WASHINGTON & JEFFERSON COLLEGE

Institutional Review Board (IRB) Policies and Guidelines

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Washington & Jefferson College Institutional Review Board Policies and Guidelines

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Introduction

The charge of the Washington & Jefferson College Institutional Review Board (IRB) is to protect the rights and welfare of human subjects involved in research by minimizing risk and ensuring that subjects agree to participate voluntarily from an informed perspective. Such protections are mandated by federal regulations governing research involving human subjects and are crafted by individual institutions to reflect the community standards of the institution. The IRB exists in order to provide a climate for research and scholarly activity that is fertile and flexible insofar as possible while protecting the well-being of human subjects.

The present system of human-subject research review is the outgrowth of concern about research on human subjects that began decades ago. In 1974 the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission published the Belmont Report., which set forth the following basic ethical principles for the conduct of research involving human subjects:

- Respect for Persons - Acknowledgment of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy
- Beneficence - A twofold responsibility: 1) do no harm, and 2) maximize possible benefits and minimize possible harm.
- Justice - Fairness in distribution of benefits expected to be realized from research as well as its burdens

The applications of these principles resulted in the establishment of review boards at institutions conducting research using human subjects. Those institutional review boards, including the W&J IRB, ensure that in the conduct of such research:

- risks are minimized and reasonable in relation to anticipated benefits
- subjects give *informed* consent
- rights and welfare of the subjects are maintained

Statement of Policy

In order to protect the rights, well-being and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Washington & Jefferson College, the policy and procedures described below have been established for the conduct of research involving human subjects.

The following general principles apply equally to all research involving human beings, whether using college resources or external funding sources. Washington & Jefferson College assumes responsibility for communicating and explaining these principles to College personnel, and for providing guidelines to effect their observance.

a. Washington & Jefferson College and the individual members of its faculty, staff and student body recognize their responsibility for protection of the rights and welfare of human subjects.
b. Appropriate professional attention and facilities shall be provided to ensure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
c. Research involving children (persons under 18 years of age), other legal incompetents, and persons unable to give informed consent may be approved if there is no risk or suffering for the individual subject. On the other hand, research involving a child, another legal incompetent, or a person unable to give informed consent should not be approved if there would be a significant risk or suffering without the possibility of benefit to the individual subject. Title 45, Code of Federal Regulations, Part 46, Subpart D, shall be followed for research involving children.
d. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
e. Before a subject participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the explanation has been understood by the subject; and the consent of the subject shall be obtained. The elements of informed consent are established by the Federal government and Washington & Jefferson College.
f. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled, within the limits of the research.

About The Institutional Review Board

Authority

Protection of the rights and well-being of human subjects involved in research is a concern of Washington & Jefferson College (W&J) and is mandated by specific provisions in the Code of Federal Regulations (CFR). As required by the federal regulations, the IRB was established at W&J to assure protection of human subjects and to ensure compliance with the regulations. Not only is the welfare of human subjects important to W&J, but there is a fiscal component as well. Non-compliance with the federal regulations can have an adverse effect on research funding. As a teaching institution, W&J values the opportunity to provide undergraduate students with a complete research experience. To this end, all original student research carried out by students and involving human subjects requires submission to the IRB for approval. All agencies of the federal government that conduct or sponsor research relating to human subjects are concerned with protection of the rights and well-being of the subjects. However, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services and the Food and Drug Administration are the lead agencies for oversight of research involving human subjects. OHRP has general responsibility for the protection of human research subjects and ensures compliance with 45 CFR 46. FDA regulates the use of experimental drugs and medical devices and ensures compliance with 21 CFR 50, 56. The College's IRB policies and procedures apply to any research activity which involves human subjects, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is funded or non-funded, and whether it involves minimal risk or more than minimal risk.

Membership

W&J's IRB is composed of at least six members. Membership includes at least one from each of the following categories: a representative of the institution, a representative from the community without ties to the College, and a nonscientist faculty member. The committee must also include at least two persons with education and training in the sciences, including specific training in human subjects research. If the membership of the committee has exactly the required number of members in one of the above four categories, an alternate must also be selected for that category; a single person may act as alternate for more than one of the above categories and there must always be at least two alternates available. The makeup of the Board is intended to provide a diversity of viewpoints and to provide complete review of human-subject research activities. An expert is consulted when projects to be reviewed are outside the expertise of the members; this is allowed and encouraged by the federal regulations.

What Needs IRB Approval?

What Constitutes Research?

According to federal regulations, research is any systematic investigation designed to develop or contribute to generalizable knowledge. The College's IRB has oversight for any research that involves the collection of data about or from human subjects.

Following are questions that should help determine whether data gathering as part of training, demonstration, or service projects meets the definition of research as related to human subjects. A "yes" answer to any of these questions indicates a research component, and the project must be approved by the IRB before any work is begun.

- Will the researcher(s) seek out subjects – or settings that contain subjects – for the project, rather than the subjects seeking the service or training?
- Will the findings of the investigation be disseminated (on-campus poster sessions are considered dissemination)?

What Data Gathering Would Not Be Considered Research?

Many forms of data gathering from human beings do not constitute research within the context of human-subject review requirements. Below are some examples:

- Data gathered for classroom training in research methods for which the only foreseeable purpose is to facilitate the student's learning of research methodologies. Neither the instructor nor the student intends to disseminate the data gathered.
- Data gathered for administrative purposes only--to learn what is happening within a unit or institution and/or to improve services or operations. These data collection procedures should be reviewed by Human Resources to ensure employee privacy and confidentiality are maintained.
- Evaluation of data gathered for a contractor about a project or operation for which he or she is responsible, if neither the researcher nor the contractor intends to disseminate the data.

When Must The IRB Confirm That A Data Gathering Activity Is Not Research?

If either of the following two conditions hold, even if a data collection activity meets one of the descriptions above, a summary of the activity must be submitted to the IRB for confirmation that the activity is not research:

- When funded by an internal or external grant for data collection from or about human subjects,
- Any data collection that is part of a class project but involves human subjects who are not enrolled in that course.

Note that faculty or departments may apply to have categories of activities (e.g. market research) pre-approved for instructional use.

Which Student Research Projects Require IRB Review And Approval?

