

Institutional Review Board for Research with Human Participants

All research involving human participants that is conducted by Washington and Lee faculty members or students must be reviewed by the Institutional Review Board for Research with Human Participants (the IRB). No matter how seemingly benign, the proposed research project must be reviewed by the IRB *before* relevant work commences. The IRB is available to consult with faculty, staff, or students in the early stages of project development regarding the review process and categories of review.

The IRB is guided by the ethical principles and guidelines for the protection of human subjects of research identified in the Belmont Report, which can be accessed online at: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

The IRB is appointed by the Provost. Federal guidelines specify that the IRB should consist of at least five members, including one member of the community who is unaffiliated with the University (and not an immediate family member of someone affiliated with W&L). It is also stipulated that the IRB should not consist entirely of men or entirely of women, nor should it consist entirely of members of one profession. At least one member should be a scientist, and at least one a non-scientist. No member shall participate in the IRB's preliminary or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

In addition to any meetings called for the purpose of full review of protocols, the IRB must be convened at least once annually, at the end of the academic year for the purpose of reviewing and summarizing the IRB's activity over the course of the year. The committee should note for its records any instances of non-compliance with IRB policies encountered in the preceding 12 months. The ensuing end-of-year report is endorsed by the members of the IRB (with any minority views noted). One copy of the full report is retained by the chair of the IRB, and one copy is provided to the Dean of the College. Minutes and documentation of all other IRB meetings and protocol reviews will be provided to the Dean of the College. The minutes of IRB meetings will include the separate deliberations, actions, and votes for each protocol undergoing preliminary or continuing review, as well as the vote on all IRB actions including the number of members voting for, against, and abstaining.

With respect to human subjects research supported or otherwise subject to regulation by the Department of Health and Human Services (HHS) or any federal agency which takes appropriate administrative action to make the policy applicable to such research, the IRB, the University, and investigators will comply with all subparts of the HHS regulations at Title 45 Code of Federal Regulations part 46 (45 CFR part 46, subparts A, B, C, and D).

Research Activity Affected by This Requirement

“Research” is defined as “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)). Research subject to review thus includes, but is not limited to:

- Any project where participants’ physical, behavioral and/or cognitive activity will be measured
- Any project where human tissue or cells will be collected or analyzed
- Any survey or questionnaire
- Any activity through which identifiable private information is obtained (e.g. information about behavior when the individual is unaware that any observation or recording is taking place; information that one would not normally expect to be made public, such as medical information)
- In-class demonstrations where human cells or tissues are used
- In-class demonstrations or projects where people will be surveyed
- In-class demonstrations or projects where people will complete any task in order to generate data for further analysis.

Any such research is subject to IRB approval whether such research takes place on or off the Washington and Lee University campus, including work done outside the United States. Class-based or lab projects should be reviewed with the IRB Chair to determine whether these projects are exempt prior to the term in which the class or laboratory is offered.

Forms

All necessary forms and instructions are available online at <http://counsel.wlu.edu/policy/>

The Review Process – Preliminary Review

Faculty members, staff members, or students who are planning research projects involving human participants are responsible for initiating the IRB review process by submitting their research proposals to the chair of the IRB. (The current IRB roster is available on the Registrar’s web site under the Faculty link.)

Investigators must submit grant proposals to the IRB for review and approval prior to submitting the proposal to the HHS.

The IRB chair or an IRB representative designated by the chair conducts a *preliminary review* of the proposed research and then assigns the proposal to either of the following categories:

- *Exempt* from IRB Review
- *IRB Review Required* (reviews may be ‘*expedited*’ or ‘*full*’)

It is expected that most research projects will fall into the exempt category. Research in the exempt category requires no further action beyond the *preliminary review*.

All proposals that are subjected to IRB review are evaluated with regard to the degree of “risk,” if any, to human subjects. At the time of *preliminary review*, the IRB uses a standard set of criteria to aid in the determination of such risk. If a research proposal is determined to involve minimal or more than minimal risk, the chair of the IRB must pass it to members of the committee for further review by one or more committee members.

