Committee for Human Subjects Research

Policies and Procedures

Last Revised: September 29th, 2022

Purpose and Background Information

Mission

The goal of the Committee for Human Subjects Research (CHSR) is to protect the rights and welfare of all human beings that participate in research. The purpose of the committee is to review all research conducted by faculty, staff, and students (whether independent of or in conjunction with other institutions or groups) that involves human subjects or participants.

The following document will spell out in detail the types of research that do and do not fall under the auspices of the committee. Although Hastings College is not mandated federally to require approval from CHSR, Hastings College is requiring Submission of research proposals is required by all staff, fa is voluntary, but faculty members and students are strongly encouraged to submit proposals for their work and the work of their students in electronic form to the current committee chair, using the proposal form, signature page, and consent forms.

Committee Logistics

The Committee for Human Subjects Research is a permanent subcommittee that reports to the Faculty Affairs Committee. It consists of elected faculty members and an institutional researcher, with varied representation from the following areas:

- Math, Science, and Business Division
- Fine Arts and Humanities Division
- Division of Education and Social Sciences
- Hastings College Institutional Researcher

Historical Background

Committees that oversee research involving human subjects now exist at many institutions, and are mandatory if the institution (or a particular research project) receives federal grant money. While Hastings College does not currently have the obligation to be in compliance with the federal regulations, our goal is to have all research conducted at Hastings College follow the federal guidelines. These guidelines are spelled out in the *Code of Federal Regulations* (Title 45, Part 46), implemented by the Office of Human Research Protection (OHRP), which is in turn overseen by the Department of Health and Human Services (DHHS). With some revisions, the *Code* goes back to the 1974 National Research Act, which contained the first federal regulations to protect human subjects in the U.S. The Act can be traced historically to decades of debate on the ethics of human subject research that followed the establishment of the Nuremberg Code, the international legal response to the atrocities

committed in the name of science at Nazi concentration camps during the Third Reich. (For more information, please consult the relevant government websites, especially http://www.hhs.gov/ohrp/index.html).

Ethical Guidelines

The following is a summary of the general ethical guidelines (as described in the *Belmont report: Ethical principles and guidelines for the protection of human subjects of research,* 1979) that underlie federal ethical regulations and guidelines.

1) **Respect for persons.** Researchers must recognize the personal dignity and autonomy of individuals. Each participant must be given an informed consent form that contains the information about the purpose of the study and study procedures, as well as the voluntary nature of participation.

2) **Beneficence.** Researchers are obligated to protect people from harm by maximizing anticipated benefits and minimizing possible risks of harm, ensuring a favorable balance between the two. Risks may include physical harm, psychological harm, harm to one's reputation or employment status, and financial harm.

3) **Justice.** Researchers must fairly distribute the benefits and burdens of research. That is, participants should be fairly selected with respect to membership in social, racial, or ethnic groups. For example, participants cannot be selected only because they are favored or disliked by a researcher. A researcher may be required to defend a decision about why a particular class of participants was chosen.

In addition to the above principles, CHSR will also consider the following *American Psychological Association* ethical principles when evaluating research proposals. For more information on the APA Code of Conduct, see https://www.apa.org/ethics/code.

1) **Informed consent.** To make an informed decision about participating in the study, participants must be informed of the following:
    a. The purpose and design of the study,
    b. Any risks (physical or psychological/emotional), expected duration, or other factors that might affect their decision to participate;
    c. The procedures involved in the experiment or study;
    d. Any possible benefits of participating;
    e. That they can withdraw from the study at any time without consequences;
    f. Whom they can contact if they have questions/concerns about the study.

    *Research involving infants, minors, individuals with impairments, or detained individuals must include special safeguarding procedures. Please consult CHSR if you will be conducting research on any vulnerable populations.

