviews protocols that are considered to involve "greater than minimal risk". New applications are submitted through an electronic system called PHIRST (Public Health Institutional Review Submission) and then are triaged to the appropriate

review team. Both IRBs meet weekly. The JHSPH IRB Office is located in Suite E1100 near the East Monument Street entrance.

Getting approval to do your research

The easiest approach for students whose research falls within the general scope and aims of an active, on-going IRB approved research project conducted by a primary faculty member in the JHSPH is to be added to an existing IRB research application as a student investigator. This addition requires an amendment to the ongoing study. The IRB considers the addition or deletion of study personnel (other than the PI) to be an "administrative" change. To add someone to the study team, the PI may submit an Administrative Amendment through our PHIRST system. Please remember that amendment applications are not considered approved until the PI hears back from the IRB and receives an official Amendment Approval Notice.

If you are adding an additional activity involving human subjects contact to an already approved research application (e.g., some new questionnaires, an additional blood draw), the PI may submit an Amendment Application with a revised research plan describing this addition or change. Again, you may not implement any change until the PI receives the IRB Amendment Approval Notice.

If you are initiating a new human subjects research project or are involved in a study conducted through another research institution, the normal research application submission procedures, with a primary faculty member as the PI and yourself as a student investigator, must be followed. If you are planning to conduct research at an external research institution in the U.S. under the supervision of a PI there and approved by the external institution's IRB, it may be possible to enter into a reliance agreement deferring JHU review responsibilities to that external IRB.

All student-initiated[1]projects involving humans or information about humans must be submitted to the IRB for a determination as to whether they qualify as "Not Research" (NR), "Not Human Subjects Research" (NHSR), "Human Subjects Research" (HSR) Exempt from IRB Review, or HSR requiring IRB review. Students may use the IRB Worksheet or the IRB guidance flowchart that are available on the IRB website www.jhsph.edu/irb under the link "Student Projects" to give them some idea as to what that determination is likely to be, but the determination itself must be made by the IRB. The JHSPH IRB Office will provide the student documentation of its determination or advise the student if the submission of a new PHIRST application is required.

The IRB Worksheet is a survey-monkey tool which will assist in directing students towards the correct IRB-related outcome. It may direct the student to complete one of the "IRB Office Determination Request forms" that are available on the IRB website www.jhsph.edu/irb under the link "Student Projects." These forms may be used for all student- or post-doc-initiated projects when it is helpful to have the IRB's preliminary opinion on whether a project requires a new PHIRST submission for human subjects research activities and IRB review. Specific timelines for submission are provided for MPH students in both forms. Whether or not you complete a worksheet, you will need to complete an IRB Office Determination Request Form unless: (1) the student is working with a PI from another institution or (2) the PI is adding you as a student investigator to an existing, IRB-approved study. There are two types of determination forms that operate as follows:

- If you are using secondary data for analysis, complete the "**IRB Office Determination Request Form for Secondary Data Analysis**" in collaboration with your advisor and submit it

[1] JHSPH IRB Policy NO. 103.02_Student Investigators [http://www.jhsph.edu/irb/Guidance_and_Policies.html]

to the JHSPH IRB Office email address at jhsph.irboffice@jhu.edu. Be sure to include your advisor in your email submission.

- If you are collecting primary new data, complete the "**IRB Office Determination Request Form for Primary (New) Data Collection**" in collaboration with your advisor and submit it to the JHSPH IRB Office email address at jhsph.irboffice@jhu.edu. Be sure to include your advisor in your email submission.

The JHSPH IRB Office will review the form and let you and your advisor know whethert a new PHIRST application is required. If a new PHIRST application is not required, the JHSPH IRB Office will provide you and your advisor with formal documentation of its determination.

Ethical Code for Student Activities that Involve Human Interactions

Regardless of whether IRB review is required, all students should apply ethical principles in their interactions with humans and/or their data.

The mission of the Johns Hopkins Bloomberg School of Public Health is dedicated to the education of a diverse group of research scientists and public health professionals, a process inseparably linked to the discovery and application of new knowledge, and through these activities, to the improvement of health and prevention of disease and disability around the world.

All activities that involve interaction with people or use of their personal information, whether for public health practice, class activities or research projects, require the highest standards of professional and ethical behavior towards others. Although there are times that collecting information from or about people is not technically "human subjects research" the expectation of the School is that all members of the public in general and the local community in particular will be treated with the same level of respect, fairness and protection of their individual rights as are participants in formal research projects that are subject to IRB oversight.

Basic expectations are described below.

1. For direct interactions with individuals, the purpose and nature of the activity must be clearly described, and the potential participant be given an opportunity to agree or decline to participate. For research studies this is called "informed consent"; for non- research activities this is a less formal agreement. Such an agreement does not require that a participant sign anything; simply that they have been provided complete information even if it is verbal, with an opportunity for them to ask questions and make sure they understand. In general, parents should be informed of activities involving their children, and provide permission. Elements of informed consent/agreement to participate should include:

    a. a brief explanation of the purpose of the activity;

    b. explanation of why the individual was selected for participation;

    c. what they're being asked to do;

    d. the approximate amount of time it will take;

    e. that the activity is voluntary, meaning they have the right to simply say no if they do not want to participate; and

f. that if they do agree to participate, they will have the right to refrain from answering any questions including having the right to stop participating at any time.

