University of Richmond Institutional Review Board Policy Document

The University of Richmond Institutional Review Board (URIRB) is responsible for monitoring faculty, staff, and student compliance with ethical standards of research with human participants. The URIRB adheres to U.S. guidelines for the registration and review of research as prescribed in public law 45 CFR 46 (the common rule). That code requires that each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution (45 CFR 46.103(b)(4)(i)). This document, the *University of Richmond Institutional Review Board (URIRB) Policy Document*, meets this requirement.

Contents

The University of Richmond Institutional Review Board (URIRB) follows the standards and procedures set forth in public law 45 CFR 46. This Policy Document supplements those federal guidelines by describing the implementation of those guidelines at the University of Richmond. Individuals seeking more general information about the ethics of research with human participants should rely on information available from the U.S. Office for Human Subjects Protections (OHRP) and the University's URIRB website.[1]

[1] *After this Policy Document has been adopted or revised by a vote of the URIRB, the Chair of the URIRB is authorized to make minor corrections and updates as necessary. Any such changes will be reported to the URIRB in writing at a convened meeting or via email, at which time the Board may provide additional direction to the Chair.*

1. Overview

All research projects conducted at University of Richmond involving human participants must be reviewed and approved by the University of Richmond Institutional Review Board (URIRB) for the Protection of Human Subjects of Research. To qualify as human subject research, an activity must be: (1) research, which is defined as a systematic investigation designed to develop or contribute to knowledge, and (2) involve human subjects. Involvement of human subjects generally means some form of interaction, including the collection of personally identifiable records about persons. All research proposals involving human subjects must be submitted to the URIRB for its review.

The President of the University of Richmond appoints the members of the URIRB and serves as the signatory official for the University's assurance agreement with the United States Department of Human Services Office for Human Research Protections (OHRP). This assurance agreement stipulates that all human subject research at the University of Richmond will adhere to the set of regulations governing human subject research (Title 45 CFR 46, the "common rule"). The URIRB also reviews human research for compliance with statutory requirements of the Commonwealth of Virginia and policies adopted by the University of Richmond pertaining to research with human participants. Those policies include the requirement that faculty, staff, and student researchers and faculty advisors of students working with human subjects complete training pertaining to the ethics of human research.

When conducting human subject research, the principal investigator (PI) must submit a proposal to the URIRB prior to beginning research. Approval is not given retroactively by the URIRB. Directions for submitting proposals can be found on the URIRB homepage. The proposal must in most cases be submitted electronically via email. Typically, the URIRB meets eight times a year. Prior to having a proposal approved, researchers must complete online training on human subject protection, as described at the University of Richmond website for the URIRB. For more information on the URIRB and human subject protection at the University of Richmond please contact the current Chair of the URIRB at IRB@richmond.edu.

2. Purposes and Goals

The purposes of the University of Richmond Institutional Review Board for the Protection of Human Subjects of Research include:

Protection. Researchers at the university seek to promote the health and welfare of all those who participate in and are affected by University of Richmond research activities. Protection of subjects is the responsibility of the faculty, students and staff who conduct research and of the administrators who oversee the programs of research. The primary goal of the URIRB is the elimination of risk to participants.

Education. Research is an integral component of students' learning experience at the University of Richmond. The URIRB provides instruction to students on the ethical conduct of research, thereby ensuring that students and faculty at the University understand the concepts of human subjects' protection. To accomplish this goal, the URIRB has supplemented the basic provisions of federal regulation to more broadly

expose the University community to the ethical principles of human subject protection. This policy is permissible under federal regulation, as institutions are provided broad latitude in their implementation of basic federal regulations.

Compliance. The URIRB monitors and sustains the University of Richmond's compliance with its Federalwide Assurance Agreement with the U.S. Office for Human Subjects Protections (OHRP). Compliance entails applying the ethical principles of the 1979 Belmont Report to all human subjects' research, regardless of its funding source. This agreement also stipulates that the University of Richmond will apply the federal policy known as "the Common Rule" to "all of its human subjects research" as well as subparts B, C, and D of the HHS regulations at 45 CFR 46. In addition, the University of Richmond's URIRB policies are designed to conform with §32.1-162.16-.20 of the *Code of Virginia* and other State laws related to the protection of human subjects of research. The URIRB does not address other local, state, federal, or international requirements or restrictions, such as regulations pertaining to the use of data (e.g., the guidelines set forth by the Family Educational Rights and Privacy Act and the Health Insurance Portability and Accountability Act of 1996) and Title IX of the Civil Rights Act of 1964.

Support. The URIRB facilitates the advancement of knowledge through scientific research by supporting the work of investigators whose studies involve humans as participants; it provides guidance to investigators regarding the ethics of their projects, supports their efforts to more fully understand the ethical implications of their procedures, and serves to validate their compliance with federal standards pertaining to research with human participants (which is required for publication of research findings and securing funding from grant agencies).

3. Definitions

3.1 Research. The University of Richmond relies on 45 CFR 46 when identifying research projects that require review. That standard defines research to be "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46, 102(l)). In consequence, the URIRB does not review projects that are explicitly excluded from review by 45 CFR 46, including (a) oral history, journalism, biography, literary criticism, legal research, and historical scholarship; (b) evaluations of specific programs (program evaluation); and (c) instructional activities that serve an educational rather than a research purpose. Individuals conducting projects involving interaction with human participants should contact the office of the URIRB if uncertain of their project's status as research.

