

**A GUIDEBOOK OF
POLICIES AND PROCEDURES
FOR
RESEARCH INVOLVING HUMAN SUBJECTS
THE COLLEGE OF WILLIAM AND MARY
PROTECTION OF HUMAN SUBJECTS COMMITTEE
Institutional Review Board**

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TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
INTRODUCTION.....	1
I. DEFINITION OF TERMS.....	2
II. STATEMENT OF PRINCIPLES.....	3
III. PHSC MEMBERSHIP	7
IV. PHSC PROCEDURES, INSTITUTIONAL RESPONSIBILITIES AND INVESTIGATORS’ RESPONSIBILITIES	9
V. PHSC CRITERIA FOR EVALUATING AND APPROVING PROPOSALS	14
VI. INFORMED CONSENT	16
WRITTEN INFORMED CONSENT REQUIREMENTS.....	19
EXAMPLE A: MINIMAL RISK POTENTIAL.....	22
EXAMPLE B: MEDICAL/BIOLOGICAL STUDY WITH LOW RISK POTENTIAL REQUIRING ASSENT OF SUBJECT AND CONSENT OF PARENT.	23
EXAMPLE C: COVER LETTER FOR MAILED QUESTIONNAIRE WHEN USE OF CONSENT FORM COULD PRESENT RISK IN AN OTHERWISE ANONYMOUS, RISK-FREE PROJECT. 25	25
EXAMPLE D: PARENTAL CONSENT LETTER.....	26
VII. EXPEDITED REVIEW.....	27
VIII. EXEMPTIONS.....	29
IX. RESEARCH ON PREGNANT WOMEN, FETUSES, PARTS OF FETUSES, AND PLACENTAS, BIOMEDICAL AND BEHAVIORAL RESEARCH ON PRISONERS, AND STUDIES OF CHILDREN AND WARDS OF THE STATE ..	31
APPENDIX.....	32
APPLICATION INSTRUCTIONS FOR APPROVAL OF INVESTIGATION INVOLVING USE OF HUMAN SUBJECTS	32

INTRODUCTION

The Protection of Human Subjects Committee (PHSC) has been operating at the College of William and Mary for many years. In January 1988, Provost Melvyn D. Schiavelli issued a clear charge to the Committee for maintaining integrity in research involving humans. In July 2002, Provost Gillian Cell, while upholding the original charge, issued the following:

The Committee is charged with insuring (a) that all research on human subjects conducted by the students, faculty, and staff of the university and any external investigators consistently meets the highest ethical standards, and (b) that such research is conducted in full compliance with applicable federal and state laws and regulations.

In order to meet this charge, the Committee shall: (a) prepare suitable documents to inform the university community of the need for research approval and of the proper procedure for securing such approval; (b) conduct prior review, as specified in appropriate regulations, of proposed research; (c) require periodic updating on the progress of long-term research; (d) have the responsibility to halt unapproved or non-compliant research; and (e) if appropriate, report all violations of guidelines and regulations to the appropriate department Chairperson or Dean and to the Provost.

To promote efficient and timely action by the University Committee, it is expected that those Schools or Departments engaging in significant amounts of human research will establish or maintain their own committees on human research. Such committees shall provide a preliminary review of proposals prior to forwarding them to the University Committee. The University Committee shall have the authority to delegate to the departmental or school committees the authority to grant final approval to demonstrations and research conducted as part of course work as long as the projects clearly meet the Federal definition of minimal risk. All undergraduate honors thesis and graduate thesis research, as well as faculty and staff research on human subjects, regardless of funding source, must, however, be approved by the University Committee.

The Committee is further charged with providing to the Provost, in June of each year, a report of its activities. Recommendations for Committee membership for the following year must be forwarded to the Provost in April of each year. The term of membership shall be from July 1 to June 30; the Committee shall operate year-round. With the approval of the Vice Provost, the Committee Chair may appoint temporary replacement Committee members during those times when the university is not in regular session.

This manual has been prepared by the Committee to partially fulfill that charge. We thank the institutional review boards of Ohio State, the University of Iowa, Eastern Virginia Medical School, Virginia Commonwealth University, and especially the University of Houston for sharing their materials with our committee. This document is based in part upon a similar manual in use at the latter institution.

Stanton F. Hoegerman
PHSC Chair, 1987-1989

The policies and procedures in this manual have been revised to incorporate an electronic submission and tracking system for proper documentation and review of studies involving human subjects at The College of William and Mary.

Raymond W. McCoy
PHSC Chair 1994-2002

I. DEFINITION OF TERMS

1. Research means systematic investigation designed to develop or contribute to generalizable knowledge. Under this definition some demonstration, service, and training projects may be considered to include research activities.
2. Human subject generally means a living individual about whom an investigator conducting research obtains a) data through intervention or interaction with the individual or b) identifiable, private information. Fetuses and fetal tissues, whether alive or dead, are also “human subjects.”
3. Private information includes 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 that has been provided for specific purposes by an individual, which that individual can reasonably expect will not be made public (i.e., a medical record). It also includes information revealed by a primary research subject about another individual without the consent of that individual.
4. Minimal risk means that the risks of harm anticipated in the proposed research are not greater in either probability or magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
5. Informed assent means the subject’s agreement to participate in the absence of full understanding. This concept commonly applies to individuals who have not attained legal majority and/or capacity.
6. Informed consent means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
7. Legally authorized representative means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the research procedure(s).

