

IFS/FASH/HRIM Human Subjects Review Policies and Procedures

To ensure that the rights and welfare of human subjects involved in research are protected, researchers are required to obtain human subjects clearance before research begins. All research involving human subjects, including research conducted by students, is subject to human subjects review. The Human Subjects Review Committee consists of the committee representative on the University Institutional Review Board (IRB) who acts as the chair, and three additional faculty members, one each from IFS, FASH, and HRIM.

Researchers--including faculty, staff, and students--who plan to collect data from individuals or to use human subjects data collected by others are responsible for understanding the policies and following the procedures for the protection of human subjects in research. Specifically, investigators must be familiar with the University's Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects, which can be found at www.udel.edu/OVPR.

Human Subjects policy applies to the following, regardless of the academic discipline or university unit involved:

- a. research sponsored by UD,
- b. research conducted under the direction of any employee in connection with his or her institutional responsibilities,
- c. research conducted by any employee using any property or facility of the institution, or
- d. Research involving use of the university's non-public information to identify prospective human subjects.

The level of approval required depends upon the research. Human Subjects approval can be given at three different levels:

1. Exempted Research
2. Research which may be reviewed through expedited review procedures, or
3. Research which requires University Human Subjects Review Board approval.

Exempted Research

Some research is exempt. This would normally include: a) certain research involving the use of survey procedures, or observation of public behavior if the identities of the persons cannot be determined, and b) research involving existing data or records. There are additional qualifications as well as populations for whom exemptions cannot be granted. For example, if the research involves children, pregnant women, individuals with disabilities or impairments, or prisoners, it cannot be exempt.

There are 6 categories of research that are defined as exempt (from 45CRF46. 101(b), 6/18/91):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies; or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if:
 - a. the human subjects are elected or appointed public officials or candidates public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

To initiate the exempted review process, the researcher should submit four (4) packets to Donald G. Unger, Ph.D. the chair of the Human Subjects Review Committee. Each packet should contain:

1. A completed [Human Subjects Form](#) as the cover sheet (if student, signature of advisor is also required).
2. A memo which:
 - a. describes the research project,
 - b. specifies the specific exemption category and the reason(s) given by the principal investigator(s) for exemption;
 - c. provides information on who the subjects will be, how many will participate, and how they will be recruited for the study; and
 - d. provides the phone number, email, and address (either on- or off-campus) of the principal investigator(s); if a student is the investigator, then the name of the advisor should also be included.
3. A copy of the protocol (interview questions, survey instrument, interview guide, observation guide, etc.) that will be used to gather the information from the human subjects.

If the Committee concurs that the research qualifies for exemption, the proposal will be forwarded to the Office of the Vice Provost for Research for review. **Only the Vice Provost for Research can grant an exemption. If the Vice Provost grants the exemption, the Research Office will send the letter granting exemption directly to the principal investigator.**

Expedited Review Procedures

Some research activities involving no more than minimal risk can be reviewed through the expedited review procedure. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. Risk may be social, economic, psychological, or physical in nature (Title 45, Code of Federal Regulations, Part 46.102).

Categories for research that commonly qualify for an expedited review are focus group research, face-to-face and telephone interviews and mail and written surveys. The categories of research that are defined as reviewable through the expedited process are listed in OPRR Reports, Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, Revised June 18, 1991, p. 17.

To initiate the expedited review process, the researcher should submit four (4) packets to Donald G. Unger, Ph.D., chair of the IFS/HRIM/FASH Human Subjects Review Committee. Each packet should contain:

1. A completed [Human Subjects Form](#) as a cover sheet (if a student, then advisor's signature is also required).
2. A memo that briefly describes the research project including the phone number, e-mail, and address (either on- or off-campus) of the principal investigator; if the investigator is a student, the advisor's name should be included.
3. A copy of the protocol (interview questions, survey instrument, interview guide, observation guide, etc.) that will be used to gather the information from the human subjects;
4. A copy of the Informed Consent Form that will be used in the research.

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and the subject's future reference. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.

Consent Guidelines. A summary of the guidelines is provided in this section. They represent a distillation of the information that is found in the federal law (45CFR46.116; 45CFR46.117) so that it is easier to understand and apply. Also, you are strongly encouraged to use the [Consent Form Checklist](#) when preparing your Consent Form.

