Reed College
Human Subjects Research Committee (HSRC)
2007-2008

Categories and Procedures of Review

Introduction

According to the provisions of the Federal Wide Assurance filed by Reed College, federally-funded research involving human participants sponsored by Reed must be reviewed according to the regulations set forth in 45 CFR 46. The College also certified that all research involving human participants at Reed, independent of funding source, will be conducted in accordance with the ethical principles enunciated in the Belmont Report. Thus, for both ethical and legal reasons, the College has committed itself to a process of internal review of all research involving human participants. Research that must be reviewed includes faculty research projects, senior theses, projects conducted outside the classroom by students (e.g., independent projects, projects funded by special grants), and a limited set of classroom projects (see separate document entitled "Research Projects in Classes"). The internal review will be conducted by the Human Subjects Research Committee (HSRC), which is registered as the College's Institutional Review Board (IRB).

Projects conducted on the Reed campus by non-Reed investigators must also undergo review by the Reed HSRC. Projects conducted by Reed investigators at off-campus sites having their own process of institutional review will undergo minimal additional review at Reed.

The Belmont Report

The ethical principles enunciated in the Belmont Report fall under three broad headings:

Respect for persons.

> "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection." (Belmont Report, 1979)
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> The primary means of ensuring participant autonomy is the acquisition of voluntary, informed consent to participate in research. The exchange of information necessary for the participant to decide initially whether to participate is often the focus of the consent process. Equally important, however, are the methods of recruitment of potential participants and the evolving relationship between researcher and participant during the project.
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> Particular problems arise when potential participants are not adults or are impaired in their abilities to make decisions for either endogenous or exogenous reasons (e.g., psychiatric illness or incarceration, respectively). Furthermore, cultural differences in notions of autonomy and authority require researchers to be sensitive to the meaning of these concepts for their participant sample.

Beneficence.

"In this document, beneficence is understood. . .as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms." (Belmont Report, 1979)

Outside the medical context, individuals rarely benefit directly from participating in research. Thus, the benefits are to society at large, or to the corpus of research-based knowledge. Potential risks of research are sometimes socio-political (e.g., influences on the autonomy of a remote society or on the flow of political events), but more commonly involve potential psychological or social harm or discomfort to individual participants. Thus, the process of assessing the benefits and risks of research is difficult and sometimes controversial. Perhaps the most important consequence of institutional review is making the process of weighing benefits and costs more explicit, as individual researchers must provide informative descriptions to a wider audience.

In this regard, the federal guidelines frequently refer to studies involving more than or no more than "minimal risk" to participants. Minimal risk is defined as: "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 tests." Determining the upper bounds of minimal risk requires consideration of the participant sample and the context of the proposed research. In general, the review process insures an explicit assessment of possible risks, assurances that adequate measures for minimizing risk are in place, and appropriate attention to obtaining informed consent.

Justice.

Research participants should not be selected on the basis of availability or vulnerability. One implication of this principle at Reed is that we should avoid coercive means of inducing students (or others) to participate in research. Examples might be the offering of course credit or other inappropriately attractive incentives for participation.

Implementation

Reed's HSRC consists of 4-5 faculty members, representing the research disciplines whose work most often comes under review (e.g., psychology, anthropology) and at least one faculty member who does not do research involving human participants. In addition, the Dean of Faculty and a representative(s) of the off-campus community sit on the Committee. The members of the Committee in 2007-2008 are: Albyn Jones (Chair), Kristen Anderson, Robert Brightman, Paul Currie, Tamara Metz, Peter Steinberger (Dean of Faculty), Diane Rohlman (community representative) and Kristine Munholland (community representative).

In setting up its system of review, the HSRC recognizes the need for consistency and predictability within a system that is efficient and yet flexible. We encourage student and faculty researchers to speak with individual members of the Committee about their research plans as early as possible, perhaps before committing to the particulars of the project. In

addition, we hope to facilitate the process of review by providing informative documents and forms, by encouraging faculty and students to develop a library of standard research protocols that can be referred to in proposals, and by encouraging departments or groups of faculty with common research interests to develop "local" guidelines for research and HSRC submissions.

Some research projects raise few, if any ethical issues, whereas others require a more thoughtful process of review. The depth or level of review will be determined primarily by the ethical issues raised by the research project. The proposal form is available on the HSRC website: http://web.reed.edu/human_subjects/index.html. The form is structured so that information needed regarding all proposals is requested on the first three pages. Thereafter, instructions are provided such that proposals requiring minimal review either end or skip unnecessary sections (see *Branchpoints* described under the first two categories of review).

Functionally, there are three levels of review. The federal guidelines provide descriptions of research falling into these categories. The Committee has found that some of these descriptions are more ambiguous than they appear at first reading. The following embodies the Committee's interpretations of these guidelines:

Exempt from Full Committee review. Certain categories of research are exempt from formal HSRC review. However, the individual investigator cannot make the determination that the research is exempt. Further, many "exempt" projects still require documentation of the processes used to obtain participants' consent. Thus, a brief description of the research is required, but "exempt" proposals will be much shorter than those in other categories.