II. STATEMENT OF PRINCIPLES

The College of William and Mary (hereafter, “the College”) is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the College seeks to protect the welfare of every person who may be involved in research and training projects. Members of the College community, although upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the College and society, and for the welfare of every participant in a project. The College gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended). Thus, the following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the *Declaration of Helsinki* and by the *Ethical Principles in the Conduct of Research with Human Participants* of the American Psychological Association.

1. Because the participation of humans in research and training projects may raise fundamental ethical and civil rights issues, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other College employees, on-campus or off-campus.
2. All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.
3. The direct or potential benefits to the subject or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research.
4. Participation in projects must be voluntary, and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the Protection of Human Subjects Committee (PHSC). Methods that are in accordance with the requirements of 45 CFR §46.116 and 45 CFR §46.117 and adequate and appropriate to the risks of the project must be used to obtain the subjects’ informed consent.

5. When required, consent must be obtained from the participants themselves whenever possible. Further, if a subject is not legally or physically capable of giving fully informed consent, a legally authorized representative should do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents, for example, may not expose their child to more than minimal risk except for the child's direct benefit.
6. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or to refuse to participate, without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue physical risk, embarrassment, discomfort, anxiety, and harassment.
7. The PHSC acknowledges the potential for a conflict of interest or coercion in an academic setting where participants in research studies are also students in a course. The primary investigator is responsible for minimizing these effects in recruiting subjects.
8. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. Such information shall not be communicated to others unless one of the following conditions is met:
 - A. Explicit permission for the release of identifying data is given by the individual.
 - B. Information about individuals may be discussed only for professional purposes and only with persons clearly involved in the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid a breach of confidentiality.
 - C. The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a subject).

Investigators must maintain confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the PHSC and carried out by the principal investigator until the records are destroyed. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project.

9. The PHSC shall initially and, later, annually review projects as set forth in Section IV. All members of the College community involved in investigation and training are responsible for continual monitoring to assure that their research complies with these principles.
10. An individual involved in the conduct and/or supervision of a specific project shall not participate in PHSC review, except to provide information.
11. A second review may be required if: (a) a long interval has elapsed between PHSC review and project initiation; (b) the proposed effort is in a rapidly evolving area; or (c) the principal investigator wishes to change procedures after the proposed project has been reviewed by the PHSC. In no case will work continue without at least an annual review.
12. In all cases, the investigator should show practical regard for The College of William and Mary community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (for example, concerning confidentiality, informed consent, debriefing, and regard for the health, safety, and welfare of all human subjects) could harm the investigator's own name and the reputation of the College. The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the investigator to obtain formal approval from the PHSC prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in institutional restrictions on the individual's research activities and/or disciplinary action against such individuals. In addition, violation of regulations may endanger all federal funding to the College.
13. When the investigator is a student, ultimate responsibility for the conduct of this research and the supervision of human subjects lies with the faculty sponsor. Following project approval, the faculty sponsor must provide proper oversight and review to ensure that subject recruitment, informed consent procedures, and subsequent contact with subjects are in conformity with approved guidelines (see Section IV). Similarly, when the investigator is a staff member, ultimate responsibility for the conduct of the research and the supervision of human subjects lies with the department director who must provide proper oversight and review as described above.

14. Outside investigators (non-William and Mary students or employees) conducting human subject research on a William and Mary campus or conducting research associated with the College are subject to the principles, procedures, and responsibilities outlined in this manual.
15. This guidebook is largely an attempt to organize and summarize federal and state regulations, which are minimal standards guiding the PHSC. THE PHSC HAS THE AUTHORITY TO MANDATE ADDITIONAL REQUIREMENTS FOR SPECIFIC PROPOSALS IF THEY ARE BASED ON ESTABLISHED RESEARCH, SAFETY, AND/OR ETHICAL CONSIDERATIONS. The federal and state regulations may be obtained from the PHSC web site: <http://www.wm.edu/grants/compliance/phsc.php>.

III. PHSC MEMBERSHIP

1. The membership of the PHSC shall include at least one community representative, the Vice Provost or his/her designated representative, and a minimum of six faculty members. Faculty members will be selected according to the College's research needs, but shall include at least one member whose primary expertise is in a non-scientific area (e.g., law, religion, or ethics). Ideally, the Committee should include members from Biology, Education, Kinesiology, Psychology, and other social sciences. The Committee shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. [45 CFR §46.107(a)]

The Committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Committee. These individuals shall have no voting rights.

Appointments to the Committee shall be made by the Provost on recommendation from the Faculty Affairs Committee, outgoing PHSC Chair, and/or the Vice Provost. Faculty representatives shall typically serve three-year terms, with one-third rotation each year. Non-faculty representatives shall serve for one-year terms. The Chair shall be appointed annually by the Provost from among the faculty committee members.

2. A majority of the members of the PHSC, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the PHSC shall then require a two-thirds vote by members present. If the PHSC agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval will be sent to the investigator with copies to the faculty advisor (if appropriate) and to the school or department internal review committee (if any).