3.2 Human Subjects. 45 CFR 46 defines a human subject as a living individual the researcher studies by collecting identifiable, private information, often (but not always) through intervention or interaction with the individual. Studies that involve analysis of secondary data sets (e.g., census information, data that are fully deidentified) is defined to be secondary research and is excluded from review. A separate board, the **Institutional Animal Care and Use Committee** (IACUC), reviews and approves research involving nonhuman subjects.

3.3. Engagement. As defined by 45 CFR 46, University of Richmond students, faculty, and staff are engaged in research when they interact with subjects in a research study (including carrying out the consent process) and/or access identifiable information about

participants for research purposes. Certain research-related activities, such as relaying information about a study to potential subjects, analyzing data that are deidentified, and authoring a report of findings, are not considered engagement. When a researcher is engaged in research that has already been approved by the IRB of another institution, they must notify URIRB that they are so engaged, provide documentation of training in the ethics of human research, and submit documentation of the IRB review of the project at that institution. Approvals (or other actions) to engage in research at other institutions will be reported by the URIRB Chair to the convened board.

3.4. Exempt Research. Some research projects qualify for exemption from compliance with 45 CFR 46. Exempted projects are **not** excluded from review; such projects must be reviewed by the URIRB. That review may indicate that the project is exempt from some or all of the requirements of 45 CFR 46 (at §46.104), but investigators and researchers cannot make that determination.

3.5. Minimal Risk. Risks to participants in research must be minimized, with minimal risk defined as "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" (45 CFR 46, 102(j)). Many factors may increase risk level beyond the minimal threshold. Proposals that address illegal behavior by subjects (such as underage drinking or drug use) are more than minimal risk because they may expose subjects to criminal liability. Other examples of factors that could increase the risk level beyond minimal risk include threats to reputation, financial standing or employability. Questions that elicit responses to life events that may cause significant distress might also increase the level of risk beyond minimal.

4. Types of Reviews

Consistent with 45 CFR 46, URIRB conducts four types of reviews: limited, expedited, convened board, and continuing. In most cases, a completed URIRB project form (which can be downloaded from irb.richmond.edu) and supporting documents (e.g., consent forms, recruitment messages) are required for the review process. Upon receipt of a protocol or query (usually, via email), the URIRB Office will determine if the project is eligible for limited review, eligible for expedited review, or requires review by the convened board. To qualify for limited or expedited review, a project must pose no more than minimal risk to subjects. The URIRB office also verifies that all personnel in the project have completed required training in the protection of human participants in research.

4.1. Limited review, conducted by the chair or URIRB administrator, is used to evaluate minor modifications to previously approved protocols, renewals, and projects that may qualify for exclusion from review (e.g., program evaluations, teaching activities).

4.2. Expedited review, conducted by the chair or a member of the URIRB, is used to evaluate minimal risk projects only. If the study qualifies for expedited review, the URIRB chair or a member of the URIRB will review the study's protocol, consent form, and data management procedures. The Chair or designated reviewer can approve the proposal; require modifications to the study protocol and documents prior to approval or return an incomplete or unclear proposal for more information. The categories for studies

that qualify for expedited review are maintained at the OHRP, and include most social and behavioral sciences projects. Expedited review can also be used when such review is approved by the convened board. The expedited process cannot be used to disapprove a proposal. All expedited actions are reported in writing to the URIRB convened board at its next meeting. At that time, the board could intervene to adjust the expedited action.

4.3. Convened-board review (full board review) is required for all studies in which risk is greater than minimal or involves vulnerable subjects, such as children, prisoners, or persons who are mentally impaired. Full board reviews may also be used when additional guidance is needed to examine fully a study's risk level (e.g., when the research uses novel procedures, is conducted in international locations, studies of at-risk individuals, such as prisoners).

4.4. Continuing review is required when research projects are renewed or modified. Studies that are not exempt from 45 CFR 46 must be reviewed annually. Researchers renewing a project should submit a renewal form that requires an accrual summary and affirmation of conformity to the previously approved protocol (which can be downloaded from irb.richmond.edu). When researchers need to revise, modify, or change an URIRB-approved, nonexempt project, they should describe the modification via email to irb@richmond.edu. Generally, a minor amendment (such as the addition of a new, related question to a survey or personnel) can be approved by limited or expedited process. Minor amendments to studies determined to be exempt from the conditions of 45 CFR 46 do not require review. Nonexempt studies that are not renewed by the principal investigator (PI) will closed one year from the original approval date. Investigators are responsible for initiating the renewal process; the URIRB is not responsible for issuing a notification of pending renewal deadlines.

5. Types of Decisions

The URIRB's review results in several types of actions (or determinations), including exclusion from review, exempt from 45 CFR 46 requirements, approval with conditions, approval, request for additional information, and disapproval/suspension.

5.1. Excluded: As noted in 45 CFR 46, a number of projects that involve humans as participants are not considered research. Such projects are excluded from review and are not subject to approval by the URIRB. Persons conducting projects that they believe are not reviewable research can receive a written determination on the matter from the URIRB by submitting in writing summary information on the topic.

5.2 Exempt. Some research involving human subjects is exempt from the provisions of Title 45, Part 46. However, the Board (or Chair) must review the proposed research and provide the exemption to researchers. *Researchers cannot determine on their own that their research is exempt.* Federal regulations list eight categories of exempt research (see 45 CFR 46.104(d)). Review will determine if the project meets the requirements for one or more of these categories. The URIRB may determine that studies that meet the federal guidelines for exemption must nonetheless include procedures required in nonexempt studies, such as documentation of informed consent. While federal regulations specify what types of research are *eligible for* exemption, it is the responsibility of the University of Richmond's IRB, not the researcher, to make this determination.