1. Say it is research. Give the Purpose/Description.

- Clear statement that this is a research study
- Brief, clear statement of the purpose of the study
- Why the subject qualifies for participation in the study (how subject was chosen)
- Length of subject's participation
- Description of procedures
- Approximate number of subjects in the study.

2. Describe confidentiality and state conditions of subject's voluntary participation

- A statement of the extent to which confidentiality of records will be maintained (e.g. will information be disclosed to specific persons or agencies?)

- Availability of medical treatment if injuries occur; what services are available and who pays (under normal circumstances, this issue is not a factor in research conducted by persons in CHEP)
- Why and when subject could be dropped by the investigator (if applicable)
- Rights to refuse and/or withdraw. Consequences of the subject's decision to withdraw from research and procedures (normally a notification that there will be no adverse consequences that will accrue to the subject upon withdrawal)
- Assurance that participation is voluntary (refusal to participate or discontinue results in no loss of benefits to which the subject is otherwise entitled)

3. Describe risks and benefits

- Description of risks or discomforts to the subject
- Description of possible immediate or future benefits

4. Explain compensation

- Compensation to subject (if applicable)
- Costs to subject--what aspects of participation will and will not be paid for by research study (i.e., reimbursement for mileage) (if applicable)

5. Say who to contact for answers about a) research, and b) subject's rights

Two contacts for questions concerning the subject's rights, research project in general, and research-related injury. Should include local phone numbers and addresses for a) principal investigator and b) Chairperson, Human Subjects Review Board, Office of the Vice-Provost for Research. “If you have questions about the project, may you contact (name of principal investigator). If you have questions regarding your rights as a participant, you may contact Chairperson...”

6. Provide space for signatures and date

- Consent required from subject over 18 years of age.
- Consent required from parent/guardian if subject is less than 18 years of age.
- Assent required from subjects under 18 who are capable of providing it
- For interviews that are done by phone in which the identity of the subject is known, a signature is not required but participants do need to be informed of their rights, and verbally agree to participate.

7. Medical Treatment

Although it would be very rare for research conducted within CHEP to be concerned about medical treatment for a subject, the following statement may be included when appropriate. Do not offer medical treatment if you have not arranged to provide it.

"In the event of physical injury as a direct result of these research procedures, you will receive emergency medical treatment. If you require additional medical treatment, you will be responsible for the cost."

8. Properly number the pages (e.g., 1 of 3, 2 of 3) and include a place for subject's initials on each page.

9. Indicate that a copy of the consent form will be provided to the participant.

After the protocol is submitted, the Human Subjects Review Committee will review the proposal and render a decision. A decision to approve an expedited review can be made by the Human Subjects Review Committee. A copy of each protocol approved by the Review Committee is sent to the Research Office for inclusion in the record. An approval by the Review Committee is effective for a period of no more than one year; less if stipulated by the reviewers. If the Review Committee declines to approve a project, it is referred to the University's Human Subjects Review Board for a final review and decision. A letter granting the approval will be sent to the researcher.

Research requiring University Institutional Review Board (IRB) approval

All research that neither qualifies for an exemption nor an expedited review goes to the University Institutional Review Board (IRB). This board meets on a monthly basis to review research proposals. For board review, the researcher submits a cover letter and fourteen (14) copies of the proposed research protocol, including the informed consent form, to the Office of the Vice Provost for Research. If, after their review, board members suggest no revision or additions, an unconditional approval of the research is issued. If minor changes are required, an approval is granted with reservations noted. The principal investigator is requested to attend the meeting of the HSRB at which his/her protocol is reviewed. Depending upon the date of the board meeting, the board's review normally takes about 2 to 5 weeks.

Lastly, the Human Subjects Renewal Process

The Human Subjects Approval is reviewed annually. A year from the date of the initial approval, the investigator needs to inform the Office of the Vice Provost for Research that the research is either a) completed, or b) still underway. If still underway, the Investigator needs to indicate any changes that have taken place. The investigator will receive a Renewal Form from the Office of the Vice Provost for Research prior to the expiration of the prior human subjects approval. This Renewal Form is to be completed by the investigator, and then sent to the IFS/FASH/HRIM Human Subjects Review Committee for approval. Upon approval, it is then forwarded to the Office of the Vice Provost for Research.

This document was adapted from Human Subjects Review: Graduate School of Urban Affairs and Public Policy (October, 2001) and documents from the Office of the Vice Provost for Research, University of Delaware.