Committee for Human Subjects Research

Policies and Procedures

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Adapted from “HSC Policies and Guidelines” (Mount Union College, Fall 2003)

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. Submission of research proposals is voluntary, but faculty members 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.

Committee Logistics

The Committee for Human Subjects Research is a permanent subcommittee that reports to the Faculty Affairs Committee. It consists of seven members, one chosen from each of the following groups:

- Biology Department;
- Communication Studies, Journalism & Media, or Business and Economics;
- Education Division;
- Political Science Department or Sociology Department;
- Psychology Department;
- Humanities Division;
- Fine Arts Division, Science Division other than Biology, or off-campus community.

In certain cases, the committee may also call in a non-voting consultant (who could come from off campus) to help with its deliberations. The first five groups in the list above represent the departments whose members are most likely to conduct research involving human subjects, while the remaining two groups were chosen to ensure roughly divisional representation on the committee. Members serve three-year terms, staggered so that no more than three members end their terms at the same time. New members are nominated by the committee and presented for approval by the FAC and then the Faculty Senate. A chair and a secretary are elected internally by the committee each spring, after the new members have been approved. The committee will meet at least twice each academic year, once early in the fall and once near the end of the spring semester.

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.

The above general guidelines underlie the following specific guidelines (translated from pages 5–7 of *Ethical principles in the conduct of research with human participants*; American Psychological Association, 1982), which will be considered by the CHSR when reviewing all research proposals. See also the guidelines for informed consent and debriefing (pages 9–10).

Obtain informed consent. To make an informed decision about participating in the study, participants must be informed of the following:

- The purpose and design of the study;
- Any risks (physical or psychological/emotional), expected duration, or other factors that might affect their decision to participate;
- The procedures involved in the experiment;
- Any possible benefits of participating;
- That they can withdraw from the study at any time without consequences;
- 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 (see the informed consent guidelines).

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 is greater than the benefits of the experiment, the study will not be approved.

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 (e.g., college students made to participate for classes; employees asked to take surveys).

Maintain privacy. Results must be kept confidential, if not anonymous.

- **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.

- **Confidentiality.** Anything learned about a research participant is held in *strictest* confidence. The researchers
  - Must keep data in a controlled situation (e.g., locked file cabinet),
  - Must minimize the number of people who see or handle the data,
  - 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.

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.

Debriefing. Immediately after the experimental session is over, participants should be informed about the actual purpose of the study. Researchers should explain *any* deception that occurred. After the completion of the study, researchers should send a letter or some type of summary information to all participants to relay the study results.

Research Reviewed by the Committee

The committee strongly encourages 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.

Although this review is voluntary from the point of view of the College, it may be required by other entities. 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. On the other hand, we do 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 do not need to be reviewed.

Note: If there is any doubt about whether a particular project should be reviewed, we encourage the researchers to consult the chair 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 encouraged to be reviewed like any other research. However, not all such studies are true research, nor do they all place their subjects at risk, so the Committee offers guidelines to help instructors determine whether they should submit class projects for review (see page 10).

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[1]). Here we summarize a few of the most important definitions.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Normally, in order to contribute to generalizable knowledge, it is required that the information gathered be published, presented, or distributed in a public forum.

Human subject means a living individual about whom an investigator conducting research obtains

1. Data through intervention or interaction with the person, or
2. Identifiable private information.

Risk means the possibility of harm to a person's physical, psychological, or financial well-being; reputation; or employment status. This includes the possibility of stress, discomfort, harassment, invasion of privacy, or threatening the person's dignity. It is not limited to harm suffered during participation in a research activity, but also includes harm suffered afterwards as a result of that participation.

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

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.

[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

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 and a printed, signed copy of the signature page via campus mail. The various forms mentioned in the previous sentence are available from the CHSR chair at chsrchair@hastings.edu.
2. The chair evaluates the proposal and determines whether the project is exempt from review, and if not, 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, 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 automatically approved without further evaluation.
    b. **Expedited.** A project that is not exempt from review, but still exposes the participants to only 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 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. The proposal for a project in this category is sent to all members of the Committee, who then discuss and vote on it until a majority agree on its status.
3. Once the status of a proposal has been determined, the chair notifies the Principal Investigator 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.

The Committee reserves the right to disapprove any project that it believes is fundamentally unethical. However, such decisions are expected to be extremely rare.

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:

- Their participation is voluntary.
- They may withdraw from the study at any time during the data collection session or immediately 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.
- All information is confidential and will be used for research purposes only.

Mail Survey Research and Informed Consent

If a survey is to be conducted via mail, the requirement that an informed consent form be signed and returned by the subject may be waived. In such cases, the cover letter accompanying the survey will serve as the informed consent document, and consent by the subject will be implied if the subject chooses to return the survey. Cover letters accompanying such surveys must include all relevant elements of the informed consent form. A waiver request should address 45 CFR 46.116 & 46.117.

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.

> **Infants.** Consent must be obtained from parents or from those serving *in loco parentis* (e.g., legal guardians).
>
> **Minors (children under 18 years of age).** Consent must be obtained from *both* parents/legal guardians and the minor. Some sample consent forms for minors and their parents are available from the CHSR Web page.
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> **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.
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> **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.

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 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 recommended

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 18 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 project proposes to investigate opinions, behaviors, or experiences regarding sensitive topics. Some examples of sensitive topics are the following:
    - Sexual orientation or behavior;
    - AIDS or HIV;
    - 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;
    - Veteran or wartime experiences.
- The subjects are placed at more than minimal risk.
- The project involves deception.
- The results might be published, presented, or distributed in a public forum.

Conditions under which approval by the CHSR is not expected

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

- The subjects cannot be identified by name or description, are all at least 18 years of age, and are not from a vulnerable population.
- The subjects are not required to reveal anything about sensitive topics, nor are they placed at more than minimal risk in any other way by their participation.
- The project does not involve deception.
- The results will not be published, presented, or distributed in a public forum.

It is the responsibility of the course instructor to determine whether a particular classroom project should be reviewed. The CHSR encourages all student researchers 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.