5.3 Approval. If review indicates that the project conforms to federal and local standards for the ethical conduct of research with human participants, the URIRB will approve the project in a written notice of action. That evaluation will be based on a number of factors, including risk to participants, benefits of the project, the safeguards in place with regards to participant well-being and privacy, the use of informed consent, data-management procedures, and the population studied. All known risks should be communicated to potential participants during the consenting process. If a protocol has been approved, the research can begin upon receipt of the notice of action sent by the URIRB Chair.

5.4. Conditional Approval. In some cases, a project may be approved, on the condition that some specific change be made in the study protocol or study materials. Such conditions may include revision of some aspect of the consenting process (e.g., the submitted consent form may state that the study has "no risks" when risks are present in all research projects) or the requirement that study personnel complete training in the ethics of human research.

5.5. Request for additional information. When the initial review requires additional details than those provided in the initial application, the URIRB will contact the investigator directly and request clarification. Review may also identify procedures that require modification to meet standards for consent, data safety, protection of privacy, and so on. If the revisions and/or clarifications require changes to the study documents, new materials should be prepared and resubmitted for review. The accrual of subjects cannot begin until the researchers receive final approval of the amended study protocol and/or consent documents. The board may authorize the Chair to take expedited action on revisions to the protocol requested by the convened board.

5.6. Disapproval and suspension. The convened board may, after deliberations, determine that the project cannot be conducted as described. The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the ethical standards or that has been associated with unexpected serious harm to subjects. Projects approved by the URIRB may be subject to further review and approval or disapproval by other administrators at the University of Richmond, but those officials may not approve research that has not been approved by URIRB. Any suspension or termination of approval shall include a statement of the reasons for the action and shall be reported promptly to the investigator and appropriate institutional officials.

6. Review Criteria

The University of Richmond URIRB review of research involving human participants is guided by the principles of ethics expressed in the Belmont Report written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the ethical standards of specific disciplines in the social sciences, and provisions of Title 45 Part 46 of the Department of Health and Human Services (DHHS) Code of Federal Regulations (CFR), Protection of Human Subjects. The criteria for that review follow (see § 46.111 *Criteria for IRB approval of research* for more information).

6.1. Risk and benefit: Risks to subjects are eliminated or minimized. All procedures in the project must not only be consistent with principles of sound research design, but they

must also minimize the possibility that participants will experience harm of any kind. The risks, if any, should be reasonable in relation to anticipated benefits, if any, to those taking part in the research and to the advancement of knowledge that may reasonably be expected to result. Risks associated with the long-range consequences of research findings in applied contexts are not weighed in this review process (45 CFR 46 states such risks are not "within the purview of its responsibility").

6.2. Fairness: Selection of subjects should be equitable, in terms of providing opportunity to take part in the investigation and inclusion of individuals from specific populations. This analysis considers the recruitment process, the purposes of the research, and the setting in which the research will be conducted. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects.

6.3. Informed consent. The principle of respect for autonomy requires that consent be sought from each prospective subject or the subject's legally authorized representative, in accordance with specific requirements of consent put forward in CFR § 46.116. Informed consent must be appropriately documented or appropriately waived in accordance with CFR § 46.117.

6.4. Data safety and monitoring. The research procedure must be one that ensures the confidentiality of the data, protects the privacy of subjects, and provides for the continuing monitoring of the fidelity of the procedures and the safety of participants. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is required.

6.5. Training. The investigator(s) should be appropriately trained in the conduct in research, and in the ethics of research involving human participants.

7. Proposal Submission Process

Any research involving human subjects at the University of Richmond must receive the URIRB's written approval or exemption before research can begin. The URIRB will provide such approval or exemption only after consideration of a written proposal. While the Chair or other members of the URIRB may provide verbal advice to researchers, only a written notice of action can be construed to reflect URIRB approval or exemption. Written notices of URIRB action will generally be provided to investigators via email by the Chair of the URIRB.

7.1. Delivery of proposals to URIRB. Researchers submit proposals directly to the URIRB office in electronic form, via email to IRB@richmond.edu. All transmitted materials should be docx or pdf type files. Proposals should, in most cases, use the template for research protocols posted at https://irb.richmond.edu/. See that website for full details regarding completion of the template.

7.2 Content of Research Proposals. Proposals will vary in content and scope depending on the nature of the research and its potential risks to human subjects. Proposals should generally include (1) information about the project, including title, date of submission, department, the principal investigator (PI), all other investigators working as researchers

on the project, and advisor (if student research); (2) a brief summary of the study, including purpose and literature review as it relates to the goal of the study; (3) a thorough listing of risks and possible benefits; (4) a description of the methods, including subjects and recruitment procedures; (5) provisions for confidentiality and/or anonymity of subjects, including a data protection/disposition plan.