2) **Minimize risks and maximize benefits to research participants.** Avoid using procedures that may cause stress or harm to the participant. If the risk to the participant i greater than the benefits of the experiment or study, the study will not be approved and data should not be collected at any time.
3) **Do not coerce participants**. Researchers should realize that they are often in a position of authority or influence over participants who may be their students, employees or clients. This relationship must not be allowed to coerce the participants to take part in, or remain in, an investigation. Therefore, people should not be forced to participate in a study.
4) **Maintain privacy**. Results must be kept confidential, if not anonymous. Proposed studies should specify how confidentiality or anonymity will be maintained, especially when dealing with FERPA related documents.
5) **Anonymity**. Individual data from an experiment should not be linked with participants' names; therefore, research ID numbers should be used to identify participants' data. In cases where identification of individual participants is necessary for the purposes of the study (e.g., medical information, diagnoses, treatment options), only the Principal Investigator should be able to match the data with the associated participant.
6) **Confidentiality**. Anything learned about a research participant is held in strictest confidence. The researchers:
    a. Must keep data in a controlled situation (e.g., for hard copy data: locked file cabinet; locked google drive not owned by the student),
    b. Must minimize the number of people who see or handle the data,
    c. Must not discuss a participant and his/her data (e.g., personal information, performance, answers) with anyone who is not a collaborator on the same project.
7) **Avoid deception**. Participants should be completely and fully informed about the nature of the research project before participating. In some situations (e.g., study of social phenomena), mild deception may be necessary to ensure the participants act naturally. If research investigators do use deception, a debriefing form should be given or read to the participants at the end of the study.
8) **Debriefing**. Immediately after data collection ends, participants should be informed about the actual purpose of the study. Researchers should explain any deception that occurred.

Research Reviewed by the Committee

The committee requires that all research projects involving human subjects conducted by Hastings College faculty, staff, or students be reviewed and approved before the research is initiated. The purpose of the review is to ensure that human subjects are protected in a manner consistent with federal regulations, so that:

1. Risks to subjects are minimized relative to benefits,

2. Selection of subjects is equitable,
3. Informed consent is sought and properly obtained,
4. Privacy and safety rights of subjects are protected and confidentiality is maintained.

Additionally, formal research or study review may be required by other entities, especially when in collaboration with outside institutions. For example, research supported by federal funds is required by law to be reviewed, and many academic disciplines require review of research as part of their codes of ethics. CHSR does not expect to review research conducted for the sole purpose of monitoring and improving the performance of the College or one of its constituent parts (i.e., for administrative purposes), such as student evaluations of teaching. Projects that reuse existing data without collecting any new data may not need to be reviewed by CHSR, contact CHSR for any inquiries.

Note: If there is any doubt about whether a particular project should be reviewed, we encourage the researchers to consult the chair(s) of the CHSR for advice.

Classroom Projects

Studies conducted by students as part of a classroom assignment, independent study, or senior project often qualify as research and may place their subjects at risk, and are thus should be reviewed like any other research. Not all such studies place their subjects at risk, so the Committee offers guidelines to help instructors determine whether they should submit class projects for review. If you are currently a student, please consult with CHSR or your supervising faculty member. The faculty member, in collaboration with CHSR, will make the determination of whether or not CHSR review is necessary.

Definitions

Full definitions of all relevant terms may be found under Title 45 of the *Code of Federal Regulations*, Part 46, Section 102 (45 CFR 46.102, which can be viewed at the Web site of the Office of Human Research Protection, definitions). Here we summarize a few of the most important definitions.

1) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research [and are deemed exempt from review through CHSR. If you are still uncertain as to what is considered 'exempt,' please contact CHSR for more information]:

a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations, surveys, or tests.

3) *Vulnerable population* is not defined precisely by the Office of Human Subjects Research; however, the Office does list the following examples of such populations: children, prisoners, pregnant women, handicapped or mentally disabled persons, and economically or educationally disadvantaged persons.

Review Procedures

The review process for a research project consists of the following steps.

1. The Principal Investigator submits a completed proposal form and signature page to the chair of the CHSR via email, a signed copy of the signature page, and a consent form and other documents if needed. The various forms mentioned in the previous sentence are available from the website here. Send all required documents to chsr@hastings.edu.

