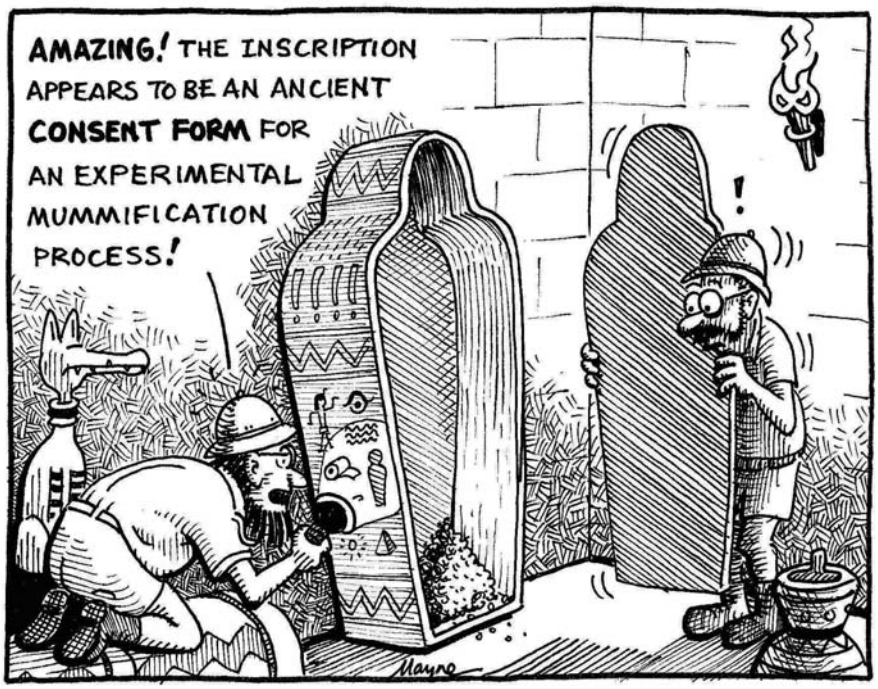
JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Navigating the BSPH Institutional Review Board (IRB):

A Primer for Students and Postdoctoral Fellows



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Navigating the Johns Hopkins Bloomberg School of Public Health (BSPH) Institutional Review Board (IRB)
A Primer for Students and Postdoctoral Fellows

The BSPH 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 BSPH, are not "engaged" in human subjects research; only the originating institution is. In that case, no BSPH IRB oversight is required. But there may be Data Use Agreement concerns, etc.: if a student is not listed on the primary study for which the data was collected, and data (or data access) will be provided to the student, the IRB strongly recommends that the data provider document permission that expresses the terms of use, whether that takes the form of a Data Use Agreement (DUA) or Letter of Permission; it doesn't matter. Documentation that you have permission to use the data is a "best practice" that will make clear the scope of the permission and ensure that you, as the recipient, will not use or sell the data in ways that the provider would not want. So it is best to submit your proposed activity to the IRB using the Student Determination Forms posted on the IRB website. For examples of being "engaged" in research, please see some examples at the end of this document.

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 full-time faculty member must agree to serve as the Principal Investigator 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 BSPH 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 BSPH IRB must also oversee your role in that study.

NOTE: If you need help getting started with your IRB application, please contact the BSPH IRB Navigator at IRBNav@jh.edu.

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 BSPH falls 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 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 BSPH 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 BSPH 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 BSPH IRB operates

Research application reviews are conducted by BSPH faculty or representatives of the local community who serve as members of one of two BSPH 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 BSPH IRB Office is working remotely and can be reached via email at jhsph..irboffice@jhu.edu.

Getting approval to do your Human Subjects Research

A. Amendments

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 BSPH 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 a study, submit an "Administrative Amendment". To do this:

To start an amendment, your faculty PI must add you as a Student Investigator to the PHIRST application of the study you propose to amend. Your PI must use the "Administrative Amendment" submission option for this purpose.

- [For your PI to do] On the left side of the study workspace, click on the "Amend/Continuing" link.

- This will open a new page where you will see “Amendment” and “Continuing Review”. This is how you open new submissions to work on; select “Amendment”.

- When you click on Amendment, you can choose either an Administrative Amendment to change study team or funding, or a Full Amendment. (Note: you may also make study team and funding changes in a full amendment along with your other changes). You may only submit one of each type of Amendment at a time; the earlier amendment must be completed before submitting another one. If an Administrative Amendment overlaps with a Full Amendment, the last one approved will overwrite the other one.

- If your student research will fall within the scope of an aim that is already IRB approved, no additional change is needed. If your student research adds an aim to the study, the PI must submit a full Amendment to revise the research plan and other study documents, as needed, to include the details of your project.