7.3. Consent. Most protocols will discuss how the consent of subjects will be obtained. Researchers should remember that consent is primarily a *process* that is documented by the consent *form* (see URIRB website for examples of consent forms). Documented consent is generally required for adult subjects (persons 18 and over). For persons under 18 years of age, subject's parents/guardians must provide consent, and in some cases the child must assent to participation, and that assent must be documented. Assent and consent forms must include all the elements of consent described by 45 CFR 46, unless a waiver of an element of consent is requested. The elements of consent, quoted from 45 CFR 46, include:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject‘s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects‘ rights, and whom to contact in the event of a research-related injury to the subject;

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

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject‘s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

For examples of consent forms, see “Informed Consent is a Process” at irb.richmond.edu.

7.4. Materials. All materials used in the study, including instructions, scripts, survey instruments, and debriefing forms, should be included as attachments to the proposal.

7.5. Additional Forms. Some studies may require completion of additional information forms for review (e.g., studies conducted at multiple sites, international research, and research studies involving children).

7.6. Continuing review applications. Federal regulations require URIRB review for nonexempt and continuing research at least annually. Typically, the University of Richmond URIRB provides approval for a period of one year (the maximum allowed by federal regulations). For renewal, the investigator must submit a report of the study progress before the study’s expiration date. Researchers are responsible for monitoring the need for study renewals, and must allow sufficient time for URIRB review prior to project renewal. Any nonexempt study that is not renewed within one-year period will be closed by the URIRB. The study cannot proceed until a new protocol is submitted, reviewed, and approved.

7.7. Reporting unanticipated problems, including unanticipated adverse events. Any unanticipated problems involving risks to subjects should be reported as soon as possible but always within three working days of the discovery of the occurrence to the Chair of the URIRB. The Chair will convene the URIRB, if necessary, to appropriately address serious unanticipated problems. If the safety of subjects is at risk, researchers can make appropriate changes as needed to protect subjects. These actions and any changes to the approved protocol that are made to protect subjects must be communicated as soon as possible but always within three working days of the discovery of the occurrence to the URIRB Chair and are subject to URIRB review.

8. Training in the Ethics of Research with Human Participants

In its September 9, 2008 meeting the University of Richmond URIRB voted to require investigators (and their mentors/supervisors) engaged in human subject research at the University of Richmond first complete training in human subjects’ protection. To facilitate training at the University of Richmond, the University has subscribed to the Collaborative Institutional Training Initiative (CITI). Faculty, staff, and students may register for course modules at: https://www.citiprogram.org.

Research proposals are not reviewed until all individuals engaged in the project have completed their CITI training, and achieved a score of at least 80% on the exit examination for the training.

8.1 Basic requirement for faculty and staff. Faculty and staff must complete the following modules examining the Belmont Report, definitions of human subjects research, regulations governing work in the social and behavioral sciences (SBR), risk assessment, informed consent, privacy, and confidentiality. Some investigators will be required to complete additional training, depending on their project's characteristics. For example, research studies of individuals in at-risk groups, such as children or employees, must supplement their basic training with modules on this protected subject population.

8.2 Requirements for students conducting research involving no more than minimal risk. Students must complete the social and behavioral research module, which examines modules definitions of human subjects research, regulations governing work in the social and behavioral sciences (SBR), risk assessment, informed consent, privacy, and confidentiality. Depending on the project, some investigators will be required to complete additional training (e.g., special protections for studies of children or employees).

8.3 Requirements for URIRB members. The URIRB shall set its own requirements for completion of training. The URIRB training requirement will consist of all of the training required of students, faculty, and staff plus other modules as the URIRB prescribes. The URIRB may require the completion of additional training when vulnerable populations are involved or other needs are indicated.

8.4. Requirements for extramural investigators. URIRB requires that all individuals named in a protocol who are engaged in the project complete training in the ethics of research with human participants and the PI is responsible for verifying that researchers from other institutions (extramural investigators) have completed appropriate training in the ethics of research. The IRB can assist the PI in making certain these records are accurate. The URIRB recognizes, however, that this requirement varies across institutions, and may not be required of researchers at other universities on projects that are determined to be exempt from the requirements of 45 CFR 46. Extramural investigators are advised to seek guidance from their university's IRB when collaborating on projects reviewed and approved by URIRB.

8.5. Other training requirements. The training specified in this policy relates to human subjects research generally. Researchers will often find that other training is a requirement of grants or special programs. For example, the National Science Foundation (NSF) requires that persons (students, faculty, and staff) working on NSF funded research will need to have training in the responsible conduct of research.

9. Meeting Process and Procedure

The University of Richmond URIRB will hold regularly scheduled meetings for the purposes of reviewing and acting on proposals, setting policies, conducting oversight, and fulfilling its other responsibilities.

9.1 Announcement of meetings. Meetings will generally occur monthly during the academic year. Meeting dates will be set by the Chair with the agreement of the Board. Additional meetings will be scheduled as necessary. Because the URIRB meets only

during the academic year, PIs planning studies requiring full-board review should plan accordingly.

9.2 Distribution of agenda and other meeting materials. The Chair will arrange for the distribution of an agenda and copies of proposals approximately one week prior to each meeting of the URIRB. The Chair may, with the concurrence of the members, produce a revised agenda at the meeting, including some additional materials, provided that there is sufficient time to review the materials.

9.3. Membership. The URIRB, by 45 CFR 46, must include at least 5 members; one member must be an individual who does not conduct research with human participants (nonscientist) and one a member of the local community who is not affiliated with the University of Richmond (unaffiliated member). The remaining members are chosen for expertise in the methods of research used in behavioral sciences, rather than representation of the schools of the University of Richmond. The URIRB also includes a chair, a vice-chair, and alternates who can serve as needed. The President will appoint such members and their names will be registered with OHRP. Alternate members have the full rights and responsibilities of a regular member when serving at convened meetings. Quorum is reached when more than half of the members are present, including both the nonscientist and the unaffiliated members. Designated alternates count towards a quorum.

