Harper College

Institutional Review Board Manual

Fall 2024

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.

HARPER COLLEGE INSTITUTIONAL REVIEW BOARD MANUAL

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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]

Additional members may be added as needed under the direction of the College President.

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.

Review Categories

1. **No Review**
   Non-research activities related to the College's outcomes assessment practices are not considered research and do not require 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.

   Note: If data collected is intended for presentation in any form outside of the College outcomes assessment activities, then additional review is required.

2. **Exempt Review**
   Research that is considered exempt <u>is</u> considered research with human subjects and is <u>not</u> exempt from review; it is, however, exempt from the provisions of the regulations. Furthermore, exempt research is subject to the ethical principles adopted by the College for conducting research with human subjects.

   Research involving commonly accepted educational practices (e.g., testing, classroom observation) are typically considered exempt research. These practices may be similar to the No Review category, but the results are intended to be shared in venues outside of the College's outcomes assessment practices.

3. **Expedited Review**
   Research that presents no more than a minimal risk to participants is subject to an expedited review. This category includes research on individual or group characteristics of behavior (e.g., cognition, language, cultural beliefs and practices, simple physical tasks, and so on); the collection of voice or video images; and collection of data through noninvasive procedures.

4. **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.

Harper Employee Research

Employees intending to conduct research involving human subjects must complete a Research Proposal Form and submit it to the Harper College IRB. There are two Research Proposal IRB Application forms (See Appendix 1 and Appendix 2).

The Research Proposal IRB Application (Primary) form is to be used if the Harper College IRB will be the only review panel. The Research Proposal IRB Application (Secondary) form is to be used if Harper College IRB will provide a secondary review of a proposal previously reviewed by an IRB at a different institution. A completed form will contain a description of the intended projects, a description of the procedures to be used, and informed consent/assent forms for all participants.

Upon receipt of these items, the IRB will review and categorize the proposal into one of four types: No review, exempt review, expedited review, or full review. The IRB Chair will respond directly to those proposals fitting the definition of no review or exempt 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 (3) 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 (See Appendix 3).

In addition, the Harper College IRB requires all researchers conducting human subjects research to complete a human subjects protection training online through CITI Programs. Information about this training is available on the employee portal.

Note: Faculty members who sponsor student research as part of their class activities must also complete CITI training.

Student Research

Learning how to conduct ethical human subjects research is an important part of a student's educational experience. Research activities that are designed as part of a course requirement for purposes of learning experience only and are not designed to develop or contribute to generalizable knowledge may not require IRB review and approval if all of the following conditions are true:

- The activity is a class assignment designed for learning purposes only and is not designed ***to develop or contribute to generalizable knowledge***.
- Results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes.
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.).
- Research procedures are no more than minimal risk.
- Vulnerable populations are not targeted (e.g., children under age 18 other than for educational research conducted in school classrooms or other commonly accepted educational setting), prisoners, persons who are cognitively impaired, etc.): If unsure, please consult the Office of Institutional Research.
- Data collected are recorded in such a manner that the subjects are not identifiable (Images in videotapes and photographs and voices on audiotape are identifiable.)
- When appropriate, an informed consent process is in place.

The course instructor is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including a process in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress. While not required, instructors are encouraged to incorporate CITI Program Human Subjects training into course curriculum.

When designing a project, students should be instructed about the ethical conduct of research and about the preparation of the IRB application when such is required. In particular, instructors and students should:

- understand the elements of informed consent
- develop appropriate consent documents
- plan appropriate strategies for recruiting subjects
- identify and minimize potential risks to subjects
- assess the risk-benefit ratio for the project
- establish and maintain strict guidelines for protecting confidentiality
- allow sufficient time for IRB review (if necessary) and completion of the project.

In making a determination of whether or not a student research requires IRB review, the instructor is encouraged to err on the side of caution and to contact the Office of Institutional Research at oir@harpercollege.edu for a determination.

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 for which the principal investigator is not an employee or student of Harper College OR the research is a component of the employee's graduate studies. Individuals or agencies under contract with the College should refer to the next section for procedures and protocols.

The College tries to support external research whenever possible and serves as a secondary IRB review.

1. To initiate this process, a written proposal must be submitted to the Director of Institutional Research for initial review. The proposal will include brief summaries of the rationale for the study, identify the population of interest, the methodology to be used, and the expected outcomes.

2. External research requests must be related to the mission and priorities of the college and the proposal should demonstrate how the college will benefit from the research. Information regarding Harper's mission and priorities can be found on Harper's Website:
    - Mission, Vision, Philosophy, Core Values: Harper College

3. Any external research project must have the support of a Harper Champion. A Harper Champion is an employee in a leadership position at the College who is connected to the research population of interest. The Director of Institutional Research will facilitate the identification of an appropriate Harper Champion.