3. Departments and schools may establish, or continue to operate internal review committees. These internal review committees shall provide preliminary reviews of their divisions' proposals prior to review by the College PHSC. The College PHSC will not consider a proposal originating from within those schools or departments that maintain internal review committees unless the proposal first has been approved by that committee.

The internal review committee must consist of at least three, but not more than five, faculty members with one of the members serving as Chair. The Chair of the internal review committee will be responsible for coordinating the electronically submitted proposals with the Grants Office and with the Chair of the College PHSC. The Chair of the internal review committee should submit the names of the committee members to the Chair of the College PHSC in September of each year.

Proposals submitted to internal review committees must be reviewed by at least two faculty members. Faculty members may not exempt or review a study in which they or their research students are involved.

All email and written correspondence between authors of proposals and reviewers will be maintained for a period of three years at the Grants Office. The Chair of the College PHSC and the Chairs of the internal review committees must forward their files to the Grants Office in August of each year.

4. All members of the College PHSC and the internal review committees must complete the National Institutes of Health (NIH) On-line Educational Module located at: <http://cme.nci.nih.gov/>. (A link to the NIH training module is posted on the PHSC Web page.) The certificate of completion for new committee members must be forwarded to the Chair of the PHSC in September of each year.

IV. PHSC PROCEDURES, INSTITUTIONAL RESPONSIBILITIES AND INVESTIGATORS' RESPONSIBILITIES

1. All human subject research proposals affiliated with The College of William and Mary will be electronically submitted for documentation and tracking. Proposals from colleges or departments that have an internal review committee will be forwarded to the Chair of that committee for initial review. The Chair of the College PHSC or the Chair of the internal review committee will determine if the proposal is exempt from the need for further review or must be reviewed by the College PHSC. Researchers cannot exempt from review their own study or research for which they are responsible. Similarly, individuals involved in the conduct and/or supervision of a research project cannot participate in its review, except to provide information to the PHSC.
2. The College PHSC has the authority to approve or disapprove all research using human subjects. "Human research" includes undergraduate research (e.g. Honors), graduate thesis research, faculty and staff research, and research conducted by external investigators. Unapproved research may not be conducted on campus under any circumstance. Individuals connected with the College must have their off campus human research approved or exempted if the researcher indicates to subjects or other participants an affiliation with the College, if College funds or equipment are used, or if the research will be used to fulfill a degree requirement at the College.
3. There are two exceptions to the requirement for review by the College PHSC. Short-term student exercises which are an integral component of regular coursework (Honors is excluded) require only prior approval of the Chair of the PHSC or the Chair of an internal review committee. Similarly, proposals that are exempt from continuing review (see Section VII) require only that their exemption be verified by the Chair of the PHSC or the Chair of an internal review committee.
4. The PHSC recognizes the need for a thorough and speedy assessment of proposals. To assure prompt consideration, the Chair may choose the most efficient procedure for processing a particular proposal. If the Chair anticipates that there will be no or few questions over a proposal, the Chair may distribute the proposal to committee members with a request that the members evaluate the proposal by written memo or email. If all

members approve the proposal as submitted, the Chair shall immediately issue a letter of approval (either paper or electronic). Any member requesting minor changes may authorize the Chair to negotiate such changes, with or without requiring that they personally approve the revisions prior to the issuance of the approval letter. If a committee member has a major objection to such a proposal, that member may call for a meeting of the full committee.

On the other hand, if the Chair initially perceives that a submitted proposal is unacceptable or that it may require major revision, the Chair may initiate discussions with the principal investigator or faculty sponsor and suggest revisions. If there are no revisions or if the Chair is of the opinion that revisions will not meet all criticisms, the Chair shall distribute the proposal to committee members for review. The principal investigator (and faculty sponsor, if appropriate) may be invited to meetings held to consider the proposal. Even if the consensus of the PHSC is favorable, the PHSC may elect to impose additional restrictions or recommendations under which the project shall be conducted.

If the PHSC disapproves an application, reasons for this negative decision will be provided in writing to the principal investigator or project director. If the researcher decides to modify the proposed research in such a way as to overcome the objections of the PHSC, the investigator may resubmit the proposal for consideration and/or have the Chair call a PHSC meeting during which the investigator may defend the proposal or the modifications.

Principal investigators must immediately report to the PHSC and the internal review committee Chair (if applicable) any emergence of problems or development of hazardous conditions for subjects. The PHSC or its designee must approve an amended protocol before the research may continue.

5. An expedited review procedure is available for those proposals that involve no more than minimal risk to subjects and fall into a research category eligible for such review (see Section VII for a list of these categories) Final determination of whether a specific project is eligible for expedited review will be made by the Chair of the PHSC.

6. When granting initial approval of a proposal, the PHSC will indicate the minimum intervals between re-evaluation of the project, assuring continued acceptance of the proposal. Routine projects will be reviewed at yearly intervals; more complex and/or potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. Projects that are determined to be exempt will not require additional review. Renewal projects should include a progress report as well as a description of any anticipated design changes. Projects may also be reevaluated if subjects involved in the research lodge a complaint with the PHSC or the principal investigator reports problems with the research. In the latter case, the PHSC may elect to review the data accumulated by the investigator and may interview both the research staff and persons at risk.
7. Investigators may submit proposals acknowledging that human subjects will be involved with the project, although plans for the involvement are indefinite. Such proposals shall be reviewed and certified in the same manner as complete applications with the understanding that further review and approval will be required as more complete plans are made, but before utilizing human subjects. In the case of an externally funded project, this later review and approval must precede the beginning of any grant budget period during which human subjects would be utilized.