- If you have any problems with the PHIRST system, contact BSPH.phirsthelp@jhu.edu

The Principal Investigator (PI) must be the one to submit the application in PHIRST. Please remember that amendment applications are not considered approved until the PI hears back from the IRB and receives an official Amendment Approval Notice.

B. New Applications

If you are initiating a new human subjects research project as a student investigator, your faculty PI must submit a full new application through the PHIRST system.

C. Human Subjects Research Approved by an External U.S., Non-JHU, IRB

If a student is engaged in human subjects research reviewed and approved by an external, non-JHU, IRB, the BSPH IRB requires submission of a new PHIRST application with the IRB approval letter and approved protocol. The student BSPH faculty advisor or another faculty member may serve as the titular PI for the PHIRST submission. The student must have appropriate supervision at the external institution over the research. The BSPH IRB will conduct an administrative review to ensure the project meets JHU institutional policies and ethical standards.

If a student is listed as an investigator on an IRB-approved study at the Johns Hopkins School of Medicine (SOM) IRB, the approval letter from the SOM IRB will suffice. Please submit a copy of that letter for your student academic file to the Office of Academic Affairs to Melissa Cooke’s attention at mjcooke@jhu.edu.

Review of Research that May Not Need IRB Oversight

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. Please see the student guidance posted on the IRB website about submitting a Student Determination: https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/student-research. These forms may be used for all student- or post-doc-initiated projects when the student is not being added to an ongoing approved IRB application. 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 to the BSPH 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 BSPH IRB Office email address at jhsph.irboffice@jhu.edu. Be sure to include your advisor in your email submission.

The BSPH IRB Office will review the form and let you and your advisor know whether or not a new PHIRST application is required. If a new PHIRST application is not required, the BSPH IRB Office will provide you and your advisor with formal documentation of its determination. If a new PHIRST application *is* required, please reach out to the IRB Navigator if you have questions about the PHIRST submission process: IRBNav@jh.edu.

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. Please make sure you are familiar with **The Ethical Code for Student Activities that involve Human Interactions** that is available on the BSPH IRB website

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. If you have questions about data security and storage issues, please contact: BSPH Cybersecurity@jhu.edu.

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 a determination request form 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 BSPH 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 BSPH 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 be returned to Office of Academic Affairs via email 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 443-927-1911 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 BSPH IRB website at www.jhsph.edu/irb.

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

3. Start preparing your research plan. Go to the BSPH IRB website at https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/forms/research-plans 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. For additional information on how to complete your research plan, there is also an Instructional Research Plan Template for the Research Plan for New Data Collection on that page.

4. Please also read the Student FAQs on the BSPH IRB's website at www.jhsph.edu/irb for further assistance.

5. If you need help navigating the IRB process, please contact the IRB Navigator IRBNav@jh.edu.

Here are some examples of being Engaged in Human Subjects Research

Exempt Submissions Requesting Acceptance of External U.S.- only IRB Exempt Determination: BSPH investigators who collaborate with other institutions in Exempt research may request that the BSPH IRB accept the Exempt determination of the external institution's IRB. The student must have a faculty PI submit a PHIRST application and check "yes" to Question 13 about deferring review to an external IRB. The BSPH IRB will consider whether or not the BSPH PI is responsible for data collection from participants and whether or not it agrees with the exempt determination when considering acceptance.

A. **Scenario 1:** The student works at another U.S. hospital, or healthcare provider, and would like to use data from that covered entity for their dissertation. The student would not otherwise have access to these data in the course of the student's job.

   Answer: If the data are de-identified, the student is not "engaged" in human subjects research. However, if the student has access to identifiers, and are de-identifying the data themselves, the student will need a PHIRST submission to include a HIPAA application requesting a HIPAA waiver.

B. **Scenario 2:** The student works at a company that is not a "covered entity" (governed by HIPAA) which will provide the student with a data set for analysis.

   Answer: Again, if the data are de-identified, the student is not engaged. But, if the student has access to that data, or receives identifiable data, the student will need to a PHIRST submission. The company may or may not require a data use agreement for the research project.

   If a student is not listed on the primary study for which the data was collected, and data (or data access) will be provided to the student, the IRB strongly recommends that the data provider document permission that expresses the terms of use, whether that takes the form of a Data Use Agreement (DUA) or Letter of Permission; it doesn't matter. Documentation that you have permission to use the data is a "best practice" that will make clear the scope of the permission and ensure that you, as the recipient, will not use or sell the data in ways that the provider would not want.

C. **Scenario 3:** The student, under a BSPH faculty's supervision, would like to work with a researcher at another academic institution who will provide the student with identifiable data that the student will de-identify.

Answer: If the student has IRB approval or an exempt determination for the research project from an external institution, a PHIRST application requesting the BSPH IRB to accept the Exempt determination. The PHIRST submission should include a copy of the approved protocol and approval/determination letter from the external institution IRB.