

# **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 available to serve as the Institutional Review Board (IRB) of record for members of the Wagner College community and community partners who are conducting research that falls within HERB's expertise.

If proposed research does not match the expertise of HERB, the project will not be reviewed by HERB and the investigator will be directed to find a suitable IRB.

For multi-site research approved by a single IRB (sIRB), HERB will cooperate with the reviewing IRB as a relying institution.

HERB ensures 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 on the Psychology Department's website.

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 proposal submitted, 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).

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 the Psychology Department'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 HERB is completing its duties in a timely and appropriate manner. The chair of HERB shall submit an annual report detailing the activities of the board to the chair of the Psychology Department. Records will be kept in Psychology Department.

The members of HERB shall be appointed annually by the chair of the Psychology Department. The board shall have at least six members (including the committee chair), including two or more members of the Psychology Department, at least 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 themselves. In accordance with federal guidelines, the membership of HERB must encompass multiple genders. 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 themselves 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. 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 minimal 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 process or justification for a waiver of informed consent. For in-person studies, participants should clearly indicate consent electronically (such as on an online questionnaire) or sign a copy of an informed consent form for the investigator's files and receive a copy of the form for their own

- use. The informed consent process 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 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 four 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 minimal 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 the following conditions:

- no payment of participants in an amount greater than \$15 or chance to win an amount greater than \$100
- 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 greater than that associated with normal, everyday activities
- no use of participants under the age of 18 or intentional recruitment of participants who would be judged to have limited freedom of consent such as with developmentally delayed persons or individuals living in a situation that complicates consent (e.g., prison)
- no procedure or activities that introduces risk of harm, persistent physical or emotional discomfort, offense, or embarrassment
- no intervention that is physically invasive or that could be harmful or painful
- any intervention only involves adult subjects who have adequate decision-making capacity to agree to participate
- any intervention is brief in duration (lasting no more than a few hours), free of harm, and painless
- one of the following conditions regarding privacy is met
  - information is recorded in such a manner that the identity of the human subjects

- cannot be readily ascertained, directly or through identifiers linked to the subjects  
or
- any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
  - either no deception of participants (concerning any aspect of purposes or procedures) or participants prospectively agree to deception
    - Prospective agreement to deception must include a statement on the informed consent form that research participants will be unaware of or misled regarding a key aspect of the nature or purpose of the research until the conclusion of the study.
    - During the consent process, the researcher must read the statement about deception to the participant or require the participant to initial that aspect of the consent form.

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 investigator 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 with child participants that meet Office of Human Research Protections (OHRP) 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 determined 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 a majority of 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 minimal 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 a majority present. HERB shall strive to arrive at a consensus in its decisions, but no project can be approved without the support of at least a majority of members. Decisions of 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 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 is 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 describe the changes in detail and request an updated letter of approval. The HERB chair will use the criteria above to determine whether changes are eligible for an expedited review. If the HERB chair determines that the changes must be reviewed in a no harm review or full review, the investigator will complete an Application for Review of Research Involving Human Experimentation and submit it for review.

The HERB chair and chair of the Psychology Department 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.

### **HERB Noncompliance**

If either of the following occurred, it would constitute serious noncompliance in HERB activities:

- Approving a project in a full review without a quorum
- Using the expedited review procedure to review research that does not satisfy the requirements for an expedited review

Continuing noncompliance in HERB activities would include not documenting information about quorum at a meeting or voting.

The HERB chair will copy all members of HERB on every determination of exemption and expedited review, as well as all no harm and full reviews.

Any member of HERB is welcome to respond with a concern regarding a determination of exemption or an approval through an expedited review. If a member expresses a concern, the chair of HERB will communicate with the member regarding whether a more extensive review is warranted. Following that communication, the member's decision will determine whether exemption or approval will be withdrawn while further review is conducted.

Any member of HERB may bring a concern of noncompliance of HERB activities to the board for discussion and determination of whether a report to OHRP is warranted. Alternatively, a member may [report](#) serious noncompliance or continuing noncompliance of HERB activities directly to OHRP.

### **Reporting Requirements**

Upon project approval or receiving a statement of exemption, investigators will be informed that they must immediately report to HERB any unanticipated problems that involve risks to subjects or others. These include any incident, experience, or outcome that meets all three of the following: (a) the problem is unexpected in nature, severity, or frequency, as well as (b) related

or possibly related to participating in the research, and also (c) suggests that the research has placed subjects or others at a greater risk of harm than was previously recognized. The statement to the investigator will state that anything that reveals unanticipated risk of physical, psychological, economic, or social harm should be reported to HERB.

If research may have unexpected adverse effects, HERB may

- Audit the plan for research
- Educate or train the investigator

HERB may consider

- Changes to protocol
- Revising research policies and procedures
- Updates to the informed consent procedure, including re-seeking consent, notifying subjects who previously consented, or revising the consent procedure
- Other corrective actions
- Suspending or terminating a study

The HERB chair will be responsible for immediately investigating any incident that reveals a serious risk to research subjects or others. Any serious unanticipated problem will be [reported](#) to OHRP within a few days. A less serious incident will be reported to OHRP by the HERB chair within a few weeks.

Serious noncompliance with HERB regulations include

- conducting nonexempt research without IRB approval (All researchers are strongly encouraged to submit a proposal to HERB for determination of whether the project is exempt.)
- conducting research without appropriate informed consent or an approved waiver of informed consent
- implementing changes to research without HERB approval, if those changes might increase the risk of physical, psychological, economic, or social harm to the subjects or others

Continuing noncompliance includes repeated or recurrent noncompliance, even if it is not serious, especially after HERB has informed the investigator of the issue.

Examples of continuing noncompliance:

- An investigator repeatedly fails to submit a progress report for continuing review and approval of an ongoing research project before the approval expires.
- Failure to document subjects' informed consent.
- Failure to use the consent procedure approved by HERB.

- Failure to follow the HERB-approved protocol for the study.

HERB will discuss evidence of continuing noncompliance to determine at what point a report to OHRP is warranted.

If HERB suspends or terminates approval for a study, including only a part of a study, the HERB chair will report this to OHRP.