Ongoing projects *modified* to include humans as subjects must be submitted to the PHSC for review and approval prior to the use of human subjects. In the case of an externally funded project, the granting agency would be notified of PHSC action before the appropriation cycle for a budget period during which human subject involvement is proposed.

8. In the case of a proposal submitted to an external funding agency, one copy of the complete proposal must be submitted to the PHSC along with the PHSC application. Certification of approval (or pending approval) of the proposal, if required, will be made at the time the proposal is submitted to the agency. If pending approval is given at the time the proposal is submitted to the agency, then final approval will be forwarded by the Grants Office to the agency when the PHSC has reviewed and approved the proposal.

9. Primary responsibility for adherence to high ethical standards, to federal and state laws, and to College regulations must remain in the hands of the individual students, staff members, and faculty who comprise this institution. They must make the initial decision as to whether their activities are or are not “human research” subject to review by the PHSC. At times, this decision is not easily made. If any investigator is unclear as to whether proposed research is subject to review, it is recommended that the investigator seek the advice of the PHSC Chair or the appropriate internal review committee, if any.
10. As set forth in 45 CFR §46.113 Suspension or Termination of IRB Approval of Research, “an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action, and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.”

The College files an Annual Report on Possible Research Misconduct with the U.S. Department of Health and Human Services Office of Research Integrity. The report includes the College’s assurance of an institutional policy for responding to allegations of research misconduct. The College’s policies concerning academic misconduct are delineated in the *Faculty Handbook*, Section E, “Integrity in Research and Scholarly Activity.”

11. The electronic submission procedures, along with these policies and procedures, sample consent forms, and links to information concerning the use of human subjects in research may be found on the PHSC web site <http://www.wm.edu/grants/compliance/phsc.php> . This site is maintained by the Grants Office under the direction of the Vice Provost. The Grants Office will log in and review the application materials for procedural omissions before forwarding them to the PHSC Chair or the Chairs of the internal review committees.
12. Researchers applying for federal funding through NIH must complete the NIH On-line Educational Module prior to beginning the study. The certification of completion from

this module must be forwarded to the Chair of the PHSC and the Grants Office. The NIH On-line Educational Module can be accessed at: <http://cme.nci.nih.gov/>.

13. Proposals must be submitted in a timely fashion for proper review. Proposals that will be exempted from formal review must be submitted at least one week before the start date of the study. Those to be reviewed using the expedited procedures must be submitted at least two weeks before the start date, and proposals requiring full committee review must be submitted at least four weeks before the start date. Additional time may be needed if a proposal must be reviewed using more than one review procedure.

V. PHSC CRITERIA FOR EVALUATING AND APPROVING PROPOSALS

Consistent with the Code of Federal Regulations §46.111 Criteria for IRB Approval of Research, the PHSC will determine that the following requirements are satisfied in order to approve research covered by this policy [45 CFR 46.111(a)(1-7)]:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive, even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Additionally, the PHSC will consider the following factors:

- A. That all rights and welfare of the subjects will be adequately protected. Each project will be scrutinized with the interests of the subjects foremost in consideration. Safeguards and emergency measures must be provided as appropriate. The PHSC is concerned with the maintenance of proper records and the protection of anonymity and confidentiality of all data collected. Furthermore, the PHSC will attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation in a study. In short, the PHSC shall make every effort to ensure that both the mental and physical well-being of the subjects are adequately protected.
- B. That the risks to the subjects are reasonable in relation to anticipated benefits. The project protocol will be evaluated to determine whether risks to subjects are reasonable relative to the anticipated benefits, if any, to the subjects and/or to the importance of the knowledge that may reasonably be expected to result. The PHSC will not allow the use of human subjects in poorly designed projects that are unlikely to elicit meaningful results. The primary responsibility for research design quality lies with the faculty sponsor. When necessary, the PHSC will withhold project approval until an adequate design is adopted by the investigators.
- C. That the informed consent of subjects will be obtained by adequate and appropriate methods (as described in Section VI). Except in rare instances when some degree of deceit is essential to the experimental design, all subjects will be fully informed by the investigator of the procedures to be followed including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable by the subjects. Written informed consent must be obtained from all subjects, unless specifically waived by the PHSC in accordance with 45 CFR §46.117 (c) (1) or (2):
 - (1) “that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or
 - (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.”

VI. INFORMED CONSENT

Informed consent means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Informed consent is more than a signed document, it is a process. Written informed consent documents this process, but cannot serve as a substitute for it.

The information given to the subject, or the subject's legally authorized representative, must be in simple, easily understood language. If the subject does not speak English, the informed consent must be presented in the appropriate language.

In most cases, written documentation of the consent process (i.e. a cover letter or cover sheet) is required. Unless consent is specifically waived by the PHSC, the subject or the subject's legally authorized representative must sign the consent document. If the subject is a minor (under age 18) or mentally incompetent, written consent of a parent, guardian, or legally authorized representative is required, unless waived by the PHSC. Such a waiver, in accordance with 45 CFR §46.116, will be granted only if the investigator can provide adequate justification for the request. In addition to obtaining parental consent, the investigator must obtain *assent* of the child unless the child is incapable of giving assent *and* the PHSC has waived the requirement. *Informed assent* is the subject's agreement to participate in the absence of full understanding and commonly applies to individuals who have not attained legal majority and/or capacity.

