Human Experimentation Review Board

Policies and Procedures

Wagner College

with acknowledgements to Hope College, the University of Kansas,
the University of Michigan, and Loyola University of Chicago

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Purpose

Wagner College is committed to the ethical treatment of all human participants in research conducted by its faculty, staff, and students. The Wagner College Human Experimentation Review Board (HERB) is responsible to review all research done under the auspices of the Psychology Department and to ensure that, in each project, human participants are treated in a just and ethical manner. HERB is one of several Institutional Review Boards (IRBs) at Wagner College. These IRBs ensure compliance 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 Psychology Department. 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 Wagner College, the HERB 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 or waived in accordance with HERB policies.

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

The HERB 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 HERB approval, but they may be submitted to the HERB at the discretion of the project director. Projects that seek to utilize Wagner College's Participant Pool must have HERB approval.

Structure

Because most of the research at Wagner College that involves human participants is done within the social sciences and sciences, the HERB chair will likely come from these areas. The chair of the HERB is responsible to ensure that the HERB is completing its duties in a timely and appropriate manner. The chair of the HERB shall submit an annual report detailing the activities of the board to the Psychology Department Chair. Records will be kept in Psychology Department.

The members of the HERB shall be appointed annually by the Psychology Department Chair. The board shall have at least six members (including the committee chair), including two members of the psychology department, one member from biological sciences, one faculty member with no expertise in science, one College student, and one member of the community not affiliated with the College. Additionally, an alternate member from the psychology department will serve if a board member from psychology must recuse him/herself. In accordance with federal guidelines, there must be both male and female members. The chair will be drawn from the faculty members on the committee. 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 HERB, but these individuals shall not be considered HERB members and shall not vote on the issue of approval of any projects. Any HERB member with a vested interest in a project shall recuse himself or herself from voting.

Procedures

Submission of Proposals. Before any activity involving humans as participants in research may be undertaken at Wagner College, the investigator (or faculty sponsor if the investigator is a student) must submit the plan of investigation to the appropriate IRB. HERB will review applications from the Psychology Department and from other offices on campus. The plan must include each of the following:

1) A completed Application for Review of Research Involving Human Experimentation (see HERB website). 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.
3) Copies of any materials to be used, including interview protocols and survey instruments.
4) A copy of the informed consent form or justification for a waiver of informed consent. 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) describe the activities in which the participant will be engaged;
    b) describe any benefits to the participant or to others which may be reasonably be expected from the research;
    c) state whether data will be collected from the participants anonymously and whether those data will be held in confidence;
    d) advise participants that they are free to withdraw from the study at any time without penalty;
    e) describe any reasonably foreseeable risks or discomforts the participant may

experience;

f) 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.

When surveys are administered online, 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 HERB makes doing so a condition of approval.

Review of Proposals.

Proposals will be reviewed under one of three conditions, depending on the potential risk or harm to participants.

1. **Expedited review**
   If the investigator indicates on the Application for Review of Research Involving Human Experimentation that the proposed project involves no risk to participants, and if the chair of the HERB agrees with that assessment, the chair may evaluate the project for expedited review. Expedited review will be available to projects that meet all of the following conditions:
   - no payment of participants
   - no substances taken internally by or applied externally to the participants
   - no mechanical or electrical devices applied to participants
   - no fluids or tissues removed from the participants
   - no expectation of participants experiencing physiological or psychological stress
   - no deception of participants concerning any aspect of purposes or procedures
   - no use of participants who would be judged to have limited freedom of consent such as individuals under the age of 18, developmentally delayed persons, or institutionalized individuals
   - no procedure or activities that might place the subjects at psychological, physical, or social risk

   If these conditions are met, the chair of the HERB may grant immediate approval of the project. If approval is granted, the chair shall give the investigators permission to begin data collection. The chair may offer approval with the provision that minor procedural changes be made in the protocol. If the chair does not approve the project, the application may be submitted for a no harm review by the committee.

2. **Review of projects that meet Office of Human Research Protections category 45 CFR 46.404**

   OHRP category 45 CFR 46.404: "Research not involving greater than minimal risk to the children. To approve this category of research, the IRB must make the following determinations:
   - the research presents no greater than minimal risk to the children; and
   - adequate provisions are made for soliciting the assent of the children and the permission of

their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408." http://www.hhs.gov/ohrp/policy/populations/children.html

Proposals identified as category 45 CFR 46.404 will be forwarded to two members of HERB (in addition to the chair or chair's designee) for review. All members of HERB will receive an email message that a project determine to meet 45 CFR 46.404 has been forwarded to reviewers, this message will inform all members of the board regarding the names of the selected reviewers, the names of the researchers, and the title of the project. Any member of HERB is welcome to call for a no harm review or full review of the project within a week of being sent this notification.

As with all other reviews, the two members selected to review the proposal will have the option (1) to call for a full review, (2) to approve the project with specific changes, or (3) to approve the project as proposed.

3. **No harm review**
   If a project does not qualify for an expedited review, if the investigator indicates on the Application for Review of Research Involving Human Experimentation that the proposed project involves no risk to participants, and if the chair of the HERB 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.

4. **Full review**
   If the investigator indicates on the Application for Review of Research Involving Human Experimentation that the proposed project involves putting the participants at risk or if the HERB 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 HERB shall be sent materials pertaining to all proposals that do not qualify for expedited review or 45 CFR 46.404 and shall be given timely notices of all meetings. No meeting can be held with fewer than four members present. The HERB 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 HERB can be appealed to the committee after revisions to the proposal have been made.

The HERB 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. The Project Status Report questionnaire is posted on the HERB webpage.

In the event that the HERB 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 HERB decisions.

The chair shall keep file 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) in the Psychology Department. All records shall be retained for at least three years.

Continued Review of Research

Investigators must complete the Project Status Report (posted online) prior to the expiration date of approval. If a project in still in operation but no significant changes have been made, an approval extension for twelve months may be granted. Any significant changes in the approved project require the investigators to complete an Application for Review of Research Involving Human Experimentation and submit it for review.

The HERB chair and Psychology Department Chair should be notified of any unanticipated problems involving risks to subjects or any serious or continuing noncompliance with the requirements or determinations of the HERB.