

Harper College

Institutional Review Board Manual

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Institutional Review Board (IRB)

Authority: US Department of Health and Human Services 45CFR, Part 46

Policy:

In accordance with the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Harper College is committed to protecting the rights and privacy of all who participate as subjects in research conducted under the auspices of the College and to ensure that such subjects are aware of the rights and protections available to them. The basic principles of human subjects research are respect for persons, beneficence, and justice. Major responsibility for assuring this commitment is assigned to the Institutional Review Board (IRB) for review and recommendation to the President. The IRB is responsible for reviewing and approving all proposed research involving human subjects.

Composition and Jurisdiction of the Institutional Review Board (IRB)

The IRB will consist of five regular members: the Director of Institutional Research, a representative of the Provost, a Harper faculty member with experience in conducting quantitative research, a Harper faculty member with experience in conducting qualitative research, and a representative of another institution of higher education that offers advanced graduate level research curricula. The Harper faculty representatives will serve staggered a two year terms. An additional consulting member from the Harper faculty from the Philosophy department would be added to the IRB for deliberations requiring the full deliberation of the IRB.

All Human Subjects Research proposals not exempted from IRB review will be subject to review by this group. The IRB may: 1) approve a research proposal as submitted; 2) approve the proposal with specific modifications; 3) return the proposal to the investigator for more extensive modification; or, 4) reject the proposal because of violations of Human Subject privacy or other protections. Appeals of any IRB decision will be adjudicated by the College president.

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CONTENTS

Contents

Introduction	3
Background	3
Definitions.....	4
Procedure.....	4
Review Categories.....	5
Use of Existing or Secondary Data.....	5
Guidelines for External Research Projects.....	6
Use of Internet for Surveys/Recruiting Subjects.....	6
Informed Consent	7
Anonymous/Confidential.....	8
Policy Compliance.....	8
Investigator Assurances	10

Link for training to Website for training of IRB members as well as research Principal Investigators: To Be Determined

Introduction

The Institutional Review Board (IRB) at Harper College has the responsibility of ensuring that data derived from, or to be derived from, human subjects affiliated with Harper College is collected and used in a matter that complies with the requirements of the Code of Federal Regulations (45 CFR 46) and the US Food and Drug Administration 21CFR, Parts 50 and 56. The IRB will consist of the following members:

- Director of Institutional Research
- Representative from the Office of the Provost
- Harper faculty member familiar with quantitative research
- Harper faculty member familiar with qualitative research
- Representative of another institution of higher education that offers advanced graduate level research curricula
- Ethicist – [Consultant for Category III]

This guide was prepared to help researchers submit applications to the IRB for review. It discusses principles and policies related to the use of human subjects in research.

Background

Belmont Principles and Federal Regulations

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published its report entitled “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” The report sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those basic principles are respect for persons, beneficence, and justice.

Respect for persons recognizes the personal dignity and autonomy of individuals, and requires special protection of those persons with diminished autonomy, e.g., children. Researchers must get full consent from individuals before conducting research. Consent involves informing them about the research procedures, the purpose of the research, and the risks and anticipated benefits.

Beneficence entails an obligation to protect persons from harm by maximizing benefits and minimizing possible risks. The appropriateness of involving vulnerable populations must be demonstrated, and the consent process must thoroughly and completely disclose relevant risks and benefits.

Justice requires that the benefits and burdens of research be distributed fairly. Researchers should not select subjects simply because they are readily available. The federal government regulates research with human subjects. The Code of Federal Regulations (45 CFR 46) incorporates the ethical principles described in the Belmont Report and provides basic guidelines for the Institutional Review Board (IRB).

Definitions

Research – a formal and systematic process of gathering and analyzing information applying the scientific method to a study or problem, designed to contribute to generalizable knowledge. Research includes, but is not limited to:

- Interviews, surveys, focus groups, or observations that are designed to gather nonpublic information about individuals or groups.
- Studies of existing data, either public or private, where the identity of individuals are known.
- Studies designed to change subjects' physical or psychological states or environments.

Private Information - 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 that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Minimal Risk – minimal risk is when the probability and magnitude of physical or psychological harm anticipated by the research are not greater than those normally encountered in the subjects' daily lives. Minimal risk is affected by the context of the research, including characteristics of the subjects.

Procedure

Individuals intending to conduct research involving human subjects must complete a Research Proposal Form and submit it to the Harper College IRB. Note that Harper College does not make available any personal contact information for its employees and students to outside parties unless those parties are under contract with the college to perform college-related work that requires such information. This form contains a description of the intended projects, a description of the procedures to be used, and informed consent/assent forms for all participants. Outside parties requesting permission to conduct research involving Harper employees and/or students must address how the proposed research will benefit the mission and priorities of the college. Information regarding Harper's mission and priorities can be found on Harper's Website:

- Strategic Plan:
http://goforward.harpercollege.edu/about/administration/planning/college_p lan/in dex.php
- Institutional Effectiveness Measure & Accountability Report:
<http://goforward.harpercollege.edu/about/administration/accountability/index.php>
- Mission & Values:
<http://goforward.harpercollege.edu/about/administration/mission.php>

Upon receipt of these items, the IRB will review and categorize the proposal into one of three types: no review/exempt, expedited review, or full review. The IRB will respond directly to those proposals fitting the definition of no review. Within a month of receipt,

the IRB will respond to proposals requiring expedited or full review. Written confirmation of approval or disapproval will be sent to the researcher by the IRB chair or designee and kept on file in the Institutional Research office for a period of three years.