4. Class time for the project may be permitted if the project is both educationally valuable and a natural part of the course content. In addition, the faculty member's permission must be obtained before class time can 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:

Dr. Anna Strati
Director of Institutional Research & Analytics
Harper College
1200 W Algonquin Road, Palatine, IL 60067-7398
847.925.6955
sa13033@harpercollege.edu

Collaborative Research

Collaborative research is defined as research conducted in cooperation with an institution or agency that is not affiliated with Harper College. When two or more institutions are engaged in research, multiple IRBs are responsible for providing oversight. To avoid duplicative review, a Data Sharing Agreement or Memorandum of Understanding (MOU) may be arranged to establish one IRB as the designated IRB of Record.

A Data Sharing Agreement or MOU is a formal, written document that provides a mechanism for shared understanding of the purpose of the research and the responsibilities of each participating party. Before Harper enters into an agreement with another entity, the Data Sharing Agreement or MOU should be reviewed by the Director of Institutional Research. (See Appendix 4 for an Example Data Sharing Agreement).

Use of Existing or Secondary Data

For the purposes of IRB review, existing data are data not generated by the researcher. Existing data may be in the form of individual records (e.g., academic, medical, financial), data sets, interview notes, biospecimens, online profiles and posts (e.g., social media), and audio- or video-recordings. These data could be available for purposes other than research, and are sometimes, but not always, identifiable.

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 likely fall within the Exempt Review category.

All 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.

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)*. See Appendix 5 for a sample informed consent form.

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.

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. Regarding 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:

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. 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
4. Other circumstances which require action 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 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.

APPENDICES

Appendix 1: Research Proposal IRB Application (Primary)

HARPER COLLEGE
RESEARCH PROPOSAL IRB APPLICATION (PRIMARY)

Please fill out the following information and return this form to Institutional Research along with:

- Summary Abstract
- Protocol
- Consent/assent forms

I. Basic Information

_____
Title of Research Project

_____
Principal Investigator/Project Director Department

_____
Phone Number email Address

_____
Co-investigator Department

_____
Phone Number email Address

Projected Start Date: _____ Projected Duration of Research:_____

Other organizations and/or agencies, if any, involved in the study: _____

Project Classification: _____New Project _____ Periodic Review of Continuing Project

II. Summary Abstract

Please attach a description that addresses the following questions. In your abstract, please reference each section by letter and title.

A. Objectives/goals of the research (What are the goals of the research to be conducted? What are the research questions?)
B. All subjects/participants in the research (Who will be the participants in the research? How many participants do you anticipate?)
C. Solicitation of subjects' participation (How will participants be contacted? Any incentives given for participation?)
D. Location of the research (What are the different locations that the research will be conducted? Has permission been obtained for research to be conducted outside of Harper College?)

E. Description of all methods to be used for data collection (What are the various procedures that will be used in collecting the data?)
F. Benefits/risks (Describe the potential benefits and risks associated with your study)
G. Disposition/confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)
H. Dissemination of results (Describe how the results of the research will be disseminated. With whom will the results be shared?) Please note: a copy of the final report/results will be due to the IRB upon completion of the study.

III. Protocol

Please attach a copy of all the protocol to be used in the study. This includes any questionnaires, surveys, recruitment letters, flyers, interview questions, focus group questions, etc.

IV. Consent Forms

Please attach a copy of all consent/assent forms to be signed by the participants and/or any statement to be read to the participants regarding their participation in the study. A sample consent form is included in the IRB manual.

V. Please read and 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.

NOTE: The original signature of the Principal Investigator must be submitted before IRB review (scanned or faxed signatures are acceptable).

Principle Investigator Signature/ Date: _____/_____

**********For internal Use only**********

IRB Chair (Check 1 Box):	Approved	Approved w/ Conditions	Not Approved	IRB Chair Initials:
LEVEL (Check 1 Box):	1, Exempt; Research Office Only	2, Expedited Review	3, Full Committee Review	Date Reviewed:

IRB Chair Signature: _____

Appendix 2: Research Proposal IRB Application (Secondary)

HARPER COLLEGE
RESEARCH PROPOSAL IRB APPLICATION (SECONDARY)

Please fill out the following information and return this form to Institutional Research along with:

- Summary Abstract
- Protocol
- Consent/assent forms

I. Basic Information

_____
Title of Research Project

_____
Principal Investigator/Project Director Department

_____
Phone Number email Address

_____
Co-investigator Department

_____
Phone Number email Address

Projected Start Date: _____ Projected Duration of Research:_____

Other organizations and/or agencies, if any, involved in the study: _____

Project Classification: _____New Project _____ Periodic Review of Continuing Project

II. Summary Abstract

Please identify the section and item from home institution's IRB application that addresses the following questions. Please do not reference the entire Home IRB application, but rather note the section and item at the end of each question.