2. The chair will first determine whether the proposal needs to be evaluated by the full committee, whether the project is exempt from review, or whether it qualifies for expedited review. A project that is not exempt and does not qualify for expedited review must undergo a full review. Here are brief descriptions of the requirements a project must satisfy to qualify for each of these categories, as well as the manner in which it is evaluated:

a. **Exempt.** A project in which the participants remain anonymous (if consent forms are used or required, your study may not be able to meet the exempt category), are not chosen from a vulnerable population, and are exposed to minimal risk qualifies as exempt from review. However, a project involving deception cannot qualify as exempt. A project that is exempt is likely to be approved, unless the CHSR chair(s) find needed modifications or revisions.

b. **Expedited.** A project that is not exempt from review, but still exposes the participants to minimal risk, qualifies for expedited review. Such a project may draw its participants from a vulnerable population or their identities may be known to the researcher(s) but kept confidential, or it may involve deception. The proposal for a project in this category is forwarded by the chair(s) to a member of the Committee who has expertise in the subject matter of the project for further evaluation. The decision of that member on the status of the proposal, which is reached in consultation with the chair, is final.

c. **Full.** A project that does not qualify for expedited review is subject to full review. Such a project may draw participants from a special population or expose them to more than minimal risk (e.g., any study that collects medical information or has medical procedures, has physical activity, may have psychological discomfort, and or collects sensitive information or material). The proposal for a project in this category is sent to all members of the Committee, who then discuss and vote on it. A majority of the votes, approval from the chair(s), and a majority within at least 2 divisions is necessary for CHSR approval. <u>Proposals that have not been approved can not be conducted.</u>

3. Once the status of a proposal has been determined, the chair notifies the supervising representative of the result, which is normally one of the following three possibilities:

a. **Approved**. The project may proceed as proposed.

b. **Approved pending specific minor revisions.** This means that a small number of straightforward and easily verified modifications are required. The chair will verify that the required revisions have been made, perhaps in consultation with other reviewers. Once verification is complete the Principal Investigator is notified by the chair and the project may proceed as revised.

c. **Revise and resubmit**. A proposal given this status requires significant revisions that are directly related to ethical considerations. A revised proposal must be submitted and will be reviewed as though it were a new proposal.

Important note: Research activities may not commence until the project proposal has been approved. Additionally, any changes made to the proposal after approval needs to be re-approved by CHSR. Investigators should not change any research protocol from what they have originally submitted.

The Committee reserves the right to disapprove any project that it believes violates ethical conduct and principles.

Guidelines for Informed Consent and Debriefing

Informed Consent

Please be sure that the information in the informed consent documents matches the information in the research proposal exactly. In particular, all risks mentioned in the research proposal should be stated in the informed consent documents, along with the procedures that will be used to minimize those risks.

The purpose of the consent form is to give participants enough information to allow them to make an informed decision about whether or not they would like to participate. The language used should be completely clear and non-technical, and there should be no grammatical or spelling errors.

Basic Elements of Informed Consent

Every consent form must include the following basic elements (see 45 CFR 46.116):

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In particular, the following information concerning the participants' rights must be stated prominently and in plain language on every consent form:

1. Their participation is voluntary.
2. They may withdraw from the study at any time during the data collection session or afterward. Withdrawal from the study will not affect any compensation to which they would otherwise be entitled. Potential participants expecting "extra credit" from their instructor for their participation must be informed that the instructor is required to offer a reasonable, comparable option so as not to coerce the students into being subjects or unduly influence them.
3. All information is confidential and will be used for research purposes only.

Groups Requiring Special Safeguarding Procedures

If infants, minors, individuals with impairments, or detained individuals are to be included in the research, special procedures for obtaining informed consent are required, as explained below.