Researchers or other persons may be invited to attend a meeting of the URIRB for the purposes of answering questions or providing information to the URIRB. Non-Board members will be asked to absent themselves when the Board discusses and votes on a proposal. For some meetings, the board will also include individuals required by 45 CFR 46, such as a prisoner representative for investigations involving studies of individuals who are incarcerated

9.4. Collaborative process. Meetings of the board will be conducted using *Robert's Rules of Order*. Materials will be made available to all members of the committee prior to the meeting, and discussion will examine the criteria set forth in 45 CFR 46. The committee will not use a primary reader process, although the chair will provide a summary of each protocol. URIRB meetings will generally follow an agenda prepared by the Chair and circulated to the Board prior to the meeting. Revisions may be made to the agenda at the request of the Chair or any Board member. Normally the order of the agenda will be:

- Review of the minutes of the preceding meeting.
- Review of expedited actions of the Chair since the last meeting.
- Review of proposals.
- Review of other business.
- Adjournment.

The URIRB may change its meeting procedures at any time when it is judged to be in the interest of protecting human subjects of research. When the Board digresses from its normal procedures, the exception and the rationale for that exception shall be included in the meeting minutes. If any member objects to the exception, that member may request a vote and a majority vote of the Board will be required to digress from normal meeting procedures.

9.5. Decisions. The URIRB's review will result in several types of actions ("determinations"), including exempt from 45 CFR 46 requirements, approval with conditions, approval, request for additional information, and disapproval/suspension. In most cases, an approval with conditions does not need to be resubmitted to the entire Board. The Chair or a subcommittee can review the modifications and approve the modified proposal, unless the Board directs that the proposal be resubmitted for review by the convened Board.

> **9.5a Disapproving a proposal**. The Chair or an URIRB subcommittee cannot disapprove a proposal. Only the convened Board can disapprove a proposal. Disapproval will take place by a recorded vote of the Board. However, the Chair and/or an URIRB subcommittee can prepare and send a notice of the Board's disapproval *without* the convened Board reviewing the final notice of action that is sent to a researcher. A resubmitted proposal that was previously disapproved by the Board must be returned to the Board for review, unless the extent of revisions in the resubmission qualifies the new proposal for expedited review. (For example, were a proposal to be modified so that it posed no more than minimal risk, met other criteria for expedited review, and did not contain provisions that the convened URIRB had found problematic, expedited action *might* be taken.)
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> **9.5b. Not acting on a proposal.** Reasons for not acting on a proposal may include the absence of necessary information on which to base a decision, the need for more time to review the proposal, lack of Board consensus on a course of action, determination that project does not meet the conditions of human subjects' research, or other reasons as determined by the URIRB. When no action is taken, the Chair will notify the researcher that no action has been taken and provide other such information as directed by the Board. The proposal will be addressed at such time as the URIRB determines what course of action should be taken. If approval is needed and no action is taken by the board, the Chair will notify the researcher of the status of his or her proposal and inform the researcher that he or she must wait for URIRB approval to proceed with his or her research. If a researcher submits a substitute proposal, it will be evaluated on its own merits. Such a proposal may qualify for expedited review.

A majority vote *of participating members* decides the action, provided that a quorum is present. The names of members will be recorded as part of the minutes.

9.6. Appointing subcommittees. The board or the chair has the authority to empower a subcommittee to finalize the notice of action to the researcher. When such an action is taken, the date of URIRB action will be the meeting date of the convened URIRB. The minutes of the URIRB will reflect the named members of the subcommittee and the language provided by the subcommittee in its written notice of action to the principal investigator.

9.7 Notifying principal investigators of URIRB actions. Based on the action of the convened URIRB, the Chair or IRB administrator will provide notices of action to principal investigators regarding their proposals. The URIRB administrator will maintain electronic copies of these records for three years from the date of the expiration of the effective date of the notice.

9.8. URIRB minutes. Minutes will be recorded and maintained by the URIRB Chair or IRB administrator in accordance with 45 CFR 46. The meeting minutes will report the discussion and votes of the convened Board. The Chair will submit a draft version of the minutes to other members of the URIRB for their review within one week of the meeting. The minutes of each URIRB meeting must be approved by a recorded majority vote at the next convened meeting of the URIRB. The minutes will include all actions of the URIRB and the basic rationale for those actions. The URIRB will include in its report to the investigators the rationale for its decisions on proposals or policies.

9.9. Report of limited and expedited reviews. Projects approved by limited or expedited review must be reported to the next convened meeting of the URIRB. The Board vote on those actions will be whether or not to receive the report of the Chair. If the Board disagrees, it may vote to reconsider the action taken. If such reconsideration is made, the Chair will notify the researchers of the new action of the Board.

9.10. IRB confidentiality. The discussions of the URIRB are considered confidential. The minutes of the URIRB will also be considered confidential, although they are subject to review by OHRP or other appropriate federal entities (e.g. NIH). The minutes will generally not include the identities of persons making arguments for or against a proposal. The principle of URIRB confidentiality will not, however, be a basis for obscuring URIRB decisions. The URIRB will attempt to communicate clearly to researchers the basis for its decisions. Reports to researchers will not be considered a breach of URIRB confidentiality. The Chair may exercise discretion in making URIRB minutes available to researchers or other University personnel. The Chair will report to the convened Board instances where minutes have been made available to non-IRB members. The URIRB Chair may report on any board matters, including confidential discussions, to University of Richmond officials. When such reports are made, the Chair will inform the URIRB at its next convened meeting or by other means as he or she deems appropriate.