a. Objectives/goals of the research (What are the goals of the research to be conducted? What are the research questions?)
b. All subjects/participants in the research (Who will be the participants in the research? How many participants do you anticipate?)
c. Solicitation of subjects' participation (How will participants be contacted? Any incentives given for participation?)
d. Location of the research (What are the different locations that the research will be

conducted? Has permission been obtained for research to be conducted outside of Harper College?)

e. Description of all methods to be used for data collection (What are the various procedures that will be used in collecting the data?)
f. Benefits/risks (Describe the potential benefits and risks associated with your study)
g. Disposition/confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)
h. Dissemination of results (Describe how the results of the research will be disseminated. With whom will the results be shared?) Please note: a copy of the final report/results will be due to the IRB upon completion of the study.

III. Protocol

Please attach a copy of all the protocol to be used in the study. This includes any questionnaires, surveys, recruitment letters, flyers, interview questions, focus group questions, etc.

IV. Consent Forms

Please attach a copy of all consent/assent forms to be signed by the participants and/or any statement to be read to the participants regarding their participation in the study.

V. Please read and 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.

Principle Investigator Signature/ Date: _____/_____

Note: The original signature of the Principal Investigator must be submitted (scanned signatures acceptable.)

VI. Home Institution IRB Approval

Please attach a copy of the home institution's IRB application and approval letter.

**********************For internal Use only**********************

IRB Chair (Check 1 Box):	Approved	Approved w/ Conditions	Not Approved	IRB Chair Initials:
LEVEL (Check 1 Box):	1, Exempt; Research Office Only	2, Expedited Review	3, Full Committee Review	Date Reviewed:

IRB Chair Signature: _____

Appendix 3: Research Amendment Form

_____/_____/_____ _____

Date Submitted **File Number**

HARPER COLLEGE INSTITUTIONAL REVIEW BOARD

RESEARCH AMENDMENT FORM

For Submitting Changes to Previously Approved
Human Subjects Research

All modifications to human subjects research must be reviewed and approved prior to implementation.

Minor modifications – Minor modifications to previously approved projects include those that do not alter the risk-benefit assessment for research. Examples include changes in the investigators; minor changes in the consent form, recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experiences with the protocol.

Major modifications – Major modifications to previously approved projects include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a deceased benefit; or that otherwise result in alienation of the risk- benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

Title of Research Project

_____ _____

Principal Investigator/Project Director **Department**

_____ _____

Phone Number **Email**

Major or Minor Modification? In the Principal Investigator's judgment, which category of modification is this?

Major _____ Minor _____

Please supply the following with this research amendment form:

1. An amended Research Proposal Form showing the revisions to the project
2. Revised consent documents, protocol, and other relevant attachments that have changed as a result of the amendment

Describe the Amendment. Describe the request change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk-benefit assessment for the research is likely to change as a result of the proposed amendments(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject population(s), research sites, or the confidentiality of private, identifiable subject information.

Describe the amendment in this section

The original signature of the Principal Investigator is required before this form can be processed.

I certify that the information provided in this form, with attachments, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IRB approval has been obtained.

Principal Investigator Name	Signature	Date
Second Investigator Name	Signature	Date
Third Investigator Name	Signature	Date

Appendix 4: Example Data Sharing Agreement

DATA SHARING AGREEMENT
between **Harper College** and

[INSERT NAME]

This Data Sharing Agreement is intended for individuals interested in gaining access to existing data that contains personally identifiable information (social security numbers, names, etc.) belonging to Harper College.

Individuals interested in gathering new or original data involving current, prospective or former students; employees; or others affiliated with Harper College must complete a Research Proposal Form rather than this agreement.

This Data Sharing Agreement is entered into by and between Harper College and _____ to establish the content, use, and protection of data needed by _____ to support the contracted service, whether such data is provided by Harper College or collected by on behalf of Harper College.

1.0 Period of Agreement

The period of this Agreement shall be in effect from _____ until _____, or until terminated in writing by either organization.

2.0 Intended Use of Data

Describe the intended use of data in this section.

3.0 Constraints on Use of Data

Data supplied by Harper College to or collected by on behalf of Harper College's students, prospective students, employees, or alumni is the property of Harper College and shall not be shared with third parties without the written permission of Harper College.

Customer data shall not be sold or used, internally or externally, for any purpose not directly related to the scope of work defined in this agreement without the written permission of Harper College.

4.0 Data

4.1 Security

_____shall employ industry best practices, both technically and procedurally, to protect Harper College data from unauthorized physical and electronic access. Methods employed are subject to annual review and approval by Harper College.

4.2 Data Elements

Data shared with _____ shall be limited to the data elements specifically defined and authorized by Harper College. If _____ wishes to collect additional data, _____ must submit a request in writing to Harper College. Under no circumstances shall _____ collect any information classified as Sensitive or Confidential without the express written approval of Harper College.

