Navigating the Homewood Institutional Review Board (HIRB):

A Primer for Students, Faculty Members Acting as the PI of a Student-Initiated Project, and Individuals New to Human Participants Research

The JHU Homewood Institutional Review Board (HIRB) Office is charged with assuring that human participant research studies conducted at JHU Homewood, by JHU affiliated individuals, or studies specifically recruiting individuals affiliated with JHU comply with JHU policies and Federal regulations designed to protect human participants. This charge extends to social and behavioral research conducted at certain institutions affiliated with JHU or research conducted by personnel of those institutions working elsewhere, specifically the Applied Physics Lab (APL), Carey School of Business, Krieger School of Arts and Sciences (KSAS), Peabody Institute, Nitze School of Advanced International Studies (SAIS), School of Education, and Whiting School of Engineering (WSE). Medical research should be reviewed by either the JHU School of Medicine IRB or the Bloomberg School of Public Health IRB on the East Baltimore campus.

The IRB process can seem overwhelming to individuals new to human participants research. The goal of this document is to provide an introduction and basic understanding of the system. Most of the IRB processes are a direct result of the Institution'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). You can view the regulations at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/ or review the HIRB's Policies and Procedures at http://web.jhu.edu/Homewood-IRB/HIRB%20Policies%20and%20Procedures.pdf .

All individuals, including students (undergraduate, masters, and doctoral students), faculty, and staff, who plan to do human participants research, must have IRB approval before working with human data or samples and before contacting human participants. "Human participants research" is broadly defined to include any activity involving living humans that seeks to test a hypothesis, answer a scientific question, or otherwise contribute to generalizable knowledge. This can include both secondary data analysis as well as research involving direct contact with participants.

What is a faculty member agreeing to do when they become a Principal Investigator (PI) on a student-initiated protocol?

All members of the JHU community who conduct human participant research are expected to comply with high standards of ethical and professional conduct; Federal, state, and local laws and regulations governing human participant research; and Homewood Institutional Review Board (HIRB) policies and procedures. Principal Investigators (PIs) have primary responsibility for ensuring that research is conducted appropriately. Failure to adhere to applicable standards, regulations, laws, and policies may create avoidable risks for study participants and warrant corrective actions by HIRB, including suspension or termination of research and restrictions on the use of data. HIRB has the authority to prevent investigators from publishing or presenting findings from studies it determines to be noncompliant.

Due to the great responsibility that comes with human participant research, students cannot be Principal Investigators (PIs). PIs of research projects approved by HIRB must be full-time, adjunct, or emeritus members of the faculty or designated senior staff members in one of the divisions overseen by HIRB.

The Principal Investigator (PI) on Homewood IRB protocol is responsible for every aspect of the human participant research project, from ensuring the quality and appropriateness of the scientific design through overseeing the actual implementation of the study procedures, to ensuring data integrity and the validity of the findings. The PI must have the scientific expertise to oversee the design

and execution of a project in the specific research area, and sufficient human participants research experience to protect participants. Adequate PI oversight includes:

- Assuming full responsibility for the study as its leader, monitoring day-to-day management of the study to ensure that the study is proceeding according to the IRB-approved protocol;

- Maintaining study documents and records including a protocol file and informed consent documents during the course of the study and for at least three years following study closure;

- Being knowledgeable about the technical aspects of the study topic and methods;

- Developing adequate standard operating procedures for study staff to follow; and

- Establishing good lines of communication among all staff and collaborators to ensure adherence to the protocol and to protect participants.

All investigators are expected to protect the rights and welfare of all study participants, follow the IRB-approved research plan without implementing any changes to the protocol without prior IRB approval (except where IRB policies permit), and comply with Federal, state, international, or local laws applicable to the site of the research.

The research protocol must be detailed in the eHIRB application. The application must include a management and oversight plan for implementing the study procedures and assuring compliance with the approved plan. The challenges associated with oversight vary depending upon the particular characteristics and procedures of the study, including the nature and magnitude of risk, the study's procedural complexity, and its location.

The adequacy of the oversight plan depends on the various factors which increase or decrease the possibility of noncompliance, harm to participants, and threats to data integrity and security. In general, there is no substitute for physical oversight by the PI to ensure appropriate study implementation and adherence to protocols. However, there are situations when oversight can be adequately provided remotely using well-developed channels of communication, monitoring and evaluation, particularly when there is clear delegation of duties to experienced co-investigators. Monitoring study operation may include the use of periodic audits of executed consent forms and research instruments submitted via email, videotaping of study procedures, and other methods of remote supervision.