10. University of Richmond Specific Policies

The University of Richmond has adopted policies in addition to those contained in federal regulations which clarify the application of the regulations and promote areas of interest specific to the institution.

10.1. All human research. The University of Richmond, through its assurance agreement with the OHRP, has voluntarily agreed to apply the "Common Rule" to all human subject research at the University, regardless of its source of funding. This assurance has been made by the University of Richmond Signatory Official (the University President) and cannot be changed by the URIRB. In consequence, all students, staff, and employees who are engaged in research involving human participants must seek approval of the project from the URIRB. Individuals who are not certain if their activities on a project involving human participants meet the definition of *engaged* should contact the URIRB for more information.

10.2. Training in the ethics of human research. The IRB requires all investigators complete training in the protection of humans in research, and that they renew that training every three years. Principal investigators are responsible for maintaining in their project record files documentation of training for all researchers engaged on the project,

including any extramural researchers (researchers who are not students, staff, or faculty at the University of Richmond). The IRB can assist the PI in making certain these records are accurate.

10.3. Multi-institutional projects. For projects that involve collaboration with researchers at other institutions, if the project has been approved by that institution's URIRB, the investigator can submit a copy of that institution's research proposal along with an email or letter explaining the nature of the investigator's participation. In most cases it will not be necessary for the investigator to prepare a new University of Richmond proposal. However, the URIRB may request whatever additional materials it deems necessary from the investigator, including a full proposal or a statement of reliance. Expedited approvals (or other actions) of requests to participate in research at other institutions will be reported by the URIRB Chair on the expedited report.

10.4. Study closure. Any nonexempt research study that is not renewed within a one-year period is closed; recruitment of participants must end and the PI should de-identify any data generated by the research (unless their procedures permitted archiving of identified data). Investigators are responsible for initiating the renewal process; the URIRB is not responsible for issuing a notification of pending renewal deadlines. Lapsed studies cannot be reopened.

10.5. Undergraduate student researchers. University of Richmond undergraduate students can serve as principal investigators on projects that are not greater than minimal risk. Students must identify a faculty member who has completed training in the ethics of research to serve as an advisor on their projects.

10.6. Jurisdiction of the URIRB. The URIRB is responsible for the protection of human subjects of research as required by 45 CFR 46, and so does not address other local, state, federal, or international requirements or restrictions, such as regulations pertaining to the use of data (e.g., the guidelines set forth by the Family Educational Rights and Privacy Act and the Health Insurance Portability and Accountability Act of 1996) Title IX of the Civil Rights Act of 1964, conflicts of interest, or the responsible conduct of research.

10.7. Withdrawal of Subjects from Research Activities. It is the position of the University of Richmond IRB that subjects should be able to withdraw consent from research participation at any time during the research process. The URIRB also advises researchers not to seek to persuade subjects to remain in a study or attempt to negotiate the "partial use" of a subject's response. The conditions which will result in termination of participation in research must also be clearly communicated to participants. The consent form must include a statement that describes anticipated circumstances under which (a) the subject's participation may be terminated by the investigator without the subject's consent or (b) the subject will not receive the described benefits (e.g., incomplete responding, failures of attention checks). Without such language, any individual who begins a study but later withdraws should receive the described benefits.

10.8. The IRB Chair. The Chair is a voting member of the Board and is expected to participate in its deliberations. The Chair will discharge other responsibilities in accordance with OHRP guidance. The Board authorizes the Chair to prepare notices of action based on the decisions of the convened Board. It is the University of Richmond's policy that the Chair or another designated member has the authority to determine if the

conditions of approval have been met and does not need to bring every proposal that has been approved by the Board back to the Board for its consideration during a convened meeting.

10.9. Consent and continuing review may be required for exempt studies. The Board may require consenting of subjects and continuing review, even if the research is exempt from other standards defined in 45 CFR 46. URIRB may take such action when review identifies risks and/or conditions that may influence participants' decision to participate.

10.10. Confidentiality and compliance. The URIRB chair will report all serious or continuing noncompliance, and all instances of serious unanticipated problems or adverse events, to OHRP. The chair will also report any suspension or termination of a previously approved study, in whole or in part, to OHRP. The URIRB Chair may also report on any board matters, including reports of noncompliance and adverse events, to University of Richmond officials, including the offices of the Provost, research integrity, compliance, general counsel, foundation, corporate and government relations, and the President.

10.11. Board determinations. While the Board will seek to make consistent and predictable decisions regarding proposals, it recognizes that each research proposal presents a unique set of benefits and risks to potential subjects. Nothing in these policies and procedures and no previous action of the URIRB shall be viewed as constraining the Board from acting on a specific proposal that the Board concludes is necessary for the protection of human subjects of research.

10.12. Translation of consent forms. The URIRB has discussed inherent difficulties in determining whether translations of questions and consent forms are true representations of the English versions reviewed by the Board. At its May 5, 2009 meeting, the URIRB agreed that it would require researchers to certify to the URIRB that the translations submitted as part of the proposal are a true representation of the content and spirit of the translated material. The URIRB may take further action to satisfy its interest in this requirement as it sees fit.