Student research that involves human subjects can be classified broadly into two categories:

1. ***Research practica***, where students learn research skills. Students often are required to take courses requiring them to interview, observe, and otherwise work with human subjects. The purpose of such project assignments is to train students in various research methods and to acquaint them with social, educational, and/or psychological processes. In this case the instructor should get general approval for the practica not the individual students, since such projects typically do not lead to generalizable knowledge and dissemination is not intended.
2. ***Course-related, directed or independent research projects***, e.g., honors, independent study projects, Magellan projects, or capstone projects, that require systematic data collection, with the intent to contribute to generalizable knowledge. Any such research project initiated or conducted by a student and that is not classifiable as a research practicum meets the definition of research. Therefore, it must be reviewed and approved by the IRB.

Is Oral History Considered Research?

The US Office for Human Research Protection, in consultation with the Oral History Association and the American Historical Association, has determined that many oral history projects should not fall under IRB review because such research does not meet the criteria of federally regulated human subjects research. Individualized interviews which do not contribute to generalizable knowledge need not undergo IRB review, though research standards often still require informed consent.

Researchers pursuing an oral history project will only need IRB review if it (1) seeks to contribute to generalizable knowledge; OR (2) poses more than minimal risk to participants; OR (3) is one that you wish to have reviewed by IRB for grant review, educational, or other purposes.

Is There Any Research That Is Exempt And Does Not Require Review?

Research activities not being performed by students in which the only involvement of human subjects will be in one or more of the following categories are exempt from college-level review by the IRB, but are still subject to any normal departmental/division review that may be required.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or on 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: (1) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the 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) Studies of publicly observable behavior are exempt from Federal regulations unless there are potential risks of the type described and the data are recorded in a way that could be used to identify subjects.
   The College interprets "public behavior" to mean behavior that is apparent to an unconcealed observer, without the use of any special or surreptitious equipment, such as binoculars, special microphones, or recording devices.
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 (2) of this section, if: (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) federal statue(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."
   State and federal laws preclude the use of certain kinds of existing data (including health care information, records of drug and alcohol treatment, and records of psychiatric care) from use by researchers without human subjects review, regardless of whether they are "existing" or recorded by the investigator in such a way that subjects cannot be identified.
5. Research and demonstration projects which are conducted by or subject to the approval of the department or agency heads, and which are designed to study, evaluate or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs, (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs."
   The "department or agency heads" referred to are federal, not state, local, or college. This category of exempt research refers to activities sponsored by federal agencies to evaluate their own benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if a food is consumed that contains a food ingredient at or below the level of and for a use 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."

The following five categories of research are not exempt, and always require college review: 1) research involving prisoners; 2) studies of pregnant women where the focus of the research is on pregnancy and/or the fetus; 3) research on fetuses in utero; 4) research on minor children unless the research qualifies as educational research in the sense of items 1. and 2. above, or where the research does not involve direct interaction with the child, and 5) research using non-public records.

When Must The IRB Confirm That A Research Activity Is Exempt And Does Not Require Review?

If either of the following two conditions hold, even if the research falls in one of the categories above, a summary of the research must be submitted to the IRB for confirmation that the activity is exempt from review:

- When funded by an internal or external grant for data collection from or about human subjects,
- Any data collection that is part of a class project but involves human subjects who are not enrolled in that course.

Note that faculty or departments may apply to have categories of activities (e.g. market research) pre-approved for instructional use.

What Is The Definition Of "Human Subject" According To Federal Regulations?

A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

What Is "Interaction"?

Interaction includes communication or interpersonal contact between investigator and subject. Following are some examples of the more common types of interaction:

- Mail questionnaires or surveys
- Personal interviews, structured or unstructured, with or without recognized instruments
- Telephone interviews and surveys
- Classroom instruments, evaluations, or exercises
- Examination of private records, e.g., medical, psychological, school, or legal records
- Observations of public behavior by identifiable individuals

What Constitutes "Identifiable Private Information"?

"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 or information that is provided for specific purposes by an individual not reasonably expected by the individual to be made public. Individually identifiable means that the identity of the subject is associated with the information or can be ascertained readily by the investigator or other parties to the research.

What Is Minimal Risk?

According to federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

What Is Informed Consent?

Informed consent is the process by which prospective human subjects, or their legal representatives, are informed

- of the nature and purpose of the proposed research, including risks, in a manner appropriate to their level of understanding and in non-technical language
- that they have the right to decline to participate or to withdraw from participation at any time without penalty
- and given adequate time to decide if they want to participate

Informed consent is a critical part of the IRB approval process, and it is essential that investigators understand and comply with the regulations. Details are provided in the Informed Consent section of this Guide.

Additional requirements for informed consent exist for special populations such as children and prisoners. Investigators should take care to observe all requirements for consent.

What Is Assurance?

An "assurance" is a document negotiated between an institution and an agency, such as the Department of Health and Human Services (DHHS), assuring that the institution conducting research supported by the agency will comply with its regulations (at 45 CFR 46) for the protection of human subjects. Typically agencies require an assurance for each project funded.

Types of Review

Full Board Review

The full IRB will review research that does not qualify for expedited or exempt review. Full review will take place at an in-person IRB meeting; a quorum must be present to rule on an application. The IRB should be composed of six members as described in Membership section. In order for an application to be approved it must be approved by a majority of the members present at the meeting. A quorum will be considered five members where the non-scientist member or their alternate must be present. An IRB member may not participate in review of a project in which they have a conflict of interest, except to provide information requested by the IRB.

IRB rulings can include approval, requirement of modifications, or disapproval. All rulings will be communicated in writing. Approval will be accompanied by a description of the investigators' requirements for reporting and continuing review. Requirement of modifications will be accompanied by a description of those requirements. Disapproval will be accompanied by an explanation of the reasons for disapproval with expression of an opportunity for the investigator to reply.

In order to approve an application, the IRB must find that all of the following hold:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.

- Selection of subjects is equitable.
- Informed consent (or its waiver, alteration, or exception) will be sought (see Informed Consent).
- Informed consent will be appropriately documented.
- The research plan makes adequate provision for monitoring the data collection process.
- There are adequate protections to subject privacy and confidentiality of data.
- That the investigators have the qualifications necessary relative to the degree of protocol complexity and risk to human subjects.