Review of applications for exemption will be conducted by a designated member of the HSRC, usually the Chair. Confirmation of exemption can be expected within a few days.

The following categories of research may be exempt:

A. Research evaluating the efficacy of educational practices in an educational setting.

B. Research involving the analysis, synthesis, or study of existing data or documents when these are publicly available or when the information is recorded in such a way that individuals cannot be identified. See definition of "anonymous" below.

C. Research involving the use of surveys, interviews, educational tests, psychological tasks or observation of public behavior when the obtained information is anonymous or when disclosure of the individual subject's responses would not create a risk of adverse consequences to the subject.

Public behavior is behavior occurring without the intervention of the researcher, and which the individual could reasonably expect to be observed. Observation of reactions to "staged" events and of behavior occurring in private settings (e.g., at home, in a bathroom stall) or in settings in which individuals have reasonable

expectations of a limited audience (e.g., classrooms, meetings of identified groups) is not exempt.

Anonymous means that the individual participant cannot be identified from the data themselves, and no identifying information is linked to the data. Video and voice recordings are not anonymous. Interview or survey data in which recorded demographic characteristics or descriptions of specific incidents could easily lead to the recognition of the individual respondent are not anonymous.

Examples of adverse consequences include:
- placing participants at risk of criminal or civil liability
- damaging the participant's academic standing or standing in any ongoing program, financial standing, employment status or employability, insurance status or insurability
- damaging the participant's reputation

D. Research approved by an off-campus IRB.

Expedited Review Certain categories of research are eligible for an expedited review process, in which three members of the HSRC will review the proposal. Research falling into this category will require more complete descriptions than research that is likely to be exempt, but because the research raises few, if any, ethical issues, these descriptions are usually short. Normally, an expedited review will be completed within 7-10 days.

Research that presents no more than minimal risk to human participants may qualify for expedited review. Examples of risks that require review by the full HSRC are specified in the section on Full Review (below). The assessment of risks requires evaluation of the specific circumstances of the proposed research, but research falling into the following categories often presents minimal risk:

A. Collection of data from voice, video, digital, or image recordings made for research purposes.

B. Research on individual or group characteristics or behavior (e.g., research on perception, cognition, motivation, identity, language, communication, religious or cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, or human factors evaluation. NOTE: Some research in this category may be exempt and some may require full committee review.

C. Certain biological measurements, such as:
- collection of blood samples by finger stick, heel stick, ear stick.
- collection of other biological specimens by noninvasive means.
- collection of physiological data through noninvasive procedures (e.g., EEG, heart rate).

D. Non-invasive questionnaires and/or straightforward, non-risky procedures that involve no deception with children under the age of 18, given that direct parental consent is obtained.

E. Continuing review of research previously approved by the HSRC. This category includes most addenda to previously approved projects and requests for continuation of approval beyond the period of initial approval (usually until the following Sept for proposals approved in the fall and the following January for proposals approved in the spring). These proposals may be reviewed by the Chair.

Full Committee Review

Research that is not exempt and that does not qualify for expedited review must be submitted to the HSRC for full review. This type of review requires a convened meeting of the Committee, with a quorum of its members present. Thus, 3-4 review cycles/semester have been established. These cycles normally entail:

- a deadline for submission of the proposal.
- a one-week period for preliminary review by HSRC members, who provide feedback and questions to the Chair.
- a meeting of the HSRC approximately 10 days after submission of the proposal.
- notification of the HSRC's action approximately 2 weeks following proposal submission. Possible actions include:
  - approval.
  - request for revisions that can be accepted by the Chair, by a designated member of the HSRC, or by the Administrative Assistant to the HSRC.
  - request for revisions that must be re-reviewed by the HSRC or by a subcommittee of the HSRC.

The review cycles for 2007-2008 appear at the end of this document.

Research in the following categories requires full committee review. Frequently used, standardized research protocols can be reviewed by the committee once/year instead of at each use.

A. Vulnerable participant samples such as: children under 18 years of age who are being asked to do somewhat risky or deceptive procedural tasks, clinical populations, incarcerated populations, individuals who for one reason or another cannot provide informed consent.

B. Procedures that involve the intentional induction of stress, or for which stress to the participants might be an unintended consequence, such as:

the use of aversive or physically painful stimuli.

the induction of emotional distress, such as embarrassment, frustration, anxiety, loss of self-esteem, anger, or sexual arousal.
the induction of physical stress through procedures such as exercise, sleep deprivation.

C. Procedures that might lead to physical injury, including the consumption of any substance, (e.g., coffee, tea, tobacco, over-the-counter medications).

D. Procedures that might raise ethical objections in participants, for example:
deception by the researcher or confederates.
manipulations of participants' attitudes or behavior.
observation of behavior in non-public settings without advance consent.

E. The collection of personally sensitive data requiring unusual procedures to ensure confidentiality.

2007-2008 HSRC Review Cycles

Proposals Submitted by noon on:	**Committee meets:**	**Notification by:**
TBD		