Optimizing PI oversight is an often challenging, but critical, component in supervision of student research, particularly in those situations in which the student's project is not integrated within the PI's own research agenda or existing projects. The design and implementation of an independent research project is a key element of student training and integral to the academic process. However, because students are not agents of the university, the role of PI on IRB protocols is limited to faculty members in part because the liability for any non-compliance falls on the school and its faculty. Thus, the advising faculty member who serves as PI ultimately bears responsibility for the conduct of the study. An appropriate oversight plan should be based on the specific characteristics of the research project and experience and capabilities of the faculty advisor/PI and student.

The IRB may determine, as part of its review and approval process for the application, that a proposed oversight plan which does not include PI visits to the study site is inadequate because the PI's physical absence adversely affects compliance to the study protocol or increases the potential for harm to human participants. Requirements for a PI's physical presence at the research site will depend upon the nature, character, and magnitude of study-related risks to participants, including physical, psychological, social, legal, and financial risks. Factors that may exacerbate or mitigate such risks include the complexity of the study protocol and the qualifications and experience of the on-site personnel. For IRB applications that do not include PI presence as part of the oversight plan, but for which the IRB determines that PI presence or visitation is warranted, the IRB will explain why such an

increased level of oversight is necessary to correct potential areas of threat to research participants or maintain adherence to the approved study protocol.

Student studies that do not have proper oversight by the Principal Investigator/faculty member will not be approved by the HIRB.

How to Submit a New IRB Application

All protocols submitted to the HIRB must be done through the Electronic Homewood Institutional Review Board (eHIRB) system. eHIRB is a paperless, electronic method to submit, track, and review the scientific, regulatory, and compliance information required for the safe conduct of human participants research at Homewood. The system provides a platform for the IRB and other research compliance committees to share critical information regarding the submission and review of new applications, amendments, continuing reviews, reportable events, and study closures.

To create an account, users should login using their JHED ID and password. If you are trying to add someone who has a JHED ID to the study team and you cannot find them in the system, that individual must first log into the eHIRB system. Once they do so, an account will be automatically created for them and they can then be added to the study team. If you are trying to add someone to the study team that does not have a JHED ID, they must email the HIRB to have an account created for them.

The protocol entered into eHIRB must be followed exactly. If you wish to make any changes to the research (including recruiting more participants than initially planned) you must file an amendment with the HIRB.

The eHIRB online system is located at: http://ehirb.jhu.edu/ehirb

How to Determine if Your Study Involves Human Participants

HHS' Protection of Human Subjects in 45 CFR Part 46 defines a human subject/participant as a living person about whom an investigator obtains either 1) data through intervening or interacting with the person OR 2) identifiable, private information. In general, if you're using coded private information, data, or specimens, your research is considered to involve human participants unless:

- Data are "publicly available", meaning the information is available to anyone, without prior clearance or qualification. Examples of publicly available data include census data, state court records, openly available national household surveys, or data available on the web. If you need a Data Use Agreement, it is not publicly available.

- The data or samples being utilized in the study are in existence at the time of the IRB application as they were collected for another purpose AND the data or samples are anonymous (no JHU researcher has the code to link the samples back to participants)

If any investigator involved in the research can determine a participant's identity or has access to identifiers, the research is considered to involve human participants and human participants requirements apply.

If you still have questions about whether your project is human participants research, you should go into eHIRB, create a new application, and select that you are "unsure if your project requires IRB review". You will then be asked to answer some questions about your project. You may also contact the IRB to discuss the specifics of your project. Do not collect or analyze research data if you are unsure. If your study does require IRB approval and you conduct human participants research without IRB approval, the IRB may require you to destroy all data collected and you will be required to start the project from the beginning.

Types of Review

Research is considered to be either minimal risk or greater than minimal risk. 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." Research activities that are usually considered to be minimal risk include collection of anthropometric or physiological data such as height and weight, behavioral assessments, interviews, and psychological questionnaires (as long as deception is not involved).

There are two categories of review for a minimal risk protocol and one for a greater than minimal risk research protocol. Most of the research submitted to the HIRB falls into one of the two minimal risk categories. The application for both types of review is the same; the HIRB will make the determination of the necessary type of review based on the information provided in the eHIRB application.