If the intended subject population includes a population that is likely vulnerable to coercion, undue influence or increased risk, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB has a special responsibility to ensure that additional safeguards are in place to protect the rights and welfare of the subjects. This may include inviting an advocate for such subjects to sit as part of the board to rule on the application.

In the case that an application is determined to not meet the criteria for approval, the board may choose to indicate that the proposal is acceptable pending certain modifications. The board must be specific about what clarifications, protocol modifications or informed consent revisions are required. The revised application must be resubmitted to the full board for approval.

Expedited Review

The IRB may review certain applications on an expedited basis if they meet specified criteria. All expedited protocols must be reviewed by the IRB at least once per year. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply to all IRB approvals regardless of the type of review - expedited or standard/full Committee - utilized by the IRB.

An expedited review consists of a review of research involving human subjects by the appropriate IRB chairperson or his/her designee. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except that the reviewer may not disapprove the research. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.

Federal regulations limit the use of expedited review procedures to specific research categories published in the Federal Register. The IRB may use the expedited review procedure to review either or both of the following: (1) applications that are both minimal risk AND fulfill one of the categories below; and/or (2) minor changes in previously approved research during the period of one year or less for which the approval is authorized. The categories on the list apply regardless of the age of subjects, except as noted.

1) Minimal Risk. Research activities that (A) present no more than minimal risk to human subjects, and (B) involve only procedures listed in one or more of the specific seven categories (see Categories of Research Eligible for Expedited Review below), may be reviewed by the IRB using the expedited review procedure.
   a) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
   b) The seven categories should not be deemed to be of minimal risk simply because they are included on the list.

c) Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place then at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Additionally, the expedited review procedure may not be used for government classified research involving human subjects.

Categories of Research Eligible for Expedited Review

The following seven expeditable categories pertain to both initial and continuing review:

1) Prospective collection of biological specimens for research purposes by noninvasive means, for example:
   a) Hair and nail clippings in a nondisfiguring manner;
   b) Excreta and external secretions (including sweat);
   c) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying dilute citric solution to the tongue;
   d) Mucosal or skin cells collected by buccal scraping or swab, skin swab or mouth washings;
   e) Sputum collected after saline mist nebulization.
2) Collection of data through noninvasive procedures. Examples:
   a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) Weighing or testing sensory acuity
   c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age weight, and health of the individual.
   d) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes.
   e) Collection of data from voice, video, digital, or image recordings made for research purposes.
   f) Research on individual or group characteristics of behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
3) Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for nonresearch purposes.
4) Collection of data from voice, video, digital or image recordings made for research purposes.
5) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, motivation, cognition, identity, language, communication, cultural beliefs and practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
6) Continuing review of research previously approved by a full IRB as follows:
   a) where (A) the research is permanently closed to enrollment of new subjects; (B) all subjects have completed all research-related interventions; and (C) the research remains active only for long-term follow-up of subjects; or
   b) where no subjects have been enrolled and no additional risks have been identified; or

c) where the research activities are limited to data analysis.

7) Continuing review of research, where the IRB has determined and documented at a full Committee convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Reviewers Must Make Certain Determinations to Approve Application

In order to approve an application, the reviewers must find that all of the following hold:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable.
- Informed consent (or its waiver, alteration, or exception) will be sought.
- Informed consent will be appropriately documented.
- The research plan makes adequate provision for monitoring the data collection process.
- There are adequate protections to subject privacy and confidentiality of data.
- That the investigators have the qualifications necessary relative to the degree of protocol complexity and risk to human subjects.

In the case that an application is determined to not meet the criteria for approval, the reviewer may choose to indicate that the proposal is acceptable pending certain modifications. The reviewer must be specific about what clarifications, protocol modifications or informed consent revisions are required. The revised application must be resubmitted to the IRB for approval. If the reviewer feels that the proposal cannot be approved under expedited review even with modifications, it must be sent to the full board for review prior to disapproval.

Notification of Committee

As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing expedited review procedures, a summary of the application must be documented in the agenda provided for the full Committee for the next possible convened meeting. This documentation must include a citation to the specific category or categories justifying the expedited review.

Expedited Review of Studies Permanently Closed To Accrual

It is the practice of the IRB to consider for expedited review revisions, amendments and other information impacting the protocol and informed consent document when all of the following conditions are met:

1) the study is permanently closed to accrual of new subjects
2) all accrued subjects have completed all study interventions
3) the study continues for follow-up only
4) the revisions, amendments or other information involving the study are determined not to have any impact on the follow-up of the subjects and reconsenting is not required, OR:
5) when no subjects have ever been accrued to the study at the local site and the PI is recommending termination of the study.

Continuing Review

Periodic review of research activity is necessary to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. All research protocols (except protocols determined by the IRB to qualify for exempt status) must be periodically reviewed, until research is closed to accrual of new subjects. A research protocol for which no new subjects will be enrolled must still be periodically reviewed until:

1) data collection has ended and data analysis has concluded that no new information needs to be provided to enrolled subjects; and
2) there is no need to re-contact enrolled subjects to obtain additional research information.

Based on its review, the IRB may require that the research be restricted, modified or halted altogether. Alternatively, special precautions or IRB-imposed restrictions may be relaxed.

Types of Continuing Review

Review by the full, convened IRB, with recorded vote, is required unless the research is otherwise appropriate for expedited review or is exempt.

1) Standard Review. The full IRB must conduct a continuing review of a protocol using standard review procedures when that protocol originally was reviewed using standard review procedures, unless the protocol has been modified such that it can be reclassified as eligible for expedited review. Alternatively, research activities that have previously been judged as exempt, or were qualified for expedited review, may change such that standard review would be required for the continuing review.
2) Expedited Review. A protocol that originally was reviewed using expedited review procedures may receive its continuing review on an expedited basis. Continuing review of research previously approved by the full IRB may be expedited where:
   a) the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
   b) no subjects have been enrolled and no additional risks have been identified; or
   c) the remaining research activities are limited to data analysis.

When conducting review under an expedited review procedure, the IRB Chair or designated IRB member conducts the review on behalf of the full IRB.

