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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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 21 CFR, 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. 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. 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 (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. 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: Doug Easterling
Director of Institutional Research
Harper College
1200 W. Algonquin Road
Palatine, IL 60067-7398
Tel: (847)925-6955
Fax: (847) 925-6055
Email: deasterl@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 8 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, Doug Easterling, 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. 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 this 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.

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

________________________________________________________________________

Principal Investigator    Date    Investigator
Date
APPENDICES

1. Research Proposal Form.......................................................... 12
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Link for training to Website for training of IRB members as well as research Principal Investigators: To Be Determined
Appendix 1

Date Submitted                                           File Number

HARPER COLLEGE
INSTITUTIONAL REVIEW BOARD

RESEARCH PROPOSAL FORM

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

- Summary Abstract
- Protocol
- Consent/assent forms

I. Basic Information

Title of Research Project

Principal Investigator/Project Director            Department            Phone
Extension                        email Address

Co-investigator                          Department            Phone Extension
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

Signature of IRB Director:                     Date:
II. Summary Abstract

Please attach a description that addresses the following questions:

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 on the following page.
Appendix 2

HARPER COLLEGE
INSTITUTIONAL REVIEW BOARD

SAMPLE INFORMED CONSENT

To Be Used For Non-Exempt Research (It is not necessary to use this form for survey research in which return of questionnaire gives implied 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 __________________________________________________________________________. In this study, you (your child/ward) will be asked to __________________________________________________________________________. Your participation should take about ____ minutes.

There are no risks to you (your child/ward). OR
The only risks to you (your child/ward) include __________________________________________________________________________.

Benefits of this study include __________________________________________________________________________.

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 ____________________________________________________________

Please feel free to contact __________________________ (names(s), title(s) of principal investigators) at _____________ phone) if you have any questions about the study. Or, for other questions, contact the Director of the Institutional Research, Douglas Easterling, at 847-925-6955.

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/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
DATA SHARING AGREEMENT

Between

Harper College District 512

And

TWP HS District 211

TWP HS District 214

Community Unit School District 220

This Data Sharing Agreement is intended to cover circumstances in which the above-named districts need access to data that contains personally identifiable information (social security numbers, names, etc.) belonging to current and former students. These circumstances include the following purposes intended to improve educational opportunities for the residents of these districts:

1. Increase collaboration between secondary and post secondary systems;
2. Reduce the need for College remediation;
3. Promote greater awareness of post secondary educational options including financial aid and academic resources;
4. Create seamless transition systems from secondary education to postsecondary education;
5. Ensure that individuals who are members of special populations have the opportunity to access and succeed;
6. Develop career pathways that contain multiple entry and exit points to facilitate student success and lifelong learning;
7. Increase curricular alignment and reduce curricular duplication;
8. Support the development of integrated and applied curricular content;
9. Increase the opportunities for students to earn college credit while enrolled in high school;
10. Increase the opportunities for students to obtain marketable postsecondary certificates or degrees that support their career goals;
11. Create professional development programs designed to simultaneously engage and support secondary and postsecondary partners;
12. Utilize data for program improvement.
1.0 Period of Agreement
The period of this Agreement shall be in effect from September 2010 until terminated in writing by a partner organization.

2.0 Constraints on Use of Data
Data supplied by the parties to this Agreement or collected by on behalf of the parties’ students, prospective students, employees or alumni is the property of the parties to this Agreement and shall not be shared with third parties without the written permission of the parties to this Agreement. 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 the parties to this Agreement.

3.0 Data Security
The parties to this Agreement shall employ industry best practices, both technically and procedurally, to protect the data from unauthorized physical and electronic access. Methods employed are subject to annual review and approval by the parties to this Agreement.

3.1.1 Data Elements
Data shared shall be limited to the data elements specifically defined and authorized by the parties to this Agreement. If one or more of the parties wishes to collect additional data, they must submit a request in writing to the other parties. Under no circumstances shall any of the parties collect any information classified as Sensitive or Confidential without the express written approval of the parties to this Agreement.

3.2 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 procedures of 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, student ID number (SID), 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: Access to these elements are tightly controlled and audited. Examples of these data are: Social Security Numbers (SSN), financial profiles, medical data, and disciplinary records.

3.3 Data Handling Requirements
Data handling requirements may vary depending on the classification of data shared with each of the parties. However, it is anticipated that most data shared with the parties to this Agreement 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
The parties to this Agreement shall limit access to Sensitive and Confidential data to those staff members with a well-defined business need.

5.2 Security Training
The parties to this Agreement 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.

5.2 Criminal Background Checks
The parties to this Agreement shall certify that all staff members with access to confidential information have been subjected to a bone fide criminal background check and have no record of any felony convictions. Any exceptions to this requirement must be approved in writing by the parties to this Agreement.

5.3 Prohibition on Mobile Devices and Removable Media
The parties to this Agreement 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
The parties to this Agreement 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, the parties to this agreement shall also comply with all provisions of the Financial Services Modernization Act (the “Gramm-Leach-Bliley Act”).
7.0 **Indemnification**  
The parties to this Agreement shall defend, indemnify, release, and hold said parties 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**  
The parties to this Agreement may amend this Agreement by mutual consent, in writing, at any time.
Appendix 4

Data Sharing Agreement: Community College District 512 & Other Outside Parties

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 Project Intake Form rather than this agreement.

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

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

5.0 Intended Use of Data
Describe the intended use of data in this section.
6.0 **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.

7.0 **Data 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.

7.1.1 **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*

7.2 **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.

7.3 Data Handling Requirements
Data handling requirements may vary depending on the classification of data shared with ____________________________ . However, it is anticipated 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.

5.2 Criminal Background Checks
_________________________________________ shall certify that all staff members with access to confidential information have been subjected to a bonafide criminal background check and have no record of any felony convictions. Any exceptions to this requirement must be approved in writing by Harper College.

5.3 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”).

8.0 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.

9.0 Amendments and Alterations to this Agreement

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

10.0 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 [Name], intending to be legally bound, agree to all of the provisions of this Data Sharing Agreement.

[Name]
Address: __________________________

By: ________________________________
Title: ______________________________
Telephone: _________________________
Email: _____________________________

Signature: _________________________
Date: ______________________________

Harper College
1200 W. Algonquin Rd.
Palatine, IL 60067

By: ________________________________
Title: ______________________________
Telephone: _________________________
Email: _____________________________

Signature: _________________________
Date: ______________________________
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

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<tr>
<th>Principal Investigator/Project Director</th>
<th>Department</th>
<th>Phone Extension</th>
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Major or Minor Modification? In the Principal Investigator’s judgment, which category of modification is this?
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.

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.

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<th>Principal Investigator</th>
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