Institutional Review Board (IRB)

The U.S. Department of Health and Human Services requires that all research projects involving human participants be screened to confirm that the participant's rights, privacy, welfare, and civil liberties are protected. The Institutional Review Board (IRB) is responsible for reviewing all research projects involving human participants affiliated with Harper College.

Contact Us
Office of Institutional Research
847.925.6950
oir@harpercollege.edu

Manual

Policy for conducting research at Harper College; Institutional Review Board (IRB) Manual

Forms

- Research Proposal IRB Application - (Primary)
  Use this form if Harper College IRB will be the only review panel.
- Research Proposal IRB Application - (Secondary)
  Use this form if Harper College IRB will provide a secondary review of a proposal previously reviewed by an IRB at a different institution.

Committee Information

- Committee Members
- Project Log

Frequently Asked Questions

Does my master thesis/doctoral dissertation require IRB review?

Graduate work (thesis or dissertation) which involves research on human subjects requires IRB review.

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Do student projects require IRB review?

Student projects or assignments involving collection of data from human subjects may or may not meet the definition of research. Course instructors are responsible for making the decision whether the activities meet the definition of research. Course instructors are encouraged to call the IRB if they have any questions.

A student project is a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to generalizable knowledge and is not to be presented outside the class in which the research is being done or published/disseminated (including publication on the Internet) in any way, presented, archived, or compiled with similar research for later publishing or presentation.

Research conducted for a seminar project, masters thesis, or dissertation does not fall under the definition of student project, and therefore, would require IRB review.

Change to "What types of research do not require full IRB review?"

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What types of research ~~are exempt from~~ do not require IRB full review?

1. Research that has been reviewed by another formal IRB committee.
   Research conducted at Harper College that has been reviewed and approved by another qualified IRB may qualify for an Expedited IRB Review. The Principal Investigator must complete the Secondary Research Proposal IRB Application and submit this with the application materials from their home institution and a copy of their project approval from their home institution's IRB. The items should be submitted to the IRB in Building A, Room 317 or electronically to oir@harpercollege.edu
2. Research that qualifies for exempt status.
   DHHS Guidelines (45 CFR Part 46.101(b) and (c)) define research as exempt from further IRB review when the research involves no risk to the subject. Research that is

considered exempt from Committee review must still be filed with the IRB and screened for exempt status.

- Some minimal risk research is exempt from full IRB review. Exemption waives only the need for full IRB review and does not negate the need for the consent of subjects where applicable.
- The authority to determine and confirm exempt status rests with the IRB and not with the investigator nor student advisor. Thus, an Exempt Screening Application Form is required for your exemption to be confirmed and granted by the IRB.

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What types of research could qualify for exempt status?

Examples of Exempt research include: Survey interview research with adult subjects; the use of unidentifiable laboratory specimens; review of nonidentified existing records; observation of the public behavior of subjects where there is no manipulation of the subject; and some educational testing and classroom activity.

For example:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education
- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program
- Interviewing public officials about a local or global issue
- Analyzing de-identified tissue samples or data set
- Analyzing de-identified national test scores
- Analyzing census data about aging or housing

- Taste testing whole grain food products
- Comparing taste or smell of molasses, cheese or milk
- Sampling texture of ice cream

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I think my research qualifies for exempt status, am I done?

No, exemption does not mean you do not apply. The authority to determine and confirm exempt status rests with the IRB and not with the investigator nor student advisor. Thus, an Exempt Screening Application Form is required for your exemption to be confirmed and granted by the IRB.

To receive a determination, complete the Harper College Exempt Protocol Form and return it to oir@harpercollege.edu.

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Are there special considerations for studies that include children or people who cannot give consent?

The consent form must be signed by the parent, guardian, or other responsible party if the study involves minors or others who are unable to sign suitable consent. Special provisions are to be made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. Factors in this judgment include age, maturity, and psychological state of the children. This judgment can be made for all children involved in the study or individual child, as the IRB deems appropriate.

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Do I need to notify the IRB every time I make a change to the study?

Yes. All changes (including study personnel changes) to a study must be approved by the IRB. Please complete and submit the attached Research Amendment Form .doc

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How do I renew my study approval?

If the IRB has not approved continuing review past the expiration date, new subjects should not be enrolled until the IRB approves the project for another year. The renewal must be submitted at

least 30 days before the expiration date. Renewals can be sent directly to the Office of Institutional Research in Building A, Room 317 for review by the IRB chair.

Studies that have expired due to submissions past the expiration date are subject to full review with a new application to the IRB.

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What if my study has expired?

The continuation of research after the expiration date is a violation of the regulations [21 CFR 56.103(al)]. Therefore, all research activities pertinent to the study should stop and no new enrollment should occur. You may submit a new application for the continuation of the project which will go through full IRB review. The IRB Chair will be pleased to provide necessary assistance to secure approval for this project with minimum delays.

All IRB protocols are approved for one year or less depending upon the level of risk. Continuing reviews are required at a frequency determined by the IRB at the time of approval to ensure the rights and welfare of research subjects.

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How long does data collected from a human research project need to be maintained by the PI?

IRB policy requires investigators to maintain their research records (includes data collection form(s) including source documents and case report form(s) for five years after completion of the study. For research, which falls under authority of other agencies or statues with longer research record retention requirements, the longer retention period applies.

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I have IRB approval from another institution. Do I have to submit a full IRB proposal to Harper College IRB?

Research conducted at Harper College that has been reviewed and approved by another qualified IRB may qualify for an Expedited IRB Review. The Principal Investigator must complete the Secondary Research Proposal IRB Application and submit this with:

1. the application materials from their home institution, and
2. a copy of their project approval from their home institution's IRB.

The items should be submitted to the IRB in Building A, Room 317 or electronically to oir@harpercollege.edu

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I am not a Harper College student, staff, or faculty member, but I wish to conduct research at Harper College. Do I need Harper College IRB approval?

It depends. Please call Katherine Coy at 847.925.6955 to discuss your research.

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What do I do if I want to access existing data that contains personally identifying information?

Existing data with personally identifying information (e.g., SSN, name, etc.) requires an approved Data Sharing agreement.

- Data Sharing Agreement Template
- Data Sharing Agreement Example

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What terminology is important to understand when conducting research involving human participants?

(Taken from the Code of Federal Regulations, Title 45, Part 46, Subpart A)

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, 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.

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

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that 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.

Vulnerable populations are groups of individuals who require additional measures to ensure that rights, privacy, welfare, and civil liberties are protected. These groups include children, prisoners, pregnant women, and people with mental, physical, and/or intellectual disability. People with intellectual disability are not officially considered a vulnerable population in the current code of federal regulations as there is no subpart devoted to this group. They are included here as their inclusion appears to be consistent with the spirit of the regulations. Refer to the current code of federal regulations for additional information concerning vulnerable populations.