3) Exempt Research Activities. Once a research protocol has been determined by the IRB to qualify for exempt status, that protocol need not be periodically reviewed by the IRB.

Criteria Considered In Continuing Review

Continuing review must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. Therefore, the IRB (or the reviewer for protocols reviewed under an expedited procedure) must determine:

1) that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
2) that the selection of subjects continues to be equitable;
3) that informed consent continues to be appropriately obtained and documented;
4) that there are:
    a) adequate provisions for monitoring the data collection process to ensure the safety of the subjects, when appropriate,
    b) adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate, and
    c) appropriate safeguards for vulnerable populations.

Consent Document

Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject in an updated consent document. Review of currently approved or proposed consent documents must occur during the scheduled continuing review of research by the IRB but may be done more frequently if new information becomes available.

New Amendments to Protocol Submitted At Time of Continuing Review

Amendments and addenda to a research protocol may be submitted at the time of continuing review. A separate cover letter describing the change and all appropriate documentation (approved consent form) must accompany the continuing review application. The amendments may not be implemented by an investigator prior to review and approval by the IRB.

Review Must Occur Not Less Than Once Per Year

The IRBs must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. Factors to be considered by the IRB in determining the appropriate interval for review may include, but are not limited to:

i. involvement of vulnerable populations;
ii. research conducted internationally;
iii. the use of waiver of informed consent procedures, e.g. surrogate consent;
iv. classified research;
v. research for which subjects would be exposed to additional risks, e.g. breach of confidentiality, disproportionate number or severity of adverse events;
vi. previous suspension of the research due to compliance, record-keeping or other concerns;
vii. recommendations from other institutional committees.

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If the IRB does not re-approve the research by the specified expiration date, subject accrual must be suspended pending re-approval of the research by the IRB. Enrollment of new subjects cannot ordinarily occur after the expiration of IRB approval. The IRB and researcher

must make every effort to link as closely as possible for annual review the receipt by the IRB of continuing review materials, the review of those materials by the IRB, and the beginning of the subsequent approval period.

Review Procedures

Materials to Be Reviewed

The following materials should be provided to the reviewer and the Chair for expedited review applications:

i. A completed IRB application;
ii. Full investigator's or sponsor's protocol;
iii. Proposed informed consent document(s) and/or script as appropriate;
iv. Copies of any surveys, questionnaires, or videotapes;
v. Copies of letters of assurance or cooperation with the research sites, if necessary;
vi. Relevant grant applications;
vii. Investigator's brochure (if one exists);
viii. Advertising intended to be seen or heard by potential subjects, including e-mail solicitations.

Determining Which Projects Require Review More Often Than Annually

The primary reviewer(s) or the chair reviewing the application must determine a review interval for the research as appropriate to the degree of risk but review must occur at least annually.

In the case that an application is approved, the board should determine the required frequency of continuing review of the approved protocols. Continuing review must occur at least once per year, but the board may require more frequent review.

Criteria Evaluated When Reviewing Protocols

In conducting any review, the designated reviewers or full IRB must review materials in sufficient detail to make the following determinations required under federal regulation:

a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
b. 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 reviewers should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research). The reviewers 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.
c. Selection of subjects is equitable. In making this assessment the reviewers 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.

d. 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 federal regulation and institutional policies, unless a waiver is approved.
e. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulation and institutional policies, unless a waiver is approved.
f. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
h. Vulnerable subjects. Additionally, when some or all of the subjects are likely to be vulnerable to coercion, undue influence or increased risk, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB reviewers must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Materials to Be Reviewed At Continuing Review

1) The full IRB should receive and review, at a minimum:
   a) a continuing review application;
   b) a status report on the progress of the research within the continuing review application should include:
      i) the total number of subjects enrolled since the study began, and the total number of subjects withdrawn from the study since the previous review;
      ii) a summary of any unanticipated problems involving risks to subjects or adverse events that were serious or unanticipated, and resulted in a change to the risk/benefit ratio since the previous review, even if the event occurred at a location for which the Washington & Jefferson College IRB is not the IRB of record.
      iii) explanation of any subject's withdrawal from the research or any complaints about the research since the previous review;
      iv) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research, reports on multi-center trials and any other relevant information, particularly information about risks associated with the research since the previous review; and
   c) a copy of the current, approved informed consent document as well as an unstamped copy of the informed consent document to be stamped with continuing approval.
2) In addition, primary reviewers should receive a copy of the current, approved IRB Application that includes any prior modifications previously approved by the IRB and supporting documentation such as an investigator's brochure, sponsor's protocol, or a grant application. They should also receive copies of any monitoring or audit reports conducted since the last review.

Amendments and addenda to a research protocol may be submitted at the time of continuing review. A separate cover letter describing the change and all appropriate documentation (approved consent form) must accompany the continuing review application. The amendments may not be implemented by an investigator prior to review and approval by the IRB.

Continuing Review/External Verification

Written procedures which the IRB Office and the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

These categories will include:

a. high risk
b. research procedures requiring significant changes to standard procedures (medical, nursing, anesthesia, surgical)
c. research crossing multiple departments
d. IND or IDE research initiated at Washington & Jefferson College
e. investigator has a financial interest in the research
f. other research as determined by the IRB on a case-by-case basis

Verification may be accomplished by:

a. conduct of a literature search and/or
b. observe the informed consent process/conduct of research by an IRB designee (i) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; (ii) for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (A) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (B) any suspension or termination of IRB approval.

Investigator Responsibilities

Human Subject Protections

The individual Investigator is the ultimate protector of the subject's rights and safety. Each Investigator is obligated to be personally certain that each subject is adequately informed and freely consents to participate in the Investigator's research. The Investigator must personally assure that every reasonable precaution is taken to reduce to a minimum any risk to the subject. The Investigator also assumes responsibility for compliance with all federal, state and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials. For example, the Investigator may not initiate any research involving human subjects without IRB review and approval. The Investigator is also responsible for understanding what other approvals may be required by any external funding agency or internal processes.

Supervision and Auditing Of Research Process

It is the responsibility of each Investigator to assure that all procedures in a study are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of Pennsylvania and the policies of Washington & Jefferson College. Further, it is the responsibility of the Investigator to regularly review their research process and address any deficiencies identified.