Please note that once the Research Proposal Form has been approved by the IRB, no changes can be made to the Research Proposal Form, consent/assent forms, protocol, or any other attachments. Any modifications to the research requires individuals to submit a Research Amendment Form. Copies of these forms are located at the end of this manual.

In addition, the Harper College IRB requires all researchers conducting human subjects research to complete a human subjects protection training online at [to be determined].

Review Categories

- i. **No Review/Exempt**
Research involving commonly accepted educational practices (e.g., testing, classroom observation) is exempt from IRB review. Included in this category are: typical exams given in class, student research assignments not involving human subjects; papers and projects; surveys; data reports conducted by Harper departments as a part of routine operations; and historical, archival, or ethnographic studies.

Proposals that the IRB chair or designee believes provide little benefit for Harper College, its students or employees, or research that may cause undue hardship for IRB members in terms of time or commitment will not be reviewed.
- ii. **Expedited Review**
Research that presents no more than a minimal risk to participants is subject to an expedited review. This category includes the collection of voice or video images and research on individual or group characteristics of behavior (e.g., cognition, language, cultural beliefs and practices, simple physical tasks, and so on).
- iii. **Full Review**
A full review is necessary when the research involves children, seriously ill or mentally or cognitively impaired adults, complex physical tasks, or the collection or recording of behaviors which could be damaging or stigmatizing to participants' reputation, financial standing, employability, insurability, physicality or the like.

Use of Existing or Secondary Data

If researchers plan to use data that already exist, the IRB must review the research if the data involve humans. If the data involve documents or records that are publicly available or if the information is recorded so that subjects cannot be identified directly or indirectly, the research will probably be reviewed at the Category I level.

All individuals or agencies wanting access to existing Harper College data containing personally identifiable information (e.g., student records) must complete a Data Sharing Agreement. This agreement specifies how data are to be gathered, used, and secured. A copy of this agreement is located on page 10 of this manual.

Guidelines for External Research Projects

The following guidelines apply to all external research projects involving Harper College. An external research project is defined as any research project or study not conducted directly by Harper College itself.

1. Normally, the College does not allow external persons or groups to conduct human subjects research, including surveys and focus groups, on its students. The College does not provide facilities of any type for external research projects.
2. Any external research project must demonstrate a direct benefit to the College in order for permission to be granted.
3. Before permission is granted, a written proposal must be submitted to the Director of Institutional Research. The proposal will include brief summaries of the rationale for the study, the methodology to be used, and the expected outcomes.
4. Unless the college feels that participation in a particular project is both educationally valuable and a natural part of the course content, class time will not be used for any project. In any event, the faculty member's permission must be obtained before class time will be used.
5. Participation in any project must be voluntary, and all participants should be informed as to the purpose of the project, as well as to what precisely participation will involve.
6. Students, faculty, or staff involved in any research project will not be identified when the findings of that project are published.

All inquiries and proposals should be submitted to:

Katherine Coy, Ph.D.
Director of Institutional Research
Harper College
1200 W. Algonquin Road
Palatine, IL 60067-7398
Tel: (847)925-6955
Fax: (847) 925-6055
Email: kcoy@harpercollege.edu

Use of Internet for Surveys/Recruiting Subjects

Internet research raises a number of complex issues for the research community. A few of the problems involved are the risks versus the benefits, consent, confidentiality, and the participation of minors. Researchers' claims about the benefits of their research depend in

large part on their ability to collect useful data. But conducting research on the Internet raises questions about data sampling techniques and the validity and reliability of the data collected. It is easy to mislead the researcher about geographical location, age, race, or gender. Minors may respond to a study involving inappropriate subject matter without the researcher knowing it.

Although survey research online is similar to traditional survey research, Internet research increases the subjects' risk of being identified or having their personal information accessed by people other than the researcher. The risk of exposure can surface at different stages, from data gathering, to data processing, to data storage and dissemination. Participants may not know that there is a record of the exchange in a cache somewhere on their system or saved in their Internet service provider's log files.

All Harper College researchers who are using Internet surveys must:

- Include the IR director's email address in addition to the IRB telephone number.
- Include either a statement saying there will be no future mailings or an opt-out message that permits addresses to have their names removed from any future mailings.
- If you plan future mailings, add a statement that says, "If you do not respond to this survey or return the "opt out" message, you will be contacted again with this request X times during the next X weeks. If you fail to respond, you will be dropped from the study."
- Use a blind copy format so that the list of recipients will not appear in the header.