In the case of certain surveys in which the only record linking the subject to the research or data would be a written signed consent form, the PHSC may waive the use of a signed consent form. Nonetheless, a statement describing the procedures and objectives of the research must be supplied to the subjects in a written format. For example, the PHSC may waive the use of a signed consent form for a project using a questionnaire that is distributed and returned anonymously through the mail. A cover letter sent with the questionnaire would include all the elements of informed consent listed in this section. If informed consent is to be obtained orally (i.e. prior to a telephone interview), a written summary of what subjects will be told must be provided to the PHSC for review and approval.

Under no circumstance may informed consent, whether oral or written, waive or limit in appearance or in fact the subject's legal rights, including any release of the institution or its agents from liability or negligence.

The general requirements for informed consent as they appear in 45 CFR §46.116 (a) through (f) are outlined below.

- a. Basic elements of informed consent: Except as provided in paragraph (c) or (d) of this section, in seeking informed consent, the following information shall be provided to each subject:
 1. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 2. A description of any reasonably foreseeable risks or discomforts to the subject;
 3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 5. A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained;
 6. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;
 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- b. Additional elements of informed consent: When appropriate, one or more of the following elements of information shall also be provided to each subject:
1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 3. Any additional costs to the subject that may result from participation in the research;
 4. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
 5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
 6. The approximate number of subjects involved in the study.
- c. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:
1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs

- or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.
- d. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research could not practicably be carried out without the waiver or alteration; and
 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- e. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed, in order for informed consent to be legally effective.
- f. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Written Informed Consent Requirements

Unless waived by the PHSC, the following information shall be supplied in all written informed consents:

1. A statement that the project is research, a brief explanation of the scope, aims, and purposes of the research, and the experimental procedures to be followed, including the expected duration of the subject's participation. This statement should include a description of any anticipated benefits the subject or others might reasonably expect.

2. Identification of the responsible investigator, as well as the name of any sponsoring or funding source supporting the research. The College of William and Mary shall be identified as the, or one of the, responsible institution(s).
3. The following statement will be included in ALL written informed consents (including cover letters). This statement should be inserted at the bottom margin of the form, letter, or portion of the form to be retained by the subject.

THIS PROJECT WAS APPROVED BY THE COLLEGE OF WILLIAM
AND MARY PROTECTION OF HUMAN SUBJECTS COMMITTEE
(phone: 757-221-3901) ON [INSERT DATE] AND EXPIRES ON [INSERT
DATE].

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A description of any reasonable, foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the potential risk is currently unknown or unmeasurable, a statement to that effect will be required.
6. A statement regarding the availability of compensation and/or medical treatment, if injury occurs, will be required for research which involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.
7. A statement that any new information developed during the course of the research which may relate to the subject's willingness to continue participation will be provided. Similarly, an offer to answer any questions the subject (or the subject's representative) might have regarding the subject's rights shall be included. This statement should include the name, address, and telephone number of the principal investigator as the contact point if questions or problems should occur.
8. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.

9. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. This statement should include a description of the consequences, if any, that would accompany such a decision to withdraw.
10. In studies where deceit is essential to the experimental design, the PHSC may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent [45 CFR §46.116(d)]. In such studies, honest debriefings must be held following the subjects' participation. The following section details federal, state, and PHSC requirements and procedures for informed consent.

A copy of the informed consent shall be supplied to the subject or the subject's legally authorized representative. Federal law mandates that copies of all informed consents be retained for a minimum of three years after the completion of the research. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records. If the investigator leaves the institution within this 3-year period, all records must be forwarded to the Grants Office for retention.

Examples of various types of informed consents are included in this section. These are to be used only as examples or guides for the formulation of individual informed consents and not as standard forms.

Example A: Minimal Risk Potential

I, _____, agree to participate in a study of individuals involved in the New Options Transitional Living program at the XXXX. New Options is a six-week live-in program designed to help severely physically disabled persons acquire adaptive skills. The purpose of this study is to evaluate the effectiveness of this program. We hope to use the information obtained from this study to modify this program so that it will better serve physically disabled persons.

As a participant, I understand that my involvement in the Transitional Living Program at XXXX will be coincident with my participation in this research project.

I understand that periodically (2-4 times) I will be expected to participate in a number of experimental tasks including the completion of forms, checklists, and questionnaires relating to my knowledge, attitudes, behavior, and the occasional observation of my activities. I have been told that I may be asked to participate further in this research several months after my involvement in the Transitional Living Program ends. If I am asked to continue participation, I will be told exactly what further participation will entail.

I have been informed that any information obtained in this study will be recorded with a code number that will allow Dr. Doe to determine my identity. At the conclusion of this study, the key that relates my name with my assigned code number will be destroyed. Under this condition, I agree that any information obtained from this research may be used in any way thought best for publication or education.