Exempt Review

Research <u>MAY</u> be designated as exempt if it is minimal risk. In addition, research may be exempt if the prospective collection of information, including the use of testing, surveys, interviews, observation of public behavior, or if the retrospective review of existing data, documents, records, or specimens does not contain identifiers, or would not be harmful to the participants if the identifiers were disclosed. "Identifiers" include information such as names, addresses, telephone numbers, birthdates, social security numbers, or other information that can be linked to an individual participant.

The IRB must make the decision that a research project is exempt. Investigators cannot make this determination. You must submit an application through eHIRB and await communication from the IRB informing you of its decision. Complete exempt applications typically take about <u>two to four weeks</u> to be processed.

Research that is exempt does not need to meet the criteria for IRB review as stated in 45CFR46 and does not require annual review by an IRB, though informed consent should still be obtained from all participants. If the research protocol is modified so that the basis of the exemption is no longer valid, the protocol must be resubmitted to the HIRB for review.

Expedited Review

Research may be considered for expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate consent procedures. Expedited review may also be used to approve minor changes to a previously approved research project during the period for which approval is authorized.

A protocol requiring expedited review can be reviewed by a single member of the Institutional Review Board; a fully convening a meeting of the entire IRB does not need to occur. The term "expedited" can be misleading; reviews of this type are *not* necessarily "quicker" or conducted with less rigor. Researchers conducting research that meets the qualifications for expedited review must obtain informed consent document unless the research meets one of the criteria for a waiver. If children (age less than 18) are involved in the research, assent from the child must be obtained, as well as informed consent from at least one parent, unless the research meets one of the criteria for a waiver.

Research that involves participants who do not speak English are expected to be given the informed consent document in a language that is understandable to them. The investigator must submit a copy of the informed consent to the IRB both in English and in the language of the participant. A Certificate of Translation in which an individual independent of the research certifies that the translation is accurate is required with the IRB application.

Expedited research protocols typically take <u>four to eight weeks</u> to be approved, depending on the quality and completion of the submitted application. Protocols involving vulnerable populations such as children or prisoners, or international research <u>may take longer</u>. Researchers must always engage in practices that minimize risk, maximize benefit and ensure privacy.

Full Board Review

Full board review is designated for research that involves greater than minimal risk (physical, medical, psychological, social, or legal/economic), or focuses on particular vulnerable populations. Research in this category may ask questions about sensitive topics such as domestic abuse, sexual activities, drug use behavior, gang activity, or other illegal activities. Research protocols that are greater than minimal risk must be reviewed by the fully convened committee, which usually meets once a month.

Since the fully convened meeting only meets once a month, full board applications typically take <u>at least two months</u> to be approved, although the time frame is dependent on the quality and completion of the submitted application. Protocols involving vulnerable populations such as children or prisoners, or international research <u>may take longer</u>.

If you believe your protocol will need full-board review, it is recommended you contact the HIRB office before submission. Please note that undergraduate students are not permitted to initiate studies that are determined by the IRB to be greater than minimal risk.

Expiration of Research Protocols

Annual renewal of all research protocols (except protocols determined by the IRB to qualify for exempt status) is mandatory every 364 days, including research protocols in which human research participant recruitment, accrual, and the research interventions have been completed but data continue to be collected or analyzed. Investigators are required to keep a protocol active as long as investigators are currently using or planning to utilize identifiable data from the IRB protocol. It is the principal investigator's responsibility to assure timely submission of the research protocol for IRB renewal approval prior to the expiration date by submitting the Research Renewal Form along with the submission of required supporting information and documents. Once the protocol expires, all research activities including data analysis must stop. If they study expires, the principal investigator will be required to submit a new IRB application, no exceptions. Research protocol renewals should be submitted to the IRB Office <u>at least six weeks prior</u> to the expiration of current approval.

Conducting unapproved or expired research is a violation of JHU policies and the Federalwide Assurance JHU holds with the U.S. Federal government and could put the University's research enterprise in jeopardy.

Once all research activities have been completed, including data analysis of identifiable data, the principal investigator must complete and submit a closure report to the IRB so that the study file can be closed.

Storage and Retention of Study Documents

All research-related records, including records of IRB activities and research records held by investigators, must be kept on campus in a secure location for at least three years after completion of the research (45 CFR 46.115(b)). All study documents for protocols involving minors (individuals under the age of 18), or *both* minor and adult participants must be maintained until the youngest individual enrolled in the study is 18 years old, or for three years following completion of the study, whichever is longer.