Investigator Training

It is the responsibility of each Investigator to complete human subjects protection (CITI) training provided by IRB prior to initiating research activities and participate in periodic training to remain up-to-date with federal regulations, Washington & Jefferson College policies and procedures, and compliance expectations. Further, it is the responsibility of each Investigator to ensure that key personnel or students who are responsible for the design and/or conduct of the study are adequately trained with regards to the use of human subjects in research.

Congruence with Funding Proposals

It is the responsibility of the Investigator to ensure that the IRB protocol is consistent with the proposal for funding for extramural or intramural support. Further, the Investigator should act as a liaison between the IRB and the sponsor.

Amendments/Requests for Change in IRB Application

It is the responsibility of the Investigator to not deviate in any way from the IRB-approved protocol until the Investigator has received written approval from the IRB.

Researchers' Records

At a minimum, Investigators must maintain research records for at least three (3) years from the date of completion of the research. All records must be accessible for inspection and copying by authorized representatives of the IRB and any external agency supporting the research. Beyond three (3) years, requirements for record retention vary with the type of research conducted and provisions of the Investigator's funding source. It is the Investigator's responsibility to clearly understand the retention requirements of any sponsor.

Confidentiality

The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations.

Adverse Events

The Investigator must report to the IRB, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research in accordance with W&J Policy for Reporting Adverse Events.

Additional Requirements for Activities Involving Pregnant Women

For activities involving pregnant women the Investigator must ensure that adequate provision has been made for monitoring the actual informed consent process. For example, the Investigator may, when appropriate, require participation of subject advocates in (a) overseeing the actual process by which individual consents are secured, or (b) monitoring the progress of the activity and intervening as necessary.

Prisoner Research

If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the IRB immediately.

Continuing Review

All approved research proposals, with the exception of those which qualify for exemption in accordance with 46 CFR 46.101(b), must receive continuing review at intervals appropriate to the degree of risk as determined by the IRB. Continuing review must be conducted not less than once per year. It is the responsibility of the Investigator to provide the IRB with all of the information requested on the Continuing Review Application in a timely fashion.

Procedure for Reporting Change in Research Activity

Any planned changes to research involving human subjects which has been ruled on by the IRB, whether the research was ruled exempt or was approved via either expedited or full review, must be approved by the IRB in advance of those changes being put into effect, except when the changes are necessary to eliminate apparent immediate hazards to the subject. This includes both changes to the conduct of a study and changes to the consent document.

Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB. When there are numerous changes to the research protocol, a summary of the changes should also be submitted. Modifications to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects already enrolled in the study. The latter may be addressed using an addendum to the initial informed consent document or, less preferably, by re-consenting the subject using the modified informed consent document.

Minor changes proposed for previously approved research may be reviewed in an expedited manner. A minor modification is defined as a change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study. Examples of minor modifications include:

- The addition of research activities that would be considered exempt or expedited if considered independent from the main research protocol;
- An increase or decrease in proposed human research subject enrollment;
- Narrowing the range of inclusion criteria;
- Broadening the range of exclusion criteria;
- Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations;
- An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring;
- A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;
- Alterations in human research subject payment or liberalization of the payment schedule with proper justification;
- Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
- The addition or deletion of qualified investigators.

Changes in the text of any research materials being provided to a subject (e.g. informed consent documents, questionnaires, scripts) that solely improve the clarity of statements or correct typographical errors, but do not alter the content or intent of the statement, may be made without review but the revised documents must be submitted to the IRB.

When a proposed change in a research study is not minor, then the IRB must review and approve changes at a convened meeting before changes can be implemented. A major modification (i.e., an amendment that is not minor) is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of major modifications may include:

- Broadening the range of inclusion criteria;
- Narrowing the range of exclusion criteria;
- Extending substantially the duration of exposure to the test material or intervention;
- The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
- The addition of serious unexpected adverse events or other significant risks to the Informed Consent Document; or
- Changes which, in the opinion of the IRB chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

Any proposed or anticipated changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review. For Claims for Exemption that were approved more than one year before the amendment was submitted, the investigator must submit a new IRB Claim for Exemption incorporating the proposed change.

Procedure for Adverse Event Reporting

The IRB is charged with the responsibility of ensuring that an effective data collection monitoring mechanism is in place. The Committee expects the investigator to report any problems or events (adverse events) involving a subject under his/her care to the Committee when the event represents a serious AND unexpected experience. Reporting must take place when the adverse event is related or possibly related to the research protocol.

Definitions:

An experience is **serious** if it: 1) results in death, (2) is life-threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability or incapacity, (5) results in a congenital anomaly or birth defect, (6) causes cancer, (7) is an overdose, or (8) any medical event which requires treatment to prevent one of the medical outcomes listed above.

An **unexpected** problem or **adverse event** is any adverse experience that does not appear as a risk in the IRB approved consent document, protocol, investigator brochure or patient literature; or in the investigator's judgment, occurs with an unexpected frequency and/or severity. This is an all encompassing term defined as any untoward occurrence or event occurring in a research subject or others (connected to the research) that affect their rights, welfare or safety. Adverse events can include harms that can be physical, psychological, financial or social and may involve events or actions that result in breach of confidentiality or unnecessary invasion of privacy.

An adverse event is **related** or **possibly related** to a research protocol if there is a reasonable possibility that the adverse event may have been caused by the protocol OR it is possible that the adverse event may have been caused by the protocol, but there is insufficient information to determine the likelihood of this possibility.

Investigator Responsibility Regarding Reporting

1. It is the responsibility of the Investigator to describe in the research protocol the plan for safety monitoring including information regarding an independent data safety monitor or an explanation why an independent data safety monitor is not necessary.
2. It is the responsibility of the Investigator to review all adverse events involving risks to research subjects, regardless of sponsorship, and determine the action needed to protect the safety of the research volunteer.
3. The Investigator is the first line of safety for research participants. In extreme circumstances involving unanticipated problems within a research study, the investigator may have to suspend research activities even before an adverse event report can be generated.
4. In accordance with local policies and federal regulations, Investigators are responsible for informing the IRB and other appropriate institutional committees, sponsors, and federal agencies (e.g., Office for Human Research Protections, Food and Drug Administration, etc.) of any adverse event and/or unanticipated problem involving risks to subjects.
5. It is the responsibility of the Investigator to submit any independent data safety monitoring (DSMB, DSC) reports to the IRB upon receipt. If modifications to the protocol or other study related documents are recommended, the Investigator shall prepare and submit the modifications as an amendment to the existing study documents.

