Human Subjects Review Board

Policies and Procedures

Hope College
Holland, Michigan

With acknowledgements to the University of Michigan and Loyola University of Chicago
Human Subjects Policies

Purpose

Hope College is committed to the ethical treatment of all human participants in research conducted by its faculty, staff, and students. The Hope College Human Subjects Review Board (HSRB) is responsible to review all research done under the auspices of the college and to ensure that, in each project, human participants are treated in a just and ethical manner. Hope College will comply with the regulations of the United States Department of Health and Human Services for the Protection of Human Research Subjects (Part 46 of Title 45 of the Code of Federal Regulations, as amended) and with the principles set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (the "Belmont Report"). Copies of both documents are available in the offices of the Carl Frost Center for Social Science Research. The three basic principles of the Belmont Report are respect for persons (acknowledging autonomy and protecting those with diminished autonomy), beneficence (maximizing possible benefits while minimizing possible harm), and justice (sharing equitably the burdens and benefits in the population). For each research project conducted at Hope College, the HSRB shall be responsible to ensure that

1) Any costs and risks to participants are so outweighed by the sum of the benefit to the participants and the importance of the knowledge to be gained as to warrant approval of the proposed project.

2) The rights and welfare of all participants will be adequately protected.

3) Informed consent will be obtained from all participants in accordance with HSRB policies.

4) On-going projects will be reviewed at timely intervals (at least once a year).

The HSRB shall have jurisdiction over the collection and analysis of data that utilize the participation of human participants and are intended primarily for research purposes. Projects done primarily for pedagogical or administrative purposes do not require prior HSRB approval, but they may be submitted to the HSRB at the discretion of the project director.

Structure

Because most of the research at Hope College that involves human participants is done within the Division of Social Sciences, the HSRB is established as a component of the Carl Frost Center for Social Science Research. The director of the Frost Center is responsible to ensure that the HSRB is completing its duties in a timely and appropriate manner. The chair of the HSRB shall submit an annual report detailing the activities of the board to the Advisory Council of the Frost Center and to the dean for social sciences.

The members of the HSRB shall be appointed annually by the president of Hope College. The board shall have at least six members, including two faculty from different departments of the Social
Science Division, one of whom will serve as chair (Note: The director of the Frost Center is not eligible to serve on the HSRB); a faculty member from the Division of Arts and Humanities with professional interests in ethics, religion, philosophy, or a closely related discipline; a faculty member from the Natural Sciences Division, someone from on- or off-campus with an advanced degree in a health-related profession; and a community member who is not affiliated with Hope College and has no immediate family member affiliated with Hope College. In accordance with federal guidelines, there must be both male and female members. The chair shall provide board members with copies of pertinent federal guidelines, the Belmont Report, and any other material that might be useful to them in their deliberations.

The board may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the HSRB, but these individuals shall not be considered HSRB members and shall not vote on the issue of approval of any projects. Any HSRB member with a vested interest in a project being reviewed must be disqualified from participating in the decision. The Frost Center director shall appoint someone with a similar background to the HSRB for consideration of that project.

Procedures

Submission of Proposals. Before any activity involving humans as participants in research may be undertaken at Hope College, the investigator (or faculty sponsor if the investigator is a student) must submit to the HSRB seven copies (one copy for each committee member plus a copy for the Frost Center files) of the plan of investigation. The plan must include each of the following:

1) A completed Application for Review of Research Involving Human Subjects (see Appendix A). The application includes a question that asks investigators to assess whether their projects put their participants at no risk (defined as no greater risk than that associated with normal, everyday activities) or at risk (defined as greater risk than that associated with normal, everyday activities).

2) A brief description of the project. The description should follow the outline specified in Appendix B.

3) Copies of any materials to be used, including interview protocols and survey instruments.

4) A copy of the informed consent form. Participants should sign a copy of the form for the investigator's files and should receive a copy of the form for their own use. The informed consent form should

   a) state that the study has been “approved by the Hope College Human Subjects Review Board” and that the subjects may contact the Hope College Board if necessary;
   b) describe the activities in which the participant will be engaged;
   c) describe any benefits to the participant or to others which may be reasonably be expected from the research;
   d) state whether data will be collected from the participants anonymously and
whether those data will be held in confidence;
e) advise participants that they are free to withdraw from the study at any time without penalty;
f) describe any reasonably foreseeable risks or discomforts the participant may experience;
g) tell participants whom to contact for answers to questions about the research, about their rights as subjects, and about any research-related stress or injuries;
h) include the principle investigator’s contact information;
i) indicate that subjects receive a copy of the consent form;
j) should include a signature of a witness.

5) If participation in the study is one way for students to fulfill a research requirement it must be clear that participation is voluntary.

When surveys are administered through the mail or over the telephone, it will not be necessary to ask participants to return a signed copy of the informed consent form unless the HSRB makes doing so a condition of approval.

