



**THE GEORGE
WASHINGTON
UNIVERSITY**
WASHINGTON, DC

Responsible University Official:
Associate Vice President for Research
Responsible Office: Office of Human
Research
Last Revised Date: November 7, 2006

TREATMENT OF HUMAN RESEARCH SUBJECTS

Policy Statement

Prior to any activity that involves human subjects, the proposal must be submitted to the university’s Office of Human Research (OHR), and reviewed and approved by the university’s Institutional Review Board (IRB). This policy applies to all human subject activity regardless of funding status or source. Engaging in Research activity involving human subjects, or analysis of data gathered from human subjects without prior approval may result in disciplinary action up to and including termination of Research privileges and/or academic appointment.

Reason for Policy

The university is committed to protecting the rights and welfare of human subjects, and to complying with federal and local regulations regarding human subject Research. The purpose of this policy is to articulate the responsibilities of university researchers who conduct Research involving human subjects.

Who is Governed by this Policy

Faculty, staff and students

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Policy

The university is committed to upholding the ethical principles of the [Belmont Report](#), and complying with the Department of Health and Human Services (DHHS) regulations (45 CFR 46, including subparts A, B, C and D) with respect to all Research involving human subjects, regardless of sponsorship. The ethical principles set forth in the [Belmont Report](#) are:

- **Respect for Persons:** Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
- **Beneficence:** Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
- **Justice:** Fairness in the distribution of research benefits and burdens.

The university is also committed to compliance with additional relevant regulations such as the U.S. Food and Drug Administration (FDA) regulations (21 CFR 50, 56, 312, 812, and 814), the Veterans Administration (VA) regulations (38 CFR 16, as well as any VA directives when applicable), the Health Insurance Portability and Accountability Act (HIPAA), and any federal, state and local law under review that pertains to Research involving human subjects.

The university follows applicable state and District of Columbia laws and regulations. In situations where there is more than one applicable law or regulation, the university will apply the most stringent.

1. Pre-Approval of Research

Federal regulations require that, prior to instituting any Research activity or study involving human subjects, all such Research must first be reviewed and approved by the university’s IRB, or determined to be exempt.

Research investigators are responsible for contacting the OHR for guidance concerning whether a Research activity constitutes human subjects Research, and if so, whether it is exempt from the requirement for IRB review. Research

investigators should become familiar with the information and guidance concerning this subject from the DHHS' Office for Human Research Protections (OHRP), which is available [online](#).

All Research investigators seeking to engage in Research involving human subjects must first submit Research proposals to the university's OHR, which is responsible for compliance with federal regulations regarding the protection of human Research subjects, and serves as the administrative office for the IRB.

The university's IRB will review and oversee all Research involving human subjects at the university, and is authorized to inspect Research facilities, obtain records, observe the consent process, suspend or terminate Research, and take other actions as necessary to comply with federal regulations. The IRB is also responsible for providing assurance to the federal government that the university is in compliance with federal regulations. Further detailed instructions regarding IRB responsibilities, procedures and regulations can be found in the OHR website. Please contact the OHR to obtain access.

Research activity involving human subjects may not proceed until: 1) the university's IRB has reviewed and approved the Research proposal; 2) an official letter has been issued to the Research investigator by OHR; and 3) the Research investigator is in possession of IRB-approved consent documents as well as any accompanying recruitment materials, if applicable.

In the event that Research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the Research, the above review and approval procedures must be followed prior to instituting the human subject Research.

2. Research Requirements

When the Research is subject to regulation by any federal department or agency, all additional conditions imposed by the department or agency for the protection of human subjects must be followed.

Special provisions are set forth in the federal regulations for Research involving pregnant women, fetuses, fetal material and/or the placenta, neonates, children and prisoners. All investigators are responsible for complying with all regulations concerning these classes of Research subjects and research material.

3. Informed Consent

No Research investigator may involve a human being as a subject in Research unless the Research investigator has obtained legally effective, written, informed consent from the subject or the subject's legally authorized representative, or

unless informed consent is specifically waived by the IRB. No exculpatory language may be included in the consent that waives or appears to waive any of the subject's legal rights, or that releases or appears to release the Research investigator, sponsor or the institution or its agents from liability for negligence.

4. Responsibilities of Investigators

- Principal investigators will promptly report proposed changes in previously approved human subject Research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- Principal investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.
- Principal investigators are responsible for submitting reports on the progress of approved Research to the OHR as often as necessary, and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.
- Principal Investigators are responsible for acquiring the appropriate knowledge regarding human subject protections, ethics, federal regulations, training, and monitoring to conduct his or her proposed Research.
- Principal Investigators must also assure that study personnel are adequately trained and knowledgeable regarding human subject protections, ethical considerations, and federal regulations applicable to the proposed Research.
- All Research investigators are responsible for complying with the training, monitoring, and human subject Research guidance as outlined in university IRB policies and procedures.
- Detailed instructions for carrying out the responsibilities in this policy can be found in the OHR website. All Research investigators engaged in human subject Research are responsible for familiarizing themselves with that information and for keeping abreast of all requirements for conducting human subject Research under the auspices of the university. Guidance and assistance in complying with these requirements should be sought from the OHR.

Definitions

Human Subject: A living individual about whom an investigator (whether faculty, staff or student) conducting Research obtains data through intervention or interaction with the individual, or obtains identifiable private information.

Research Investigators: All members of the university's Research community engaged in Research activities, including but not limited to principal investigators, researchers and research scientists, research staff, and student researchers.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute Research involving human subjects.

Research: A systematic investigation, including Research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Related Information

21 CFR 50, 56, 312, 812, and 814 (FDA regulations)

38 CFR 16 (VA regulations)

[45 CFR 46](#) *et seq.* (DHHS regulations)

[Belmont Report: Ethical Principles and Guidelines for the Protection of Human](#)

[Subject Research](#), DHHS, Office for Human Research Protections

[Collaborative IRB Training Initiative \(CITI\)](#)

[Department of Health and Human Services \(DHHS\)](#)

[DHHS Human Subjects Decision Charts](#)

[Food and Drug Administration](#)

[Good Clinical Practice in FDA-Regulated Clinical Trials](#)

[NIH Education Requirements](#)

[Office for Human Research Protections Frequently Asked Questions](#)

[Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical](#)

[Trials](#)

Contacts

Contact	Telephone	Email
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Document History

- **Last Reviewed Date:** July 17, 2017
- **Last Revised Date:** November 7, 2006
- **Policy Origination Date:** November 16, 1978

Who Approved This Policy

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Leo M. Chalupa, Vice President for Research
Steven Lerman, Provost and Executive Vice President for Academic Affairs
Beth Nolan, Senior Vice President and General Counsel

This policy, as well as all [university policies](#), are located on the [Office of Compliance and Privacy's](#) home page.