Wittenberg University

Research Ethics and Compliance

Policy on the Protection of Human Subjects in Research

PURPOSE

The purpose of this policy is to facilitate the protection of human subjects in research conducted at Wittenberg University. It is intended to assure that subjects of research are aware of their rights and protections. Moreover, the University is required to assure the federal government that such safeguards are being provided and enforced. These safeguards are derived from ethical principles articulated in the Belmont Report issued by the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, and enforced in the Code of Federal Regulations (45 CFR 46). The Wittenberg Institutional Review Board (IRB) is the body charged with reviewing, prior to its commencement, all research, whether funded or not, involving human subjects conducted under the auspices of Wittenberg University. The procedures for IRB review are described in the *Policy for the Institutional Review Board*.

DEFINITIONS

Data: facts, figures, and information. For the purpose of this policy, the term "data" is considered to be material from primary sources analyzed as part of scholarly efforts.
Harm: any physical, psychological, social, or financial damage or injury, which might have been avoided without sacrificing the goals of the activity, as well as any damage or injury whatsoever whose extent cannot be justified by the contribution of the research to the expansion of human understanding.
Human subject: any specific living person, or information about a living person, who is the subject (participant) or object of study for the purpose of expanding our knowledge or understanding.
IRB: Institutional Review Board
Minimal risk: Federal guidelines state, "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 tests."
Principal investigator: the primary person conducting the research. The principal investigator (P.I.) can be a professional or a student.
Review: a process of oversight resulting in an acknowledgment of the status ("approved," "pending required amendments," or "not approved") of a project under the guidelines of this policy.
Research: a systematic investigation designed to develop or contribute to generalizable knowledge
Risk: potential for physical, psychological, social, or financial harm.

POLICY ON PROTECTING HUMAN SUBJECTS

Wittenberg University adheres to the three principles from the Belmont Report (1979) that guide regulations and procedures related to the review of human subjects' research: 1) respect for persons, 2) beneficence, and 3) justice. At least three important premises underlie these principles. The first is that studies with human subjects are necessary for improvements in health and welfare. Second, to conduct such research is a privilege, not a right, extended to researchers by society, institutions, and the research subjects themselves. Finally, neither the risks nor the costs of any research study should outweigh the likely benefits.

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.'

Vulnerable Subjects

The U.S. federal regulations and international guidelines, such as the Declaration of Helsinki, have designated as vulnerable: prisoners, children, pregnant women, human fetuses, and neonates. These regulations and guidelines require special protections researchers must incorporate into their studies when enrolling and conducting research with these subjects. Researchers must provide adequate justification when enrolling vulnerable subjects. Many IRBs have determined that in some situations, other subject groups are vulnerable when there is a power differential between the researcher and the subjects (such as influence, authority, or control).

Beneficence

'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.'

Justice

'An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly... For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.'

CONDUCTING RESEARCH WITH HUMAN SUBJECTS

All researchers conducting research are responsible for protecting their subjects from the risk of unreasonable harm. The principal investigator has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of his/her courses or departmental/program curriculum.

The principal investigator should refer to and follow the guidelines of the relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research have a responsibility for introducing students to the Responsible Conduct of Research.

At the minimum, research activities should conform to the following:

1. Subjects should be made fully aware of:
    - the objectives of the research
    - the procedures to be followed
    - any risks and potential benefits of participation in research.
2. Investigators shall not use individuals as subjects unless satisfied that the subjects, or others legally responsible for the subject's well- being, freely consent to participate with a full understanding of the consequences.

3. Investigators shall respect the privacy of their subjects. Investigators shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.
4. Subjects, including students who are participating in classroom experiments or faculty scholarship, shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participation in research, some other mechanism to "earn" that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participation should be in line with the burden imposed by participation.
5. It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this shall be clearly stated as part of the informed consent statement.
6. Faculty who assign or supervise research conducted by students are responsible for ensuring that these students are qualified to safeguard adequately the well-being of the subjects.
7. Subjects of human research are generally provided the opportunity of access to the benefits of that research at its conclusion.
8. An investigator shall disclose to a subject, upon request, the source of support for the research.

Informed Consent

Subjects of research learn about the research and agree to participate through the process of Informed consent. Researchers must write consent documents (forms) clearly and at a level understandable by the subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be defined in plain language. The consent document should be written at the reading level appropriate for the community of potential subjects. Assent forms for minors and any related recruitment materials must reflect the reading ability of the minors.

The elements of informed consent are outlined in the Code of Federal Regulations (45 CFR 46) and include:

- A statement that the study involves research
- Purpose of the research
- Procedures involved in the research
- Alternatives available should a subject decide not to participate in the research
- Foreseeable risks and discomforts to the subjects, including not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.)
- Benefits of the research to society and to the individual human subject
- Length of time the subject is expected to participate
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Payment for participation (if applicable)
- Persons to contact for study-related questions and for questions regarding the rights of research participants
- Persons to contact for procedures to follow in the event of a research-related injury or emergency
- Statement that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive

- Subjects right to confidentiality and right to withdraw from the study at any time without any consequences

Privacy/Confidentiality

The protections of privacy and confidentiality are important issues in the protection of human research subjects. The researcher must describe plans to protect the participant's identity as well as the confidentiality of the research records. Privacy is the right to control the extent, timing, and circumstances of sharing information about oneself (physically, behaviorally, or intellectually) with others.

Confidentiality pertains to the treatment of identifiable and private information that the subject has disclosed to the researcher with the expectation that it will not be divulged to others in ways that are inconsistent with the terms of the consent process. The researcher must provide a plan to keep identifiable research records confidential. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose and for what period. Video and audiotaped data, as well as photographs require plans for confidentiality since these media can provide additional means for subject identification.

The process of garnering informed consent shows respect for the autonomy of persons in being able to voluntarily decide to be a research participant.

Recruitment and Payments to Human Subjects in Research

Research subjects who are paid to participate in a study must be paid by the University. They must not be paid by personal check or cash. Students who are University employees should be paid by the Student Employment Office. Faculty members should be paid by Human Resources. Other individuals, including students, who are not University employees should be paid by the Account Services Office. To issue a check, the Business Office will need the subject's name, address, and social security number, and a brief explanation of the reason for the payment.

HUMAN SUBJECTS RESEARCH TRAINING

Any investigator that intends to submit a research proposal to the Institutional Review Board must show evidence of completed Human Subjects-Responsible Conduct of Research Training. The IRB will not review or approve a research proposal from an investigator that has not completed some type of training. For information on available training, contact the IRB Administrator, in the Office of Academic Affairs and Institutional Research at 937-591-1024 or hillerd@wittenberg.edu.

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