

Homewood Institutional Review Board (HIRB)

- The primary purpose of the HIRB is to ensure that the rights and welfare of human research participants are protected.
 - federal regulations govern the operation of the IRB
 - protection of participants is important not only for research with obvious risks, such as testing new drugs, but also for research that seems much more innocuous
 - confidentiality/privacy
 - right to be informed
 - psychological, social, economic risks
- Faculty, staff, and students must submit for review any research with human participants, regardless of the source of funding (or lack of funding), and regardless of the location at which the research will be conducted.
- All projects involving human research participants must receive IRB clearance before the research is undertaken. Research has a specialized definition in federal regulations. If you are not proposing research according to this definition, you do not have to submit to the HIRB. Please refer below for more information
- Clearance takes one of three forms:
 - an exemption issued by the IRB
 - means that IRB review for compliance with regulations not required
 - informed consent not required, although still usually recommended
 - IRB approval based on expedited review
 - does not mean you apply for expedited review when you need approval quickly
 - means that full board does not have to review application
 - all requirements for informed consent, etc., must be fulfilled
 - IRB approval based on full-board review
- The type of clearance required depends upon the nature of the research, and especially the risks to participants.
 - regulations determine how projects can be treated
 - certain categories of research defined as eligible for exemption, expedited review
 - certain special categories of participants may require special treatment
 - children

- cognitively impaired
- non-English speakers/readers
- prisoners

Review Criteria

- Risks to participants are minimized, and are reasonable in relation to benefits
- Selection of participants is equitable
- Recruitment methods provide appropriate information and are non-coercive
- Informed consent is obtained and documented
- Privacy of participants and confidentiality of data are protected
- When appropriate, additional safeguards are included to protect the rights and welfare of participants
- Researchers have undergone appropriate training in protection of human research participants

Applying

- fill out application carefully & completely; be sure to include enough detail so that we can evaluate potential risks to participants
- allow enough time for review
 - usually a few iterations are needed
 - about one month for exempt/expedited, two months for full board

For more information consult the HIRB website: <http://web.jhu.edu/Homewood-IRB/index.html>

The website includes

- information about how to decide what form of clearance is required
- application forms
- information about training requirements
- contact information

When is HIRB Review Not Required?

Does your project involve research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A paper written to be shared with only a professor would not constitute research and would not be needed to be submitted to the Homewood IRB. This activity does not constitute generalizable knowledge. NOTE: Not submitting to the Homewood IRB for review would preclude using the data in the future as part of a research project.

Does your project involve human subjects?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject (for example interviews and survey procedures).

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

If your project involves pregnant women, fetuses, neonates, or prisoners, then you should verify with the Homewood IRB whether your project needs to be reviewed. Please review the attached link which is another resource providing a flow chart as to whether or not Homewood IRB review is required

(<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1>). If you are unsure about whether a project requires Homewood IRB review or have any questions about the review process, please get in touch with the Homewood IRB at hirb@jhu.edu or 410-516-6580.