Human Subjects Review
Graduate School of Urban Affairs & Public Policy
Policies, Procedures & Sample Informed Consent Forms

Adopted June 1996, Updated September 2004

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 of SUAPP consists of the School representative on the University Institutional Review Board (IRB)who acts as the chair and two members of the School faculty and/or professional staff. The level of approval required depends upon the nature of 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 categories of research are exempt. For purposes of the School, that would normally include: (1) certain research involving the use of survey procedures, or observation of public behavior, and (2) research involving existing data or records.

Note: 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.

To determine if a proposed project qualifies for an exemption, describe the proposed human subjects protocol (or include it) and explain why it is exempt. The categories of research that are defined as exempt (from 45CRF46. 101(b), 6/18/91) are:

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 for 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.

STARTING THE PROCESS: To initiate the exempted review process in the School, the researcher should submit a packet to the chair of the School's Human Subjects Review Committee (Dr. Danilo Yanich). The packet should contain:

1. A memo which briefly describes the research project, specifies the reason(s) given by the principal investigator(s) for exemption and includes the phone number and address (either on- or off-campus) of the principal investigator;

2. 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, 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

The packet should be submitted electronically to Dr. Yanich at: dyanich@udel.edu.

Expedited Review Procedures

Some research activities involving no more than minimal risk can be reviewed through the expedited review procedure of the School. 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. The publication is available in the Dean's office. Common categories for research that qualify for an expedited review used in this School are focus group research, face-to-face and telephone interviews and mail and written surveys.

Upon approval of the faculty, the School submitted to the Vice Provost for Research a set of standard research protocols for annual approval. Research conducted under the terms of these protocols will follow procedures for expedited review.

STARTING THE PROCESS: To initiate the expedited review process in the School, the researcher should submit a packet to the chair of the School's Human Subjects Review Committee (Dr. Danilo Yanich). The packet should be submitted to Dr. Yanich electronically at: dyanich@udel.edu. The packet should contain:

1. A memo which briefly describes the research project including the phone number and address (either on- or off-campus) of the principal investigator (in the body of the email);

2. A copy (in an attachment) of the protocol (interview questions, survey instrument, interview guide, observation guide, etc.) that will be used to gather the information from the human subjects;

3. A copy (in an attachment of the Informed Consent Form that will be implemented in the research. A sample Informed Consent Form appears on the last page of these guidelines.

The School committee will review all proposals in this category and render a decision. A decision to approve an expedited review can be made by the School's Human Subjects Review Committee. A copy of each protocol approved by the School review committee is sent to the Research Office for inclusion in the record. An approval by the School's review committee or the University's full board is effective for a period of no more than one year; less if stipulated by the reviewers. If the School's review committee declines to approve a project, it is referred to the University's Human Subjects Review Board for a final review and decision. Expedited reviews by the SUAPP committee typically take less than one week and the 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.

SUPPORTING DOCUMENTS:This summary was based on procedures used at the university as well as the documents (available in the Dean's office) listed below. For additional information consult:

--OPRR Reports, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (4/18/79).

--OPRR Reports, *Protection of Human Subject*. Title 45, Code of Federal Regulations, Part 46, revised 6/18/91.

--*Multiple Project Assurance of Compliance with DHHS Regulations for the Protection of Human Subjects*, University of Delaware (March, 1993).

General Description of Informed Consent Guidelines & Informed Consent Form

These guidelines have been adopted by the University's Human Subjects Review Board. They represent a distillation of the information that is found in the federal law (45CFR46.116) so that it is easier to understand and apply. They represent the points you should address (if the point is appropriate) in each informed consent form that you develop for your research. At the end of the guidelines, a sample informed consent form appears that you may use as a guide. If you have questions, please contact Danilo Yanich, Chair of the School's Human Subject Review Committee at ext 1710 or email: dyanich@udel.edu.