I understand that there is no personal risk or discomfort directly involved with this research and that I am free to withdraw my consent and discontinue participation in this study at any time. A decision to withdraw from the study will not affect the services available to me from XXXX or my participation in the New Options Transitional Living Program. If I have any questions or problems that arise in connection with my participation in this study, I should contact Dr. Doe, the project director at 749-XXXX (work) or 492-XXXX (home) or Dr. XXX, Chair of the Protection of Human Subjects Committee at the College of William and Mary at 221-XXXX. My signature below signifies that I am at least 18 years of age and that I have received a copy of this consent form.

Date

Signature of Transitional Living Participant

Date

Investigator

Date

Witness*

THIS PROJECT WAS APPROVED BY THE COLLEGE OF WILLIAM AND MARY PROTECTION OF HUMAN SUBJECTS COMMITTEE (phone: 757-221-3901) ON [INSERT DATE] AND EXPIRES ON [INSERT DATE].

*Witness signatures are required whenever the capacity of the subject to understand the description of the project and its associated risks is in question or when required by the PHSC.

Example B: Medical/Biological Study with Low Risk Potential Requiring Assent of Subject and Consent of Parent.

THE NATURE OF THE PROJECT

You are being asked to allow your son or daughter to take part in a study that is being conducted by Dr. Doe of the Biology Department of The College of William and Mary. This study will determine whether several chemicals which have an effect on how cells make their normal genetic material also have an effect on the frequency with which the fragile X chromosome is expressed in cells grown in tissue culture.

The immediate goal is to bring about the development of improved diagnostic techniques. As you probably know, some people who actually carry the defective chromosome have normal lab results. In at least some such people, the lab results are negative because the frequency of fragile X expression (perhaps around one in 200 cells) is so low that, by chance, no cell showing the abnormality is included among the cells studied through the microscope. If we can increase the frequency of fragile X expression, we can improve our diagnostic accuracy.

A secondary goal is to discover information on the basic mechanism behind fragile X expression. Information on what causes the X chromosome to break may possibly lead to a fuller understanding of the basic biology of the associated disease and then to rational therapy. I consider this a relatively unlikely outcome and thus rate this goal as secondary.

In general, it would be best to conduct such studies with either animals or cells from long-term tissue culture but, unfortunately, neither of these approaches is possible here. There is no animal model of the fragile X syndrome and the biochemistry of fragile X expression in blood cells is so different from that in other cell types that blood cells would be needed for the development of any test which uses blood cells. Therefore, there is no alternative to the use of blood cells from the patients themselves.

THE PROCEDURE

If you are willing to have your son or daughter help us with this study and if he or she is willing to participate, blood will be drawn from a vein in his or her arm into small glass tubes. At the very most, 30cc of blood (which is equal to 3 regular sized blood tubes, each holding about a teaspoon) would be drawn at any one time. I may ask for a blood sample once per month for a maximum of 6 times per year. The blood would be drawn, at your convenience, by your personal physician (or by an employee of your personal physician). We will be happy to pay your physician's bill for this service. In addition, we will be happy to offer an honorarium of \$10 to the patient for his or her help.

The process involves some slight discomfort and there is a small risk of bruising, fainting, and/or infection. In addition, there is a small chance that your son or daughter will become unduly agitated or upset by the process. I will write a letter to all participating physicians asking that they immediately stop attempting to draw the blood if the patient objects or becomes upset.

Any important findings of this study will of course, be shared with you and, if you desire, with your doctor. All parents have the right to withdraw their son or daughter from the study at any time without prejudice. Information gained from this study may eventually be published but patients' and their families' names would not be used.

PROBLEMS OR QUESTIONS

Should you have any unsettled questions, problems, concerns, or complaints about this project, please contact either Dr. Doe at the Department of Biology, The College of William and Mary, Williamsburg, VA 23187 (phone: 757-221-4240) or Dr. XXX, Chair of the Protection of Human Subjects Committee at the College of William and Mary (phone: 757-221-XXXX).

If you are willing to participate, please return one copy of this form to me in the enclosed envelope.

PARENT'S CONSENT

Date _____

I, _____, do hereby state that I have read and understand the above. I give permission for my son or daughter _____ to participate in this research on the fragile X syndrome.

I have received a copy of this form.

Signed _____

Parent or guardian

I feel that it is ethically essential that your son or daughter understand exactly what will be expected of him or her and agree to participate. Your child must also understand that he or she can "call it quits" at any time. Would you please help explain this and have your son or daughter sign (or make a mark) below.

SUBJECT'S ASSENT

Date _____

IT IS OK TO USE A NEEDLE TO TAKE SOME EXTRA BLOOD.

Signed _____

Patient

Signed _____

Witness

THIS PROJECT WAS APPROVED BY THE COLLEGE OF WILLIAM AND MARY PROTECTION OF HUMAN SUBJECTS COMMITTEE (phone: 757-221-3901) ON [INSERT DATE] AND EXPIRES ON [INSERT DATE].

Example C: Cover Letter for Mailed Questionnaire when Use of Consent Form Could Present Risk in an Otherwise Anonymous, Risk-Free Project.

Dear _____:

We are asking for your help. Please take a minute to read this letter.

The Personnel Psychology Services Center in the Department of Psychology of the University of Utopia currently is involved in a multi-organization study of employee turnover. This research project is funded by the Department of Labor. The objective of this research project is to attempt to understand why people leave their jobs.