Informed Consent

Researchers must obtain the signed **informed consent** of participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's **assent**, which is defined as the participant's agreement to participate in the study. (*Note: a signed consent form is not needed for most survey and focus group research; see number 9 below*).

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequence.
6. Statement regarding the participant's permission for the use of voice and/or image recordings.
7. An offer to answer any questions the participant may have.
8. Contact information of all Principal Investigators, and also contact information for Harper College's Director of Institutional Research, Katherine Coy, 847-925-6955.

9. Line for signature of participants and/or parents or legal guardian **except for questionnaire research in which return of questionnaire gives implied consent.**
10. Statement that participant is 18 years of age or older unless parent or legal guardian (includes high school administrator) has given consent.

In situations where participants will be intentionally **deceived** as part of the research design, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants “after the fact” in order to guarantee informed consent. (see sample consent form [here](#))

Anonymous/Confidential

In the consent form, researchers should explain clearly how they will use the collected data and how it will be handled. The most secure procedure is not to ask for names or any other identifying information—to keep the identity of the subjects completely anonymous. Only those studies that do not ask for names or any easily identifiable information may be described as anonymous. Anonymity means that the researcher cannot link the data to individually identifiable subjects.

Although anonymity may be useful for some studies, it is not practical for others. In studies that are not anonymous, subjects' data should be confidential. A coding procedure should be used in which each subject's identifying name or number is linked to a code number. The code number should be used on all data. A list linking the identifier to the code number should be kept secure, and a limited number of people should have access to the list. Researchers must tell subjects who will have access to the code list and what will happen to it upon completion of the study. When data are not anonymous, consent forms should include a statement such as, "We will take all reasonable steps to protect your identity." Researchers should not promise that they will maintain confidentiality, because any data could be obtained by court order.

Policy Compliance

The Harper College Institutional Review Board (IRB) is responsible for the review of all research involving human subjects conducted by people affiliated with Harper College. In regard to research activities affiliated with Harper College, the IRB has the authority to approve, require modifications in, disapprove, suspend, or terminate research activities involving human subjects that do not comply with the Harper College IRB policy. The IRB also has the authority to observe or monitor ongoing research, as necessary, to protect human subjects. It is the responsibility of the principal investigator and/or faculty sponsor to adhere to the IRB policies, to respond promptly to the IRB requests, and to notify the IRB of any changes to the research protocol. Violations of the IRB policy may include, but are not limited to the following:

1. Breaches of IRB policies and procedures by a principal investigator or other investigators.

2. Adverse events that are not immediately reported by the principal investigator or other investigators after causing physical, psychological, social, or other harm to participants.
3. Changes in the risks and benefits of a study encountered during the course of the research; and/or
4. Other circumstances which require action in order to protect human subjects from harm.

Violations of the Harper College IRB policies may result in any of the following sanctions:

1. The data may be rendered as unusable.
2. The IRB may request the surrender of documents.
3. A citation of violation of academic integrity may be entered in the individual's professional file.
4. The collected data may be destroyed.
5. The principal investigator and/or other investigators may be required to provide a letter of apology to research participants and representatives of external organizations including a plan of correction to address deficiencies in human participants protections.
6. The principal investigator and/or other investigators may be required to provide a memorandum addressed to the IRB explaining the actions of the investigator(s), acknowledging a violation of IRB policies and procedures, and providing assurances that future violations will not occur.
7. The principal investigator may be required to submit an acknowledgement in published work or work submitted for publication that the research did not conform to IRB policies and procedures.
8. The IRB may direct a formal memorandum of censure to the principal investigator, and, where appropriate, the principal investigator's faculty sponsor, department head, or dean (or any other recipient of the data); and/or
9. Other actions warranted by the specific circumstances surrounding the violation.

The Harper College IRB will make a determination regarding the need for additional information or further investigation. Any suspension or termination of approval will include a statement of the reasons for the IRB's suspension or termination action and the sanctions imposed. These will be sent promptly to the principal investigator and/or other investigators and any other necessary university representative. Any appropriate agencies may also be notified of terminations and/or suspensions of the research. A principal investigator who believes that there have been 'errors in fact' in relation to decisions made by the IRB may appeal those decisions to the Harper College President.

Investigator Assurances

The original signature of the Principal Investigator is required before an application can be processed (scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.

I agree to comply with all Harper College policies and procedures, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

I certify that:

- The project will be performed by qualified personnel in accordance with the Harper IRB Manual., as defined by
- The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- No change will be made to the human subjects protocol or consent form (s) until approved by the Harper College IRB.
- Legally effective informed consent or assent will be obtained from human subjects as required
- Unanticipated problems, adverse events, and new information that may affect the risk-benefit assessment for this research will be reported to the Harper College IRB Office.
- Student and guest investigators on this project are knowledgeable about the regulations and policies governing this research.
- I agree to meet with the principal investigator(s), if different from myself, on a regular basis to monitor study progress.
- If I will be unavailable, as when on sabbatical or other leave, including vacation, I will arrange for an alternate investigator to assume responsibility during my absence. I will advise the Harper College IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.