Data to be shared or collected shall be limited to the following elements:

Describe the data elements in this section

4.3 Data Categories

The following definitions shall be used to classify data for security purposes:

Normal: The least restrictive class of data. Although it must be protected from unauthorized disclosure and/or modification, it is often public information or generally releasable under College procedures for processing public records requests. Examples of this class of data are: class schedules, course catalogs, general ledger data, and employee demographic statistics.

Sensitive: This class includes data for which specific protections are required by law or for which agencies are obligated to prevent identity theft or similar crimes or abuses. Examples of this class of data are: peoples' names in combination with any of the following: driver's license numbers, birth date, employee ID number (EID), address, e-mail addresses, telephone numbers. Also included are: agency source code or object code, agency security data, education records including papers, grades, and test results, or information identifiable to an individual that relates to any of these types of information.

Confidential: This class includes those data elements that are either passwords in the traditional sense or function in the role of an access control such as a credit card number, expiration date, PIN, and card security code. Access to these elements are tightly controlled and audited. Examples of these data are: Social Security Numbers (SSN), credit card numbers, expiration dates, PINs, and card security codes, financial profiles, bank routing numbers, medical data, law enforcement records.

4.4 Data Handling Requirements

Data handling requirements may vary depending on the classification of data shared with _____. It is anticipated, however, that most data shared with _____ will involve a mix of data classes including Sensitive and possibly Confidential information. Therefore, whenever data elements are aggregated for collection, transmission, or storage, the aggregate data shall be handled using the protocols that apply to the most sensitive data element.

5.0 Personnel

5.1 Access to Data

_____ shall limit access to Sensitive and Confidential data to those staff members with a well-defined business need.

5.2 Security Training

_____shall provide periodic training for staff on internal security policies and procedures, and on applicable state and federal legal requirements for protecting Sensitive and Confidential data.

5.3 Criminal Background Checks

_____ shall certify that all staff members with access to confidential information have been subjected to an official criminal background check and have no record of any felony convictions. Any exceptions to this requirement must be approved in writing by Harper College.

5.4 Prohibition on Mobile Devices and Removable Media

_____ shall have a written policy prohibiting the transfer or storage of unencrypted customer information on employee mobile

devices or removable storage media for any reason. This policy shall be made available to each employee individually and shall be strictly enforced.

6.0 Compliance with Applicable Laws and Regulations

_____ shall comply with all applicable federal laws and regulations protecting the privacy of citizens including the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA).

Where applicable, _____ shall also comply with all provisions of the Financial Services Modernization Act (the "Gramm-Leach-Bliley Act").

7.0 Indemnification

_____ shall defend, indemnify, release, and hold Harper College harmless from and against all Claims, Losses, and Expenses when arising out of or incidental to this Agreement regardless of the negligence or fault of the person.

8.0 Amendments and Alterations to this Agreement

Harper College and _____ may amend this Agreement by mutual consent, in writing, at any time.

9.0 Termination of Services

In the event Harper College or _____ terminates this Agreement, or _____ ceases operation, _____ shall return to Harper College all data collected in the course of providing the application service.

_____shall certify in writing within five business days that all copies of the data stored on _____ servers, backup servers, backup media, or other media including paper copies have been permanently erased or destroyed.

By the signatures of their duly authorized representative below, Harper College and _____, intending to be legally bound, agree to all of the provisions of this Data Sharing Agreement.

_____
Entity Name

Address: _____

By: _____

Title: _____

Signature: _____

Date: _____

Harper College
1200 W Algonquin Rd, Palatine, IL 60067

By: _____

Title: _____

Signature: _____

Date: _____

Appendix 5 – Sample Informed Consent

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving ***informed consent***. (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine [statement of study goals]. In this study, you (your child/ward) will be asked to [description of participant's activities]. Your (and your child's/ward's) participation should take about _____ minutes.

There are no risks to you (your child/ward). **OR** The only risks to you (your child/ward) include [comprehensive list of risks].

Benefits of this study include [description of benefits].

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported. Any voice or image recording of you that is used during this study will be kept confidential and destroyed after use.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply [instructions on procedure/protocol].

Please feel free to contact [names(s), title(s) of principal investigators] at [phone and/or email address] if you have any questions about the study. For other questions, contact the Director of Institutional Research & Analytics, Dr. Anna Strati, at 847.925.6955 or oir@harpercollege.edu.

If the participant is of age (18 years old or older), use:
I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____ _____
Signature of Participant Date

If the participant is not of age, use:
I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

_____ _____
Signature of Parent or Guardian Date

ASSENT format:
I understand what I must do in this study and I want to take part in the study.

_____ _____

Signature of Child/Ward Date