Minimal Risk - Proposals suitable for *expedited review* will be assigned by the chair of the IRB to one member of the committee who will examine the proposal and provide the chair with feedback.

Moderate to Substantial Risk - Proposals that raise more complex risk-related issues will be subject to *full review* by at least a simple majority of the IRB, including at least one member whose primary concerns are in nonscientific areas.

Any IRB review may result in one of the following outcomes:

- *Approved*: the work may proceed (approvals are in effect for a period of one year after the IRB’s action)
- *Revise & Resubmit*: changes to the protocol are required before the work can proceed
- *Denied*: the type of work described cannot be approved because of the level or nature of risk involved

Questions about the committee’s action or requests for appeal of a decision should be brought to the chair of the IRB.

The Review Process – Continuing Review

All approved protocols must be re-submitted to the IRB on an annual basis.

At the discretion of the IRB, projects of moderate or high risk involving adult subjects and projects of greater than minimal risk involving minor subjects may be reviewed more frequently than annually. The minutes of the IRB meetings will clearly reflect these determinations regarding the review interval of the risk and approval period.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review. The IRB, at its discretion, may request such verification in projects with an unusual level or type of risk to subjects or where concerns about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

Data collection involving human participants that extends beyond one year MUST be re-reviewed, and re-approval granted, by the IRB Chair if the status of the research is exempt, or by one or more IRB members if the status of the research is expedited or full review.

Changes in the procedures of collecting data from human subjects MUST be re-reviewed and approved by the IRB. See “Protocol Changes”, below, for more information.

Categories of Review

All research, including that which the investigator believes falls into the exempt category, must be submitted to the departmental reviewer for confirmation of the relevant review category. The criteria used to determine the categories of review are described below.

Exempt

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.
2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of subjects’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B). **Category B 2 studies that include minors should be submitted for expedited review.**
5. The research does not involve deception.
6. The procedures of this research are generally **free of foreseeable risk** to the subject.
7. The research does not require a waiver from informed consent procedures.

Part B (at least one item should apply)

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on 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, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). **[NB: All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt, whether or not data collection is anonymous.]**

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (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.

5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects 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.

3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of this research present **no more than minimal risk** to the subject. ("Minimal risk", defined at 45 CFR 46.102(i), means that the probability and magnitude of harm or discomfort anticipated in the proposed 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.)

Part B (at least one item should apply)

1. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. [NB: **These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or-video-tapes, names will be recorded, even if they are not directly associated with the data).**]

2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc); b) 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; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

3. Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:

a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [NB: **Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or videotapes, names will be recorded, even if they are not directly associated with the data).**]
6. Research that involves deception. [NB: **Deception must be scientifically justified and de-briefing procedures must be outlined in detail.**]
7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.
8. Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

Full Committee Review

If ANY of these apply:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. The research involves the collection or recording of behavior which, if known 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. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve **more than minimal risk to the subject** (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

Educational Training

All IRB members must complete the assurance training at: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp> and certify to the IRB chair that they have done so.

Principal investigators, project staff conducting the informed consent process, and all others engaged in human subjects research must complete the web-based training at: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. Proof of completion of such training must be provided in writing to the IRB committee before any work on the project commences. In addition to this initial certification, recertification is required every three years.

Record-keeping

IRB Minutes and Documentation: Minutes and documentation of all other IRB meetings and protocol reviews will be provided to the Dean of the College. The minutes of IRB meetings will include the separate deliberations, actions, and votes for each protocol undergoing preliminary or continuing review, as well as the vote on all IRB actions including the number of members voting for, against, and abstaining. The minutes should reflect IRB determinations regarding risk and approval period (review interval). For research undergoing an expedited review, these findings should be documented by the IRB Chair and communicated to all IRB members for inclusion in the IRB minutes.

IRB: All protocols and descriptions of relevant IRB actions are to be retained by the chair of the IRB for three years after the expiration of the protocol's approval (expiration date is one year after the committee's action – the protocol expires if renewal is not sought by the expiration date).

Investigator: Retain for three years beyond the date of completion of the research or project all protocols, copies of correspondence with the IRB, informed consent forms, progress reports, reports of injuries to participants, and other correspondence related to the use of human participants.