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

2. Conditions of Subject Participation
   - A statement of the extent, if any, to which confidentiality of records will be maintained
   - 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 the School of Urban Affairs & Public Policy; see section 8)
   - Why, when subject could be terminated by the investigator
   - 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 of notification of significant findings that may determine the subject's willingness to continue

3. Risk and Benefits
   - Description of risks or discomforts to the subject
   - Description of possible immediate or future benefits

4. Financial Considerations
   - 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)

5. Contacts
   - Contacts for questions concerning the subject's rights, research project in general and research-related injury (Should include phone numbers of principal investigator and University Associate Provost for Research, Dr. Richard Holsten, 302/ 831-2136.

6. Assurances
   - Assurance that participation will be considered voluntary (refusal to participate or discontinuation results in no loss of benefits to which the subject is otherwise entitled)

7. Consent Signatures
   - *Consent* required from subject over 18 years of age.

- *Consent* required from parent/guardian if subject is under 18 years of age.
- *Assent* required from subjects under 18 who are capable of providing it

8. Medical Treatment
   - Although it would be very rare for research conducted within the School 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.

Sample Informed Consent Form*
(Face to Face Structured Interview)

The University of Delaware is conducting research regarding the attitudes of citizens about various institutions in our society. The purpose of the study is to determine the extent to which citizens trust the activities of these institutions. You have been chosen at random from the citizens in the state of Delaware to participate in the study. Overall, 500 persons will be included in the study. Participation in the study will require answering questions from a survey and will take approximately 15-20 minutes of your time.

Your answers will be kept confidential and your responses will not be linked to you personally; they will be reported as a group. You can refuse to answer any question or to stop the interview at any time. Withdrawing from the project will not result in any negative consequences for you.

Essentially your participation poses no risks to you. The benefits will accrue to the institutions that are the subject of the survey.

If you have questions about the project you may contact (name of principal investigator) at (phone number). If you have questions regarding your rights as a participant, you may contact Dr. Richard Holsten, Associate Provost for Research, University of Delaware at 302/ 831-2136.

Do you wish to participate?

By your signature below, you agree to participate in the study. You will be given a copy of this form.

_____ _____
Participant signature Date Project Director Date

_____ _____

* *This is a sample consent form for a research project that would qualify under the "expedited" review and that involves face-to-face structured interviews. For interviews that are done by phone in which the identity of the subject is known, obviously, no signature is possible. In telephone interviews where the subjects are chosen by random digit dialing and their identities are unknown, the research qualifies for exemption.*

Note: If the Informed Consent Form exceeds 1 page, each page other than the signature page must be numbered using the "n of n" (ex. 2 of 3) format and contain a place for the subject's initials.

Sample Informed Consent Form
(Semi-Structured Face-to-Face Interview w/ audio-taping)

The University of Delaware is conducting research on historic preservation in Delaware. The purpose of the research is to determine the activities of cities and towns (specifically those that employ planners and/or historic preservationists) in identifying and preserving historically important structures. Ten such jurisdictions were randomly selected. Due to your position as planner/historic preservationist in one of the selected communities, you have been chosen to participate. Overall, ten to fifteen persons in similar roles across the state will be included in the study. Participation in the study will involve a 20-30 minute interview.

Your answers may be reported by position, but individual names will not be included in the analysis. The interview will be audio-taped. The audiotape and the the interview notes will be destroyed within one year of the completion of the project. You can refuse to answer any question or to stop the interview at any time. Withdrawing from the project will not result in any negative consequences for you.

Essentially your participation poses no risks to you. The benefits will accrue to the jurisdictions that are the subjects of the survey.

If you have questions about the project you may contact (name of principal investigator) at (phone number). If you have questions regarding your rights as a participant, you may contact Dr. Richard Holsten, Associate Provost for Research, University of Delaware at 302/ 831-2136.

Do you wish to participate? Please initial here _____ if you agree to the audio-taping of the interview. You are free to stop the audio-taping at any time during the interview.

By your signature below, you agree to participate in the study. You will be given a copy of this form.

_____ _____

Participant signature Date Project Director Date

Note: If the Informed Consent Form exceeds 1 page, each page other than the signature page must be numbered using the "n of n" (ex. 2 of 3) format and contain a place for the subject's initials.

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