1. **Infants.** Consent must be obtained from parents or from those serving in loco parentis (e.g., legal guardians).
2. **Minors** (children under 19 years of age in the State of Nebraska). Consent must be obtained from both parents/legal guardians and the minor.
3. **Individuals with impairments**. In situations where individuals may not be able to fully understand the study or communicate their decision to participate, researchers should consider employing a comprehension tool and/or having an advocate who is capable of understanding the individual's reaction and decision (e.g., close family member, therapist) present during the informed consent process.
4. **Detained individuals** (e.g., prisoners). Particular care should be taken over informed consent, paying attention to the special circumstances that may affect the person's ability to give free informed consent, such as mechanical restraint or isolation.

Debriefing

Not all research projects require a debriefing. The aim of a debriefing is to inform the participants of the purposes of the study and to minimize any negative effects of the study. Debriefing can be accomplished via written and/or oral means. As in the informed consent document, the language should be clear and non-technical, and the debriefer should allow the subjects to ask questions. Debriefings are particularly important if deception is involved or if the study involves sensitive topics. It is the researcher's responsibility to minimize any negative feelings that a subject may have as a result of participating in the study. Debriefing can also be used to share important contact information to participants in cases where research was related to something emotionally or psychologically uncomfortable.

Informed Consent Form Template

The Committee has developed a template for informed consent forms and strongly encourages its use.

Guidelines for Classroom Projects Using Human Subjects

Many projects conducted to fulfill course requirements involve research with human subjects. Occasionally, such research entails certain risks to these subjects. Because faculty and students vary in expertise regarding research procedures designed to protect the rights of human subjects, the committee recommends the following guidelines regarding classroom-based research projects. These guidelines are intended to make clear which types of projects should be reviewed by the CHSR and which do not need committee approval. Instructors who have questions about whether a particular project should be submitted for review are advised to contact the chair of the CHSR.

Conditions under which approval by the CHSR is required.

A project should be reviewed if it satisfies **any** of the following conditions:

- The project can identify the subjects by direct correlation, by the responses to specific questions, or by specific behaviors.
- The project involves the use of subjects under the age of 19 years
- The project systematically selects subjects from a vulnerable population, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, and collects data from them regarding their opinions, behavior, or experiences.
- The subjects are placed at more than minimal risk;
- The project involves deception;
- The project involves a high degree of physical or mental exertion;

- The results might be published, presented, or distributed in a public forum (including Academic Showcase).
- The project proposes to investigate opinions, behaviors, or experiences regarding sensitive topics. Some examples of sensitive topics are the following:
    - Sexual orientation or behavior;
    - Any disease or illness;
    - Incest, rape or date rape, sexual molestation;
    - Contraception, pregnancy, or abortion;
    - Substance use or abuse;
    - Criminal behavior;
    - Eating disorders or behaviors;
    - A subject's mental health;
    - Religious orientation or views;
    - Political viewpoints;
    - Taboo subjects;
    - Veteran or wartime experiences;

Conditions under which approval by the CHSR is not expected

A project may not need to be reviewed if it meets **all** of the following criteria:

- The subjects cannot be identified by name or description, are all at least 19 years of age, and are not from a vulnerable population.
- The subjects are not required to reveal anything about sensitive topics (listed above), nor are they placed at more than minimal risk in any other way by their participation.
- The project does not involve deception.
- The project uses only historical/past information and or data.
- The results will not be published, presented, or distributed in a public and nonprivate classroom forum (e.g., academic showcase).

It is the responsibility of the course instructor or faculty member advisor of research to determine whether a particular classroom project should be reviewed. The CHSR encourages all student researchers (as well as faculty members conducting research with students) to submit a proposal form if the project may eventually constitute "research" as defined by our committee. Of course, any project may be submitted for normal review if the instructor feels the experience would benefit the students involved.

HR land for repercussions. VPASA (first two offenses - verbal/ written). Physical harm Brain Hessler - facilities and campus security. CITI training? cost to institution - cost for faculty and or students. Medical humanities minor (scientists behaving badly).