Research data must also be available for inspection and should be stored in a manner consistent with protecting participant confidentiality. All research-related documents that include identifying information should be stored on campus in a locked office or on a password protected computer in order to ensure the safety of confidential information. In the event a faculty member, staff, or student leaves the University, all research-related documents must remain on campus unless other arrangements are agreed upon with the IRB.

All study documents must be accessible for inspection and copying by authorized representatives of the JHU IRB and/or DHHS at reasonable times and in a reasonable manner.

How the HIRB Operates

Protocol reviews are conducted by faculty or representatives of the local community who serve as members of the IRB. For those studies that qualify for expedited review, one or two HIRB members are asked to review the protocol and the protocol does not need to go to a fully convened IRB meeting for review. Those protocols that are considered to involve "greater than minimal risk" must be reviewed by the full committee at an IRB meeting. Meetings are typically scheduled once a month.

Getting approval to do your research

For students who want to get involved in an ongoing IRB approved research protocol, they can be added as a student investigator. This addition requires an amendment to the ongoing study. If the protocol is in the eHIRB system, the amendment request is submitted through the eHIRB system as a Further Study Action (FSA). The Principal Investigator must submit the amendment request in eHIRB asking that the individual be added to that protocol. Please remember that such requests are not considered approved until the Principal Investigator receives a letter that the amendment was approved.

When adding or changing an activity to an already IRB approved protocol (e.g., a new question to a survey or an additional questionnaire, etc.), the PI needs to submit an amendment with a revised research plan describing this addition. Again, such requests are not considered approved until the Principal Investigator hears back from the IRB.

Additional Comments

New researchers sometimes fear that if they identify any possible risks in their protocol, the protocol will not be approved. This is not true, and in fact all studies have SOME risk, even if it is just the potential for loss of privacy or confidentiality. It is perfectly acceptable to have risk in your study as long as the benefits of the study outweigh the risks and the risks are minimized.

What You Need to do to Get Started

1. Complete CITI (Collaborative Institutional Training Initiative), the online human participants training module. You can do this at any time and do not have to complete it all in one sitting. Instructions are provided in the CITI FAQs document. The website is https://www.citiprogram.org/.

PLEASE NOTE THAT YOU DO NOT NEED TO COMPLETE THE RESPONSIBLE CONDUCT OF RESEARCH TRAINING FOR HIRB PURPOSES. PLEASE LOOK ON THE HIRB WEBSITE FOR INSTRUCTIONS ON SELECTING THE CORRECT TRAINING.

2. If you are not a Faculty member or a senior staff member, you must ask a faculty member who is familiar with human participant research to be the Principal Investigator for your study. The PI must be involved with the protocol preparation and with conducting the study and must have completed Human Subjects Research Training. The PI is responsible for the oversight of the research and is ultimately responsible for the research.

3. Start preparing your research plan. Go to the HIRB website to review the policies applicable to your research (http://web.jhu.edu/Homewood-IRB/policies.html). Once you are familiar with the policies, you can begin to prepare your application in eHIRB. Contact the HIRB with any questions.

Frequently Asked Questions

What is the HIRB?

The Homewood Institutional Review Board (HIRB) is a JHU committee tasked with the oversight of all research that involves human participants. The IRB's role is to assure ongoing research is ethical.

Who are the IRB Committee Members?
The IRB is composed of JHU faculty across a wide variety of disciplines, as well as a representative from the local community.

Why does JHU have an IRB Review Process?
University faculty and students are subject to Federal regulations that stipulate "Each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee...No human research shall be conducted or authorized by such institution or agency unless...such committee has reviewed and approved the proposed human research project..."

Does the IRB ever actually disapprove a project?
Although it is rare, the JHU Institutional Review Board is both permitted and when necessary, expected, to disapprove research protocols involving excess risk to the human participants. In most cases, the IRB tries to work with the researcher to modify their protocol in a way that provides appropriate levels of protection for the participants.

How does IRB approval benefit me?
Having your research protocol approved by the IRB tells your research participants that you have taken the appropriate steps to assure their protection. In the event this is called into question, you have additional protection because you have followed the appropriate procedures. In addition, IRB approval also makes it possible for the results of your research to be published in professional journals, many of which have set standards for treatment of human research participants in accordance with Federal guidelines.

Why isn't student research automatically exempt?
All human participant research, regardless of who conducts it, can only be exempt if it satisfies the exempt criteria.