Enclosed with this letter is a brief questionnaire that asks a variety of questions about your attitudes toward your job with the University. We are asking you to look over the questionnaire, and if you choose to do so, to complete the questionnaire and to send it back to us at the Department of Psychology. Do not write your name on the questionnaire. We do not need to know who you are. The results of this project will be summarized and appropriate people with the University will receive a summary report. We emphasize that this is a research project. We guarantee that your choice to participate and your responses if you do participate will not be identified with you personally. Nothing you say or do will in any way affect your past or even future employment with the University. Also this information will not affect your use of the University as a previous employer and any job references that you may list. We plan to compare the answers of people who have left with a group of people who are still employed with the University.

We hope you will take a few minutes to complete this questionnaire and to return it in the enclosed self-addressed, stamped envelope. Without the help of people like you, research on employees could not be conducted. Regardless of whether or not you choose to participate, we will send you a summary of our findings. To receive a summary, use the enclosed letter sized self-addressed, stamped envelope and the address form. To preserve your anonymity, you can send this request by separate mail. In this way, we have no way of knowing who sent back a questionnaire and who requested a summary of results.

Understanding why people quit their jobs is very important. Through your participation, we eventually hope to understand how best to satisfy the needs of organizations and the needs of employees. We ask your participation and thank you for reading this letter.

Cordially,

John Q. Doe, Associate Professor
Department of Psychology
The College of William and Mary
Phone: 757-221-2222

THIS PROJECT WAS APPROVED BY THE COLLEGE OF WILLIAM AND MARY PROTECTION OF HUMAN SUBJECTS COMMITTEE (phone: 757-221-3901) ON [INSERT DATE] AND EXPIRES ON [INSERT DATE].

Example D: Parental Consent Letter

Dear Parents:

I will be conducting a research project designed to study how children think and develop strategies in games. I request permission for your child to participate. The study consists of two twenty-minute sessions where children will play tic-tac-toe one day and a guessing game on another. The goals of the study are to detail the strategies of game-playing used by children of different ages and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity, and will accompany me only if he or she is willing to do so. Children usually enjoy games, so I expect that children will be interested and enthusiastic about participating; however, any child who expresses a desire to return to the classroom will be escorted back immediately. I will conduct interviews and my research assistant will videotape them. Children's responses will be reported as group results only. Individual taped responses will be used as examples of scoring procedures; however, the children will not be identified by name. I will retain the videotapes at the study's conclusion. These tapes may be reviewed by the child's teachers, and some may be shown to groups when the study is presented to students and teachers and at professional conferences. To preserve confidentiality, only first names will be used to identify children. In addition to game participation, I will need to look at the school's records in order to obtain your child's birth date and mathematics scores on the Iowa Tests of Basic Skills.

Your decision whether or not to allow your child to participate will in no way affect your child's standing in his or her class or school. At the conclusion of the study, a summary of group results will be available to all interested parents and teachers. Should you have any questions or desire further information, please call me at 749-2222. Thank you in advance for your cooperation and support.

Sincerely,

John Q. Doe, Assistant Professor
Department of Curriculum and Instruction
The College of William and Mary

THIS PROJECT WAS APPROVED BY THE COLLEGE OF WILLIAM AND MARY PROTECTION OF HUMAN SUBJECTS COMMITTEE (phone: 757-221-3901) ON [INSERT DATE] AND EXPIRES ON [INSERT DATE].

Please indicate whether or not you wish to have your child participate in this project, by checking a statement below and returning this letter to your child's teacher as quickly as possible.

I do grant permission for my child, _____ to participate in this project.

I do not grant permission for my child, _____ to participate in this project.

Parent/Guardian's signature

VII. EXPEDITED REVIEW

DHHS regulations recognize that there are certain categories of research which involve procedures that pose no more than minimal risks to subjects and for which clear standards can be set (Addendum: 46 FR 8392). Accordingly, research projects that fall within one of these categories listed below will be reviewed by the PHSC Chair and, if deemed necessary, by one or more PHSC members.

All members involved in an expedited review must agree that the protocol falls under one of the expedited categories. Any member engaged in an expedited review may object to the application of the expedited review procedure or may have further questions that the investigator must answer. Similarly, each member has the option of referring the application to the PHSC for full review.

If the application is approved using expedited review procedures, the PHSC Chair will issue an approval letter as with any other approved proposal.

Investigators should be aware that even though applications for expedited review are less complicated to review and, if there is no need for revision or modification, are generally approved more quickly than other proposals, there can be no guarantee that this will be the case. If, for example, a proposal initially is submitted for expedited review but the reviewers feel that the entire PHSC should review the proposal, the total time required may actually be lengthened.

Listed below are eleven research categories which, by federal regulations, are eligible for expedited review. *Only* research protocols that fall in one of these categories are eligible for expedited review:

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction;
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;

3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures include weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (i.e., x-rays and microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant;
5. Collection of both supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
6. Voice recordings made for research purposes such as investigations of speech defects;
7. Moderate exercise by healthy volunteers;
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens;
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
11. Minor modifications or additions to existing approved studies.

VIII. EXEMPTIONS

The College has adopted five categories of human research as exempt from the need for PHSC approval based upon DHHS regulations published in the Federal Regulations 45 CFR 46.101.b. The investigator should indicate the number of the category under which an exemption is claimed on the electronic application form. The determination as to whether a research project is exempt will be made by the Chair of the appropriate internal review committees or by the Chair of the College PHSC. If a research project is certified as exempt by the PHSC, the investigator need not submit the project for continuing review as long as there are no modifications.