10.13. Employee safeguards. For the purposes of human subject protection, the University of Richmond URIRB considers persons on scholarships (such as a student athlete) to be employees and affords such individuals, when subjects in research, special protections.

Addendum: Organization and Responsibilities

The President of the University of Richmond is the signatory official for the University's assurance agreement with the U.S. Office for Human Research Protections. The Institutional Review Board takes actions on URIRB policies and matters that are not expeditible. The Chair of the URIRB is responsible for the day to day operation and administration of the URIRB and for taking action on proposals that are expeditible. Investigators (whether faculty members, staff members, or students) are ultimately responsible for the protection of subjects and for ensuring that the participation of subjects in research is voluntary and based on informed consent. Responsibilities for various participants in the process for protecting human subjects of research are spelled out in detail below.

Responsibilities of Investigators. Ultimately, the protection of human subjects is the responsibility of researchers or investigators conducting the research. Investigators must make sure that they possess the knowledge and competence to carry out their research. They must exercise judgment with regards to unanticipated events which may adversely affect subjects. They must take action to terminate research if subjects are harmed and to report any such events as soon as possible but always within three working days of the discovery of the occurrence to the URIRB. Investigators must abide by international, federal, state and university policies involving the conduct of research with human subjects. Undergraduate students can serve as principal investigators at the University of Richmond, and like all researchers they are responsible for the protection of the human subjects of their research. However, a faculty advisor who has completed training in the ethics of research will serve as an advisor on student research projects, and student research involving human subjects is generally limited to research involving no more than "minimal risk" to subjects.

Responsibilities of the President as Signatory Official. The President of the University of Richmond reviews and signs the Federalwide Assurance (FWA) document, which is the University's formal agreement with the U.S. government regarding research with human subjects. Such an agreement is generally required before an institution can receive federal funds in support of research activities. The University's FWA document states that the University of Richmond will be guided by the ethical principles of the Belmont Report and that the University "elects to apply" to all of human subjects' research "the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46." In addition, the President appoints an URIRB administrator (the Chair of the URIRB) and members of the URIRB. Appointments are typically based on recommendations made by the URIRB Chair in consultation with the Board and various department and program chairs on campus. The President also states in the assurance agreement that "providing research investigators, URIRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied." To promote compliance with this Assurance, the President directed the URIRB to develop a mandatory training program for University researchers working with or collecting data about human subjects. Action on the President's directive was taken by the URIRB in September of 2008 and is the basis for the URIRB's educational requirements. (It should be noted that such training requirements are strongly recommended by OHRP and are typical for universities in the United States.)

Responsibilities of the Institutional Review Board (IRB) for the Protection of Human Subjects of Research. Members of the Institutional Review Board (IRB) are appointed by the University President for indefinite terms. Membership of the URIRB must conform to the provisions of Section 46.107 and consist of at least five members, including at least one non-affiliated (or community) member and one nonscientist. Alternate members are appointed to ensure continuing expertise on the Board. Both regular and alternate members of the URIRB must be registered with OHRP.

Members of the URIRB are responsible for reviewing and acting on all research proposals submitted to the URIRB, unless the proposals are acted on through the expedited process. Members are required to attend scheduled and called meetings of the

URIRB and to prepare themselves for such meetings by reviewing proposals and other materials referred to them in advance of the meeting. Members are responsible for completing training on human subjects' protection and for determining training requirements for other University researchers. Members of the URIRB are responsible for the review and approval of University of Richmond policies related to the protection of human subjects of research. URIRB members are responsible for recusing themselves on votes where they have a conflict of interest and such recusal shall be noted in meeting minutes. Other responsibilities of members, such as serving on URIRB subcommittees, may be elective. Basic regulatory responsibilities of Institutional Review Boards are outlined in the sections detailed below (principally in Sections 46.108 and 46.109 of 45 CFR 46.) The Board may assign itself other responsibilities that it deems appropriate for the protection of human subjects of research.

The Institutional Review Board serves as an advocate for the human subjects of research, ensuring that the Belmont Report's principles of respect for persons, beneficence, and respect for persons are adhered to.

Institutional Review Boards derive their authority from federal law and regulations. Researchers should be aware that much federal guidance on URIRB responsibilities has been established through reviews of URIRB practices by the Office for Human Research Protection (OHRP) and that OHRP often disseminates information through policies published on its website, training activities, and the publication of "OHRP correspondence" providing guidance on specific topics that it publishes on its website. Often it is necessary for an URIRB to visit multiple sources of authority before exercising its judgment in the review of a proposal.

As noted earlier, an institution signs an "assurance agreement" with the federal government. The University of Richmond has signed an assurance agreement which extends the conditions of the "Common Rule" to all of its research, whether it is federally funded or not. Federal rules and regulations are a "floor," not a "ceiling," for the protection of human subjects. An institution's URIRB can adopt policies that go beyond those required by the federal regulations in 45 CFR 46 and other sources. The University of Richmond has adopted policies specifically related to research at the University. These policies are identified in this URIRB Policy Document.

The University of Richmond URIRB has determined that it may invite non-IRB members to participate in the review process when it deems that their expertise is needed. Meeting practices of the URIRB are more fully described in Section 8 of this guide, "Meetings of the URIRB."