2. Respect for Persons: All individuals must be treated with respect, courtesy, and discretion. Be aware that subjects that may be normal topics of discussion with your peers may be viewed as sensitive or intrusive by members of different age groups or cultures. Unless the project is conducted with IRB oversight, do not ask others to report on illegal activities or provide opinions that may compromise their job security. Recognize that children are people too and even if a parent agrees that they can participate, the child must also be allowed to say no.

3. Privacy: All interactions with individuals must be conducted in such a way as to protect their personal privacy. Discussions of sensitive topics must take place where others cannot overhear. Be sensitive to situations in which onlookers may misinterpret your presence or questioning of others. Interacting with adolescents or children raise special concerns, including those outlined in the JHU Child Safety Protocol, and the potential need for parental notification.

4. Data Security and confidentiality: Identifiable personal data, regardless of how seemingly innocuous they may seem, require maximum data protections. The biggest risk of loss occurs during data transport – whether physical transport, or electronic. If you plan to keep identifiers, separate them from the data and use a numeric code system. Use encryption and other protective methodologies when transporting sensitive and identifiable electronic data. The primary source of data loss reported to us is due to theft from vehicles– do not leave data on a laptop or other device in a car for any period longer than absolutely necessary for its transport.

Please make sure you are familiar with **The Ethical Code for Student Activities that involve Human Interactions** that is available on the JHSPH IRB website www.jhsph.edu/irb.

Special considerations by degree type

The general procedures for evaluation of student research projects are the same, regardless of degree. However, some special degree-specific considerations apply.

MPH Capstones

MPH capstones typically fall into one of four categories.

- Simulated grant proposal or research plan. This is not research and does not need IRB approval.

- Public health program proposal that is not conducted. Again, not research/no approval needed.

- Research report: data collection and/or analysis. By definition, this is research and requires IRB approval. See sections above for information.

- Analysis of a public health problem. This is a more complex issue because some activities that involve program evaluation require IRB approval while others do not. The rule of thumb is

to submit the project to the IRB for consideration. The IRB reviewers will determine whether or not your project is "public health practice" or "human subjects research". In general, public health practice means that: 1) your activity will not generate knowledge that would be useful beyond the specific program you are evaluating, and 2) you do not plan to ever publish or otherwise disseminate this information to groups that do not include the agency. The JHSPH IRB Office will provide you with documentation of a determination.

To facilitate the timetable of the capstones, two IRB liaisons have been established within the MPH office to expedite and assist in the process for MPH students. Please direct your initial questions to the MPH Program Office at mphprog@jhu.edu. They will work with the JHSPH IRB Office to provide guidance based on your particular circumstances. All students must submit the **IRB Office Determination Request Form** to the IRB Office email address at jhsph.irboffice@jhu.edu even if you have IRB approval for your project from another institution's IRB.

Doctoral Research

The Office of Academic Affairs facilitates adherence to the School's policies and procedures for satisfactory degree completion. In fulfillment of this mission, one of Academic Affairs' tasks is to track IRB and/or ACUC approval for doctoral students to ensure that doctoral degree students conduct dissertation research under proper institutional approvals. Once you have a final research application for your dissertation research project, you should initiate the appropriate steps to obtain those approvals. Academic Affairs will send doctoral students an email approximately 3 months after passing their preliminary oral exams and forming a thesis advisory committee. The email reminds students of the requirement to obtain IRB and/or ACUC approval for student dissertation projects, if applicable. Also, the email will contain an attached ***thesis documentation form*** that students must complete. This form documents their IRB/ACUC approval and is signed by both the student advisor and the academic coordinator. The form must either be returned to Office of Academic Affairs in W1513 or sent electronically to Melissa Cooke (mjcooke@jhu.edu) so that it may be placed in the student's academic file.

Please don't put your ability to graduate or ever publish your results in jeopardy by not seeking IRB approval for the work, which must be done **before** you begin your research. In order to graduate, certification that you are a student on an IRB approved research application that is the basis for your dissertation (either on a new application or listed via an amendment application to an existing research application) MUST be on file in the Office of Academic Affairs at the address below. All students must submit the **IRB Office Determination Request Form** to the IRB Office email address at jhsph.irboffice@jhu.edu even if you have IRB approval for your project from another institution's IRB.

Finally, there has been some confusion in the past as to whether a copy of your dissertation is required; it is **not** even after you have completed the work. For questions concerning these requirements, please contact Melissa Cooke at 410-955-3348 or mjcooke@jhu.edu.

What you need to do to get started

1. Complete CITI, the on-line human subjects training module. This takes approximately 1 hour, and you can do this at any time. Instructions are provided in the CITI FAQs document that is available on the JHSPH IRB website at www.jhsph.edu/irb.

2. Register in the JHSPH electronic application system. Instructions are provided in the PHIRST FAQs document that is available on the JHSPH IRB website at www.jhsph.edu/irb.

3. Start preparing your research plan. Go to the JHSPH IRB website at www.jhsph.edu/irb and click on the link for "Forms and Templates" to get the Research Plan template. Your research plan should answer the questions provided in the template that pertain to your study.