IRB Review of Adverse Events and Unanticipated Problems Involving Risks to Subjects

The level and promptness of IRB review of adverse events and unanticipated problems involving risks to subjects depends upon the following factors:

- the seriousness of the event;
- relationship of the event to study participation (related or possibly related);
- whether the event is described in the study procedures, investigator's brochure and/or the consent document (anticipated);
- whether the event occurred to a subject at a location under the jurisdiction of the W&J IRB (internal or external event); and
- whether the event changes the harm-benefit ratio for the research participants necessitating a revision to the study protocol, consent document, nature and frequency of IRB, and whether or not currently enrolled subjects should be re-consented.

Reporting Requirements

Unexpected serious internal adverse events must be reported to the IRB within 24 hours of the event or of the investigator having knowledge of the event using the provided Internal Adverse Event Report form. Unexpected internal adverse events which are not serious must be reported to the IRB within 48 hours of the event or of the investigator having knowledge of the event using the provided Internal Adverse Event Report form. The IRB Chair/Administrator will acknowledge receipt and determine, with the Investigator, if an immediate action is required to grant protection to current participants until further investigation can be carried out. If an immediate action is not needed, the adverse event report will be reviewed by the full IRB at the next scheduled meeting. The IRB will review the information submitted by the Investigator and may concur with the investigator's recommendations or recommend additional actions including an increase in the frequency of continuing review to more closely monitor the study.

External adverse events, those not directly under the supervision of the W&J IRB, are reported to the IRB at the time of continuing review along with the most current data safety monitoring board report and recommendations. However, if the Investigator determines the harm/benefit ratio has changed as a result of the event, he/she should report the event to the IRB along with recommendations for revisions to the research documents.

IRB Monitoring/Auditing Of Research

The Institutional Review Board is charged with the task of overseeing all internal and external monitoring and/or auditing efforts in order to ensure the protection of human research participants and compliance with federal regulations and local IRB policies. An investigator, any member of the research team or any member of an auditing team is obligated to report to the IRB Chair and/or IRB Administrator any suspected episodes of noncompliance to the research plan, IRB policies, or federal and/or state regulations that are associated with unexpected harm to subjects. Suspected episodes of noncompliance must be reported within 24 hours of discovery. Noncompliance is defined as any action or activity that deviates from the protocol and results in an increased risk for harm to research subjects or is a violation of federal or state regulations.

In addition to the ongoing, periodic auditing program of the IRB, the IRB Chairperson and/or the IRB may request directed audits when deemed necessary. A periodic audit is a systematic method to audit IRB approved research on a regular basis. A directed audit is an audit conducted in response to identified concerns that require an IRB determination. It is also the responsibility of the Principal investigator to provide to the IRB, in a timely manner, a copy of any externally conducted research audit.

Monitoring and/or auditing activities may include, but are not limited to the following:

- Request progress reports from investigators;
- Audit advertisements and other recruiting materials as deemed appropriate by the IRB;
- Review projects to verify from sources other than the investigator(s) that no unapproved changes have occurred since previous IRB review; and/or
- Other monitoring or auditing activities deemed appropriate by the IRB.

After notification of the Investigator the IRB may also:

- Examine research records;
- Contact research subjects;
- Assign observers to the sites where research involving human subjects and/or the informed consent process is being conducted to observe activities including consenting process.

Following monitoring, the IRB may request additional safety monitoring or the creation of an independent data safety monitor. If the information gained during the monitoring or auditing process indicates that human subjects of a research project were exposed to unexpected risk or harm, or that the policies of the IRB were not met, the IRB may suspend or terminate the research.

Auditing priority will be given to those studies that are:

1. investigator initiated and greater than minimal risk;
2. involving vulnerable populations;
3. conducted internationally;
4. utilizing a waiver of informed consent procedure, e.g. surrogate consent;
5. classified research;
6. involving exposure to additional risks, e.g. breach of confidentiality, Phase 1 studies, disproportionate number or severity of adverse events;
7. known to have a previous suspension of the research due to compliance, record-keeping or other concerns;
8. recommended from other institutional committees.

Studies meeting at least one of these criteria may also be subject to verification by external sources that changes to the study have not occurred during either the audit or continuing review.

For activities involving vulnerable populations such as pregnant women, prisoners, children, or the cognitively impaired, the IRB should determine that adequate provisions have been made by the investigator for monitoring

the actual informed consent process. The IRB may oversee the actual informed consent process, not limited to the following activities:

- verifying that subject selection is appropriate and observing the actual informed consent process by which individual consents are obtained, or
- monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

The results of any monitoring or auditing activity by the IRB will be reported in writing to the Chairperson of the IRB. Resolution of any serious noncompliance discovered during monitoring or auditing activity will be addressed as described above. All monitoring and/or auditing information will be maintained on file in the IRB office.

Policy for Serious or Continuing Noncompliance of Research and Suspension or Termination of Approval for Cause

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB Policies, is not in compliance with federal and/or state regulations, or has been associated with unexpected serious harm to subjects. Any letter of suspension or termination of approval to an Investigator must include a statement of the reasons for the IRB's action. Regulatory authorities such as the OHRP, FDA, NIH or other federal sponsoring departments or agencies will also be promptly notified by the IRB of any serious or continuing noncompliance resulting in suspension or termination of research.

An example of suspensions or terminations for cause might include: inappropriate involvement of human subjects in research, serious or continuing noncompliance with federal regulations or IRB policies, new information regarding increased risk to human subjects, etc.

The IRB will investigate all credible reports of alleged noncompliance. This investigation will include the institutional compliance officer and risk manager. Notice of this preliminary noncompliance will be provided to the Vice President for Finance and Business. The level of the IRB investigation will depend on the seriousness of the situation and the potential risk to subjects. Investigating and managing issues of potential noncompliance may include, but is not limited to:

- Ensuring the safety of subjects;
- Developing action plans to prevent reoccurrence, and promote future compliance;
- Requiring research staff education to ensure they understand FDA and OHRP guidelines and regulations, and IRB policies and procedures.