In summary, the URIRB is responsible for reviewing and approving or disapproving research proposals. The Board can also require researchers to make changes to their studies. The URIRB can suspend or terminate its approval of research and has the right to observe and verify that research is being conducted in accordance with its conditions of approval. As specified in Section 46.116 of 45 CFR 46, the Board may require documentation of informed consent or may waive the requirements for documentation of informed consent.

Responsibilities of the Chair of the URIRB. The Chair of the URIRB is appointed by the signatory official of the URIRB, the President of the University of Richmond. The

responsibilities of the Chair of the URIRB are designated by the signatory official, the URIRB, and this URIRB Policy Document. In addition, the Chair directly reports to the University of Richmond Provost and receives assignments from the Provost.

Currently, the Chair has been delegated the following duties and responsibilities:

1. Serve as the University of Richmond's liaison to the U.S. Office for Human Research Protections (OHRP), including:
2. Preparation of the University's Federalwide Assurance Agreement (FWA) with the OHRP for the University President's periodic review and signature.
3. Ensuring that the FWA is always up to date.
4. Preparing the URIRB's organizational registration forms for OHRP and ensuring that the University's registration is up to date.
5. Preparation of necessary materials to be submitted to OHRP through the OHRP Electronic Submission System, such as information on the URIRB's administration, Board membership and alternates, and other information.
6. Submission of reports as required or necessary (reports of noncompliance, adverse events, etc.)
7. Communication with OHRP staff on questions or matters of interest to the URIRB.
8. Staying up to date on OHRP policies and procedures and communicating relevant information to the Board and the University research community.
    a. Serve as a voting member of the URIRB.
    b. Chair meetings of the convened Institutional Review Board.
    c. Provide or coordinate administrative support for URIRB meetings.
    d. Prepare and maintain minutes of URIRB meetings and other records as required by 45 CFR 46.115 URIRB Records. Submit these minutes to members of the URIRB for their review, correction (if necessary), and approval. Maintain electronic and hard copy versions of minutes. (See Section 8 "Meetings of the URIRB" and Section 9 "Records of the URIRB" for more detail on minutes and meetings.)
    e. Prepare notices of URIRB meeting actions and communicate these notices of action to researchers via email.
    f. Receive proposals and perform expedited reviews in categories as allowed by the University URIRB and in accordance with OHRP guidance and University policy. (Note, in some cases other members of the URIRB may be designated to take expedited action on a proposal. In such cases, the member will provide appropriate records to the Chair for filing.) Normally, the URIRB Chair will take the following actions on an expeditible proposal:
        i. Receive the proposal and establish both a full electronic file (in permanent University "Exchange" folders) Electronic records are part of a limited access folder maintained by the Office of the Provost.

ii. Determine whether or not expedited action may be taken on a proposal. (The Chair may consult with other members of the URIRB in making such a determination.) If it is determined that the proposal must be reviewed by the convened URIRB, the Chair will so inform the researcher and place the proposal on the agenda for the next URIRB meeting.

iii. If applicable, determine that a student researcher's faculty advisor has reviewed the proposal and approved its submission to the URIRB.

iv. Determine the appropriate action for a proposal reviewed by the expedited process. Such actions may include:

1. Approval.
2. Approval with conditions.
3. Exemption.
4. Request for more information.

v. Ensure that the researchers have completed training as required. (Training is required for approved proposals.)

vi. Prepare a notice of action informing the researcher of the expedited action. Email the researcher(s) a copy of the notice of action. A notice of action will include:

1. The date of the URIRB action.
2. The action taken by the URIRB.
3. The time period to which the action applies. (IRB actions are to be reviewed dependent on the level of risk but not less than once a year according to 45 CFR 46.109(e).)
4. Any conditions of approval. Conditions of approval must be addressed by the researcher prior to full URIRB approval. On most URIRB actions of "approval with conditions," the URIRB Chair is authorized to review the researcher's revisions and make a final determination. Where the Board determines that additional review by the convened Board is necessary, that determination will be part of the Board's action. The Chair may also elect to refer revisions to the convened Board.
5. The reasons for the URIRB's action, if appropriate.
6. Directions to report any changes to the research to the URIRB and receive URIRB approval before implementing those changes.
7. Directions to report any adverse events involving subjects to the URIRB Chair as soon as possible but always within three working days of the discovery of the occurrence and to suspend research under such circumstances.
8. Contact information for the investigator to use in contacting the URIRB Chair.
9. Other information as required.

vii. Complete the file for the proposal, including a copy of the proposal, a copy of the notice of action, all correspondence (typically in email form) related to the proposal, and other items that may be relevant (such as information related to decision, e.g. the rationale for the expedited action or an exemption).

viii. Include relevant information regarding the expedited review on a spreadsheet to be presented to the convened Board at its next meeting. This information should include:

1. The date the proposal was received.
2. The name of the principal investigator.
3. The applicant's category (student, faculty, staff, other).
4. The faculty advisor, if applicable.
5. The course for which the research was prepared, if applicable.
6. The title of the proposal.
7. A brief summary of the methods used in the proposal (i.e. survey, interviews, experiment, etc.).
8. Comments on the proposal (e.g. minimal risk survey providing confidentiality to subjects).
9. Date of notice of action to applicant.
10. Action taken (i.e. approval, exemption, returned for more information).

g. Make determinations of exempt research in accordance with 46.101(b) when appropriate or refer such determinations to the full Board. Such determinations may be made as notices of action. Such notices may be provided either when a proposal or request for renewal has been submitted.

h. Reply to queries on whether or not URIRB review is necessary. In some cases the