Why is online training required for both the faculty member/PI and the student?
JHU policy requires that all personnel who are involved with the human participants portion of a research project must complete mandatory training at least every three years at the following web address: https://www.citiprogram.org/ . This policy was developed in response to heightened Federal and state guidelines that have resulted in increased scrutiny of university research programs. As JHU students perform their research under the responsibility of an academic supervisor, the University must be able to certify that both the student and faculty member/PI have completed the training.

What kind of criteria do the reviewers apply when looking at a human participants research project?
The overall criterion for IRB reviewers is that the research plan provides adequate protection for the rights and welfare of the human participants involved.

In particular, the IRB focuses on the following areas:
- Purpose
- Methodology
- Risks/Benefits
- Informed consent
- Whether the research deals with high risk or sensitive issues and if so, whether the benefits outweigh the potential risks imposed
- The degree to which confidentiality is both assured (commitment made to the participant) and protected (steps taken to fulfill that commitment)

How much time does the approval process take?
The average review process takes approximately 5-6 weeks, although it will vary depending on when the protocol is submitted and how complete in information the protocol is. Particularly high volume times such as the beginning and end of the semester may result in slightly longer review periods. In

addition, protocols that involve vulnerable populations or involve international research may take longer.

If the IRB requests modifications, there will be a subsequent reevaluation of the protocol, which can take additional time. In submitting your protocol, you should plan ahead to allow for sufficient lead time before the actual research must begin.

What can I do to get a protocol approved quickly?
- Ensure your protocol application is well though through, complete, and tailored to address the issues of concern to the IRB.
- Cover, in detail, all issues relating to participant confidentiality and informed consent.
- If your research will involve a vulnerable population, contact the IRB in advance to discuss the feasibility of conducting the study.
- If you are requesting oral consent/waiver of written consent, ensure you complete the appropriate form for this.
- Ensure all research team members have completed CITI Training. Submit the certificates with the application.

If I am doing data analysis only that does not involve contact with human participants, do I have to submit to the IRB?
All projects which include information collected from or about humans should be submitted to the IRB for a formal determination as to whether the project is human participants research. Make it clear that the data have already been collected, where the data is being obtained from, if it is publicly available, and if there will be access to identifiers.

Do I have to submit my entire research proposal for IRB review if I have received IRB approval at another institution?
This depends on the situation, unless the other institution is affiliated with JHU. If your research was submitted to JHU SOM IRB or JHU BSPH IRB, you do not need to submit the application to Homewood. Please contact the IRB for more information.

I want to enroll children in my research study. What is important to know about involving children in research?
Research involving children must be no more than minimal risk unless there is the possibility of direct benefit to the child participating. In addition, consent is required from a parent or legal guardian of the child before the child can be enrolled. The research should also be explained to the child in a way that they can understand, and the child should asked be asked whether they would like to participate. This is called "assent" and should be done through written procedures for children at the age of 12 or greater, but can be done orally for children younger than 12. You should complete the appropriate documentation (assent checklist, child checklist) and include it with your IRB submission.

Can I tell people about the research if my application is pending IRB approval?
Yes, you can tell people about the study, but may not begin recruitment, consenting, or data collection until you receive IRB approval.

Can I be added to an active, ongoing IRB-approved study?
Yes, if the PI has agreed to add you as a new research team member on an active, ongoing IRB approved study, the submission of an Amendment Application signed by the PI is required.

CITI TRAINING FAQS

What is CITI?
The Collaborative IRB Training Initiative (CITI) is a web-based training program on issues relating to human participants research. The CITI web site is maintained by the University of Miami, with content developed by a national consortium. CITI contains modules on topics such as informed consent, vulnerable populations, ethical principles and IRB regulations. Each module has short quiz at the end to assess understanding.

Who is required to complete the CITI modules?
The training is required every five years of all faculty, staff and students who are engaged in research at Homewood. A total score of at least 80% is required to pass.

Do I have to take CITI again if I took it at another institution?
No, if taken within five years. When you submit your research application, include your certificate from your completed training.

I have had different training at my old or another institution, am I required to take the modules through CITI?
Yes, you should take the JHU CITI training.

Are non-JHU researchers/collaborators required to complete CITI?
Investigators from other institutions who can provide the HIRB Office with documentation of human participants training from their own institution do not need to complete CITI.

Is CITI available in any languages other than English?
CITI has modules in Spanish, French, Russian, Portuguese, Japanese, Korean, and Chinese. These are available at the CITI website under "International Course Site".

If you have additional questions, please contact the HIRB at hirb@jhu.edu.

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