The first step with all reports of alleged noncompliance is determining if subjects are at risk. If subjects are not in imminent risk of harm, the IRB may determine that a study may continue during the investigation. The results of the investigation can be reviewed at a future committee meeting. At any time during an investigation, if the IRB suspects or identifies that participants are at risk, a study can be suspended pending an investigation. The following criteria must be considered for all suspensions and documented with supporting information: suspension for recruitment; suspension for participant screening and enrollment; and suspension for continued interaction or intervention with subjects already enrolled.

All communications to and requirements of an investigator must be in writing, with clear and specific criteria, along with notification of any designated timelines as determined by the IRB.

The IRB may choose to suspend other projects with the same investigator based on preliminary information, the seriousness of the situation, and the potential risk of harm to participants. If allegations are not associated with a specific study, but are investigator specific, the IRB will determine if suspension of projects under the direction of that investigator is warranted. If the IRB determines suspension is necessary, a written notice of suspension and the criteria for suspension will be sent to the investigator for each study suspended.

The initial investigation may consist of a letter to the investigator citing the alleged areas of noncompliance and the associated regulations. The letter should ask the investigator to respond to the allegation and provide a corrective action plan within a specified timeframe. Additional information may be requested from the investigator. The IRB may find the additional information and the investigator's plan of action adequate or the IRB may add additional suggestions or impose additional restrictions/oversight in the research, based on the results of the investigation.

An audit can be conducted of an ongoing study or a study that has been suspended pending investigation. If an audit is to be conducted, the investigator should be notified in writing of the purpose of the audit and what information should be provided to the IRB. The audit may include only information requested from and provided by an investigator or may require an on-site visit where original documentation is reviewed and/or observed. The IRB will develop and implement a plan for a detailed audit focusing on the areas of concern. If at any time during the audit new areas of concern are discovered, they will be reported in writing to the IRB for consideration in determining additional actions. The results of any investigation will be reported to the IRB.

The following determinations and actions may be considered at any time during an investigation of alleged non-compliance:

- The IRB may determine that the research study under review is in compliance with federal regulations and IRB policy, and that no further actions are warranted; or
- The IRB may determine that the research study under review is substantially in compliance with federal regulations and IRB policy but may make specific recommendations to improve or enhance the study's human subjects' protections, or impose additional research oversight such as: verifying that the subject selection process is appropriate and observing the actual informed consent process; increase monitoring of the research activity and intervening as necessary through such steps as visits to the investigative site(s) and continuing evaluation to determine if any unanticipated risks have arisen; require focused human subject education from the IRB or other available resources. These recommendations will be detailed in a letter from the IRB requesting a written response from the investigator; or
- The IRB may determine that the research study under review is not in compliance with federal regulations and/or IRB policy and/or that the investigator's response is not adequate to satisfy the committee's concern. However, the incident appears to be isolated, and in essence, a miscommunication or misunderstanding of a non-serious and non-continuing nature. These cases should be reported promptly in writing to the IRB. The IRB may impose restrictions and/or require additional subjects' protection such as: special reporting to and rigorous oversight by the IRB specific to areas of concern; oversight or mentoring by the investigator's division chair, department chair, or more senior investigator; verifying that subject selection is appropriate and observing the actual informed consent process; monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and

continuing evaluation to determine if any unanticipated risks have arisen; and/or requesting an ad hoc review from an independent source with expertise in the specific area of concern. These additional restrictions will be carefully detailed in a letter from the IRB. The investigator will be asked to submit, in writing within a specified time period, a detailed corrective action plan that includes acknowledgement of the additional restrictions. The principal investigator will also be invited to the committee meeting to discuss the corrective action plan and address the concerns of the IRB; or

- The IRB may determine that the investigator's failures to comply with federal regulations and/or IRB policy pose such significant risk to participants in the research that the IRB may suspend or terminate its approval of the study for cause. When suspension or termination of IRB approval for cause relates to an investigator's failure to comply with federal regulations, state regulations, or IRB policy, the IRB will notify in writing the appropriate institutional officials of the determinations of the IRB. Three findings will be strongly considered during IRB deliberations: whether the investigator's behavior or actions represent a significant departure from accepted practices of the research community; was the noncompliance committed intentionally, knowingly, or recklessly; and whether the allegations of noncompliance were proven by a preponderance of the evidence.

When the IRB is considering a suspension or termination for cause for a study, the details of the investigation will be presented to the IRB for open discussion, consideration, and vote at the next committee meeting. In addition, the IRB may request an ad hoc review from an independent source with expertise in the type of research being conducted or expertise in a specific area of concern. These actions/concerns will be carefully detailed in a letter from the IRB. The principal investigator will be asked to submit a response in writing. Upon receipt of a written response the principal investigator can be invited to the next committee meeting to discuss the concerns of the IRB.

Episodes of serious non-compliance will be referred to the Human Resources Department.

Informed Consent

Generally, the IRB must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative. Additionally, documentation of informed consent must be obtained unless alternate procedures are approved by the IRB. The IRB must review all informed consent documents and assure the adequacy of the information contained in the consent document.

Each subject or his/her legally authorized representative must sign and date a copy of the current IRB-approved consent form prior to enrolling or any participation in any phase of the study, unless the requirement is waived by the IRB.

Please note that some college students may be minors and may require any consent forms to be signed by a legally authorized representative.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For example, a parent of a minor or a legal guardian may be a legally authorized representative.

Elements of Informed Consent

Federal regulations require that specific elements be contained in all informed consent documents unless waived by the IRB. Required elements of informed consent may not be omitted (unless waived by the IRB) and there may not be discrepancies between the IRB application and the informed consent documents regarding the purpose, risks, and benefits of the research. The IRB encourages investigators to use their template informed consent document when developing consent documents.