Timetable

The IRB, or members thereof, will meet on an at-need basis. If no full meetings are necessary throughout the year, the IRB will convene at least once annually at the end of the school year.

The investigator must submit all documents to the IRB Chair at least two weeks in advance of an IRB meeting or review. Any IRB members reviewing proposals for an expedited or full review must be given at least two weeks time to further review documents.

IRB approval MUST precede commencement of any work involving human participants.

The IRB Chair MUST be notified promptly if adverse events occur during the research project. Adverse events include injuries, accidents, unauthorized release of sensitive information, or other unanticipated problems involving risks to human subjects and others. See “Compliance and Oversight”, below, for more information.

Proposal Components

Each proposal submitted for preliminary review should include the full protocol, a proposed informed consent document, any relevant grant application(s), the investigator’s brochure (if one exists), and any recruitment materials, including letters or advertisements intended to be seen or heard by potential subjects. The protocol should indicate the purpose of the project, a description of the subjects, a full description of all procedures, and copies of all instruments (e.g., questionnaires, surveys, consent forms, recruitment flyers and procedures).

Each proposal submitted for continuing review should submit a protocol summary and a status report on the progress of the research, including: (i) the number of subjects accrued; (ii) a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review; (iii) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review; (iv) any relevant multi-center trial reports; (v) any other relevant information, especially information about risks associated with the research; and (vi) a copy of the current informed consent document and any newly proposed consent document.

Components of Informed Consent

Subjects must have sufficient information to make an informed decision to participate in the research study. If subjects cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, legal representatives are required.

Consent documents should be clearly written and understandable to subjects. The consent form should include language that is nontechnical. Scientific, technical, or medical terms should be plainly defined.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Where required, informed consent must be 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. A copy must be given to the person signing the form. For exceptions, see “Circumstances in Which a Written Consent Form May Not Be Required”, below.

The consent form must include:

A statement that the study involves research, a readily understood explanation of the purpose(s) of the research and the expected duration of the subject's participation, a simple description of the procedures to be followed, identification of any procedures which are experimental, and if deception will be involved. If deception is involved, there should be an indication that the research cannot be fully described at this time, but that at the conclusion of the subject's participation an explanation will be provided.

A description of any reasonably foreseeable risks or discomforts to the subject. These include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience.

A description of any benefits to the subject or to others which may reasonably be expected from the research (if no direct benefit, this should be stated).

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

A statement concerning costs or compensation to the subject, if any. 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.

An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject. Phone numbers should be provided.

Description of the extent, if any, to which confidentiality of records identifying the subject will be maintained.

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Assent

Children (those under 18) should be given an explanation—at a level appropriate to the child's age, maturity, experience, and condition—of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of an affirmative agreement, be construed as assent. In the proposal, the investigator should indicate: 1)

how assent will be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); 2) how assent will be documented. The child may either sign a very brief assent form or verbally indicate a willingness to participate.

Circumstances in Which a Written Consent Form May Not Be Required

There are two types of situations in which a written consent form may not be required.

- 1) If the principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research (e.g., studies on potentially sensitive topics such as illegal drug use, other illegal conduct, or sexual behavior) and the consent document is the only record linking the subject with the research, the subject should be asked whether the subject wants documentation linking the subject to the research. The subject's wishes will govern.
- 2) Written consent is not required if the research presents no more than minimal risk and involves procedures that do not require written consent when they are preformed outside of a research setting.

If there is no written consent form required, an oral presentation of the research to be provided to the subjects must be made by the investigator, and the investigator must offer the subject a written summary of the oral presentation that has been approved by the IRB.

Review Outcomes

For proposals reviewed by the IRB, a letter will be sent to the investigator by the IRB chair, indicating one of three possible outcomes:

- A. **Approved:** A protocol which has been approved by the IRB requires no further action from the investigator prior to initiating the study. If the study should extend beyond 12 months, the investigator should send a letter to the IRB chair, informing her/him of the current status of the project, any changes in the protocol, and whether any adverse events have occurred.
- B. **Revise and Resubmit:** A protocol that has been deferred by the IRB usually requires that additional information be submitted to the IRB prior to approval. A revised application should be submitted to the IRB clarifying the issues involved or providing the requested documentation. The IRB will review the revised application at its next meeting.
- C. **Denial:** A protocol that has been denied approval by the IRB cannot be initiated by the investigator. The reasons for the denial are provided in writing. The investigator will be given the opportunity to respond either in writing or in person at the next meeting of the IRB.