The use of the term “exempt” refers to the requirement for continuing PHSC review, but not the general requirements for informed consent and protection of subjects. Thus, even if your project is exempt you still must inform potential subjects of the proposed procedures and of their rights as subjects.

The following categories of exemption have been adopted by the College:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as: (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

The College PHSC interprets these areas of disclosure to include research that deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug or alcohol use, and sexual behavior.

This exemption does not apply to research involving survey or interview procedures of children unless the observation is of public behavior when the investigator does not participate in the activities being observed (45 CFR 46, Subpart D, 46.401.b).

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of 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, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

IX. RESEARCH ON PREGNANT WOMEN, FETUSES, PARTS OF FETUSES, AND PLACENTAS, BIOMEDICAL AND BEHAVIORAL RESEARCH ON PRISONERS, AND STUDIES OF CHILDREN AND WARDS OF THE STATE

The federal regulations dealing with studies on the above categories of human subjects are complex. Before submitting a proposal, investigators contemplating research utilizing these populations should obtain a copy of the most recent revision of the Code of Federal Regulations (45 CFR 46, Protection of Human Subjects), Subparts: B – Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human *in vitro* Fertilization; C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and D – Additional Protections for Children Involved as Subjects in Research. These regulations may be obtained from the PHSC web site: <http://www.wm.edu/grants/compliance/phsc.php>

APPENDIX

Instructions for Submitting a Human Subjects Proposal

HUMAN SUBJECTS PROPOSALS ARE SUBMITTED FOR APPROVAL BY USING THE ELECTRONIC FORM LOCATED IN myWM, using the Self Service tab at <https://my.wm.edu/cp/home/displaylogin> . BEFORE COMPLETING THE ELECTRONIC PROPOSAL FORM, THE PRINCIPAL INVESTIGATOR OR PROJECT DIRECTOR SHOULD BE FAMILIAR WITH THE POLICIES AND PROCEDURES OF THE COLLEGE OF WILLIAM AND MARY AS DESCRIBED IN A *GUIDEBOOK OF POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS* (hereafter referred to as *Guidebook*).

INVESTIGATORS MAY NOT INITIATE ANY RESEARCH INVOLVING HUMANS UNTIL THEY HAVE RECEIVED NOTIFICATION OF PHSC APPROVAL AND HAVE AGREED TO COMPLY WITH ALL CONTINGENCIES MADE IN CONNECTION WITH THAT APPROVAL.

The investigator must complete the electronic proposal form. If the investigator is a student, the application must be approved by the student's faculty sponsor. The electronic proposal and all supporting materials are forwarded to the Grants Office for preliminary review and distribution. Supporting materials such as questionnaires, approval letters from cooperating institutions, consent forms, etc., must be included as attachments and forwarded with the proposal. Any investigator who has submitted or plans to submit a project to an external agency for funding must forward one complete copy of the external proposal to the Committee as soon as it is available. The external proposal should be considered as a supplement or appendix to the PHSC application.

If the investigator's school or department maintains an internal review committee, the Grants Office will forward the proposal to that committee for review. Otherwise, the Grants Office will send the proposal directly to the PHSC for review. The Chair of the internal review committee or the PHSC Chair will notify each applicant of the committee's decision.

Investigators may electronically submit proposals for full committee review, expedited review, or exemption from review. Investigators must indicate the “Level of Review” on the electronic proposal form and the applicable category justifying this request.

Review of proposals may be expedited if they fall under one of the eleven categories of eligibility of expedited review. Under federal regulations, the PHSC may give expedited review to only certain categories of research which pose no more than minimal risk to potential subjects. The investigator must indicate the number of the expedited review category applicable to the project. The research categories eligible for expedited review are listed in the *Guidebook* on pages 27 and 28. If the research does not fall under one of these categories, it cannot receive expedited review.

Proposals may be exempt from PHSC review if they fall under one of the five categories for exemption (See Section VIII, pp. 29-30 of *Guidebook*). If an investigator believes that the research is exempt from review, the investigator must ensure that the application clearly states how the project meets the criteria for the exemption claimed. For example, one of the criteria for Exempt Category 2 is that responses be returned anonymously. It must be indicated that completed questionnaires will not be coded with any individual identifying number, and thus, responses will be anonymous.

A written informed consent form documents the consent process. This process consists of a description of the specific research project, the procedures each subject will undergo, and a delineation of the individual’s rights as a research subject (see Section VI, pages 16-21 of the *Guidebook* for a complete discussion of the elements of informed consent).

Informed consent must normally be obtained in a written format that requires the subject’s signature or that of the subject’s legally authorized representative. The PHSC may grant a waiver of this requirement if the investigator provides adequate justification for the request. In all cases a copy of the written informed consent must be given to the subject unless the PHSC specifically waives this requirement.

Proposals must be submitted in a timely fashion for proper review. Proposals that will be exempted from formal review must be submitted at least one week before the start date of the study. Those to be reviewed using the expedited procedures must be submitted at least two

weeks before the start date, and proposals requiring full committee review must be submitted at least four weeks before the start date. Additional time may be needed if a proposal must be reviewed using more than one review procedure.