The required elements of consent to be included in every informed consent document are:

a. A clear statement that the study involves "research";
b. An explanation of the purposes of the research;
c. The expected duration of the subject's participation;
d. A complete description of the procedures to be followed, and identification of any procedures which are experimental;
e. An adequate description of any reasonably foreseeable risks and discomforts;
f. An adequate description of any benefits to the subject or others that may reasonably be expected from the research;
g. A description of how confidentiality and privacy will be maintained, where studies are not anonymous; The Washington & Jefferson College IRB has approved the following statement, as appropriate for use in informed consent documents: "Efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law." If applicable, include the following as well: "Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: [List relevant agencies like the National Cancer Institute, Food and Drug Administration, study sponsor, etc.]."
h. An explanation of whom to contact for answers to questions about research subject's rights (e.g., the IRB), and whom to contact in the event of a research-related injury to the subject;
i. 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.

The language of the consent document should be in the second person style (*i.e.*, "you") which may help convey that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style. The information provided in the informed consent documents must be in language understandable by the subject. The informed consent document should not include complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.

Documentation of Informed Consent

There are two options for documentation of informed consent. The IRB may approve procedures for documentation of informed consent that involve either (a) a written consent form signed by the subject; (b) electronic consent via a website; or (c) in limited circumstances, waiver of signed written consent form. Each of these options is described in detail below. It is the responsibility of the IRB to determine which of the procedures

described below is appropriate for documenting informed consent in protocols that it reviews. Generally, only options (a) or (b) will be appropriate.

Option A: Written Consent Form Signed by Subject or Legally Authorized Representative.

In most circumstances, the IRB should require that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. This consent form must embody the required elements of informed consent described above. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be given to the person signing the form.

The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with an informed consent document written in a language understandable to them.

Option B: Electronic Consent via a Website

In cases where a study involves an electronic survey, it is acceptable to provide an electronic informed consent document to subjects as a required first question within the survey. Such electronic consent documents must follow the same guidelines as written consent forms described under Option A, with the additional requirement that subjects be prompted that they may print or save the consent form for their records before proceeding.

Special attention should be given to making it clear, in non-technical language, that proceeding into the study is equivalent to giving affirmative consent to participate in the study.

Option C: Waiver of Documentation.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

i. 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
ii. 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.

In cases in which the documentation requirement is waived, the IRB may require the Principal Investigator to provide subjects with a written statement regarding the research.

The IRB may approve a process that allows the informed consent document to be delivered by mail, email or facsimile to the potential subject or the potential subject's legally authorized representative and to conduct the consent interview by telephone when the subject or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

Waiver of Informed Consent

Generally, the IRB must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject's legally authorized representative. There are only two circumstances under which the regulations give the IRB authority to waive the required informed consent.

Option One: Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent (see Elements of Informed Consent section), or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that the research could not practicably be carried out without the waiver or alteration and 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.

Option Two: Waiver for Minimal Risk Studies.

Additionally, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent (see Elements of Informed Consent section), or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that:

i. the research involves no more than minimal risk to the subjects; and
ii. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
iii. the research could not practicably be carried out without the waiver or alteration; and
iv. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

When approving a procedure which alters or waives the requirements for informed consent the minutes of the IRB meeting must document that the Committee made the findings required above.

IRB Office Records

The IRB Office files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports. The IRB Office must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. Note: Record retention time frames are different for sponsors and investigators - sponsors/investigators should consult the appropriate regulations for record retention within their offices.

Research approved by the IRB and initiated: records will be retained for at least three (3) years after completion of the research. Completion of the research will be defined as the point when all research interventions have been

completed at the Washington & Jefferson College site including follow-up for survival and data analysis is completed and study is closed by sponsor or investigator.

Research approved by the IRB but no participants are ever accrued: records will be retained for three (3) years from the initial approval date.

Research not approved by the IRB: records will be retained for three (3) years from the final disapproval/withdrawal date.

Minutes, attendance records, educational records and membership rosters of the IRB will be kept for 20 years.

The IRB Office must make all records accessible for inspection and copying by authorized representatives of any external sponsoring department or agency at reasonable times and in a reasonable manner. Official identification will be required from anyone presenting and requesting to review documents. The IRB maintains the right to verify all identification and requests prior to releasing research records.

The IRB Office must prepare and/or maintain the following documents:

a. Copies of all research applications reviewed, including scientific evaluations, if any, approved sample consent documents, data safety monitoring board reports, progress reports submitted by investigators, and reports of injuries to subjects.
b. The minutes of all IRB meetings,
c. Records of continuing review activities.
d. Copies of all correspondence between the IRB and the investigators.
e. A list of IRB members identified by (i) name; (ii) earned degrees; (iii) representative capacity; (iv) indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and (v) any employment or other relationship between each member and the institution (for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant). Changes in IRB membership (regular and alternates only) are promptly reported to OHRP.
f. Written procedures which the IRB Office and the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
g. Statements of 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 subjects.

At the end of the third year following the completion of the research, the IRB Administrator is authorized to destroy all IRB records satisfying the definition of "study completion". Destruction of paper documents is to be carried out through shredding. Electronic documents must be deleted from all storage media, including any automated backups.

Definitions:

Termination date: date study was terminated at Washington & Jefferson College.

Study Completion date: date when data analysis has been completed and study is closed by sponsor or investigator.

Destruction date: any date following the close of the 3rd year after the completion date of the study or the initial approval date if no participants were accrued to the study.

Process:

a. If the study was not approved by the IRB, determined as not human subject research or approved but no participants were ever accrued to the study, the records may be destroyed at the close of the 3rdyear following the initial IRB action.
b. When an active study has reached the close of the 3rd year following termination and the completion status is unknown, a contact will be made with the investigator to determine the status. If the study has been completed, a destruction date 3 years from the study completion date will be calculated. The database will be coded with the destruction date and destroyed at that time. If the study is not yet completed, the file must be maintained. An estimated date of completion can be solicited from the investigator, file coded with date and renewed contact with the investigator be made at that time.
c. Studies determined exempt from further IRB review will be held for three years and then a contact will be made with the investigator to determine the status of the study. If the study has been completed, a destruction date 3 years from the completion date will be calculated. The database will be coded with the destruction date and destroyed at that time.
d. A database of the destroyed studies will be maintained. The database will include the IRB tracking number, name of the study, name of investigator, date of destruction or date of pending destruction and name of person completing the destruction.