Review of Proposals. If the investigator indicates on the Application for Review of Research Involving Human Subjects that the proposed project involves no risk to participants, and if the chair of the HSRB agrees with that assessment, the chair will distribute copies of the plan of investigation to each board member. If at least four members provide the chair a written notice of approval of the project, no meeting will be held and the chair shall give the investigators permission to begin data collection. Board members may offer approval with the provision that minor procedural changes be made in the protocol. If the suggestions appear to the chair to be reasonable, and the chair conveys them to the investigator, and the investigator agrees to implement the suggestions, it will not be necessary to convene the board to discuss them. If at least one member of the committee does not want to approve the project without a meeting, or if the chair believes that the suggestions offered by one or more board members should be discussed, then the chair shall schedule a meeting to review the project.

If the investigator indicates on the Application for Review of Research Involving Human Subjects that the proposed project involves putting the participants at risk or if the HSRB chair disagrees with the investigator's assessment that the project involves no risk to participants, the chair will distribute copies of the plan of investigation to each committee member and will schedule a meeting to discuss the project.

All members of the HSRB shall be sent materials pertaining to each proposal and shall be given timely notices of all meetings. No meeting can be held with fewer than four members present. The HSRB shall strive to arrive at a consensus in its decisions, but no project can be approved without the support of at least four members. Decisions of the HSRB can be appealed to the Deans' Council of Hope College.

The HSRB chair shall notify all investigators of the board's decisions regarding their applications.
Approval of applications will last for twelve months; investigators will be given an expiration date when they receive their approval. In the event that the HSRB did not approve an application, the chair will explain to the investigator why approval was not granted and will specify the changes that would be necessary for the application to be approved. The chair also shall notify investigators of their right to appeal HSRB decisions to the Deans' Council.

The chair shall place in the Frost Center files copies of all correspondence with committee members, correspondence with investigators, and minutes of all meetings (including discussions of substantive issues, the resolution of those issues, and any vote counts). All records shall be retained for at least three years.
Appendix A

Application for Review of Research Involving Human Subjects

Date: ___________________________

Name of Investigator: ___________________________________________________________

Name of Faculty Sponsor (if different from above):
___________________________________________________________

Department ___________________________________________________________

Campus Phone _________________

Home Phone _________________

Name(s) of Additional Investigator(s)
___________________________________________________________

Title of Project: ______________________________

Purpose of Project:

_____ Faculty research proposal to be submitted for external funding

_____ Faculty research proposal not to be submitted for external funding

_____ Student independent research proposal

_____ Class project for ________________________________________________

(please give course title and number)

I believe that participants in this study will be

_____ not at risk (defined as no greater risk than that associated with normal, everyday activities)

_____ at risk (defined as greater risk than that associated with normal, everyday activities).
Certifications

1. I am familiar with the policies and procedures of the Hope College Human Subjects Review Board and with the principles of ethical treatment of human participants in research projects as set forth in the Belmont Report [i.e., respect for persons (acknowledging autonomy and protecting those with diminished autonomy), beneficence (maximizing possible benefits while minimizing possible harm), and justice (sharing equitably the burdens and benefits in the population)].

2. I have informed all those who will work on this project of the Belmont Report principles.

3. I will, in a timely manner, debrief all those who participate in this project, and will inform them of the project's purpose, the results of our investigation, and of the use we will make of those results.

4. If substantive changes in the procedures involving participants become necessary, I will submit these changes for review before they are implemented.

Signature of Investigator: ________________________________________________

Signature of Faculty Sponsor: _______________________________________________(if different from Investigator)
Appendix B

Outline of Project Description

Please provide a summary of your proposed project (approximately two pages) that uses the following outline as a model. Please include each subsection, clearly marked by its heading.

INVESTIGATOR: Name and department

FACULTY SPONSOR: If different from Investigator

TITLE: Please use the same title as used on the Application for Review of Research Involving Human Subjects.

RATIONALE: Provide a brief statement of the project's general aims in relation to the broader area of research in the field.

SPECIFIC AIMS: Identify the variables to be manipulated and/or measured and describe their expected relationships.

SUBJECT SELECTION: Identify the sample population and describe the method of subject recruitment, including any incentives offered for participation.

PROCEDURE: Describe the activities in which the participants will be engaged. DESCRIBE IN DETAIL ANY DECEPTION USED and explain why there is no other acceptable alternative.

DISSEMINATION: Explain plans for dissemination of study findings

POTENTIAL RISK: Identify possible sources of physical, psychological, or social risk, including potential violations of rights to privacy and free choice.

SAFEGUARDS: Identify procedures designed to reduce the risks involved. If debriefing is to be used as a safeguard, please describe the text in detail.

BENEFIT TO SUBJECTS: Explain how participants might gain from the experience, including any educational benefits.

OTHER BENEFITS: Describe any potential personal or social benefits to non-participants.