Protocol Changes

Proposed changes to any research must be reviewed by one or more IRB members. Changes in approved research, during the period in which IRB approval already has been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. The IRB, at its discretion, may randomly select research records for audit to ensure that investigators do not implement any protocol changes without such prior IRB review and approval.

If minor changes are being made to research which was under an expedited review procedure, the IRB Chair may approve the change or enlist the help of one or more other IRB members for review. For research under a full review, changes must be evaluated at a convened IRB meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.

Each revision to a research protocol should be incorporated into the original written protocol. Revision dates should be noted on each revised page and on the first page of the protocol itself. This ensures that there is only one complete written protocol.

Compliance and Oversight

The IRB is charged with the responsibility to oversee the conduct of the research that it approves, and it shall have authority to observe or have a third party observe the consent process and the research.

The IRB is required to review any observations of noncompliance with this policy, or any allegations of such noncompliance. Such allegations may arise from research subjects, institutional officials, the investigator, or other parties. Incidents of noncompliance will be investigated by the IRB and the findings will be recorded in writing. Incidents that are deemed to be serious or ongoing may be reported to the Dean or appropriate department head, at the discretion of the IRB chair.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that results in unexpected serious harm to subjects. In accordance with 45 CFR 46.113, any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, and, if applicable, to the Office of Human Research Protections (OHRP).

Guidance on Reporting Adverse Incidents to the OHRP

Research that is supported or funded by the federal government is subject to additional compliance rules and reporting requirements with respect to adverse incidents. Adverse incidents include: 1) injuries to human subjects or other unanticipated problems involving risks to subjects or others; 2) any serious or continuing noncompliance with this policy or

the requirements or determinations of the IRB; and 3) any suspension or termination of IRB approval.

In the event that an adverse incident occurs during the conduct of research covered by the Federalwide Assurance, Washington and Lee will promptly submit an incident report to the OHRP and include the following information:

- Title of the research project and/or grant proposal at issue
- Name of the principal investigator on the protocol
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
- A detailed description of the problem/noncompliance/reason for suspension or termination
- Actions that Washington and Lee is taking or plans to take to address the problem/noncompliance/suspension or termination, which may include any of the following as appropriate: revisions to protocol or informed consent documents; increased monitoring of investigator or subjects; education of investigator, research staff or subjects; suspension of investigator; random audits.

The timeframe for reporting such incidents to OHRP will vary depending on the severity of the incident; a serious incident should be reported within days. The IRB Chair is responsible for submitting the incident report, and shall simultaneously submit the report to the Dean of the College.

Research Conducted Outside of the United States

Research conducted outside of the United States by Washington and Lee faculty, students, or staff must be reviewed in accordance with Washington and Lee University IRB review procedures. Such research must also conform to the standards for research involving human subjects of the host country. Collaboration with colleagues at a local institution in the host country often provides a good method for ensuring compliance with host country law and human subject conventions in research.

Outside Investigators Wishing to Use Washington and Lee Students as Subjects

The investigator should send a copy of the proposal, including interview schedules, consent forms, and copies of flyers or advertisements to the Office of the Dean of the College. If the Dean approves the proposal, he or she will forward it to the IRB for human subjects review. If he or she does not approve the project, the investigator will be informed of this by the Dean and no action will be taken by the IRB.

Research Conducted at Off-Campus Sites with Their Own Human Subjects Committees

If some portion of the research is conducted at another institution, that institution must also review and approve the research protocol. The Washington and Lee University IRB

will normally request some evidence of review and agreement from the host institution. If the host institution does not have a Human Subjects Review Committee, a letter on institutional letterhead signed by an official of the host institution agreeing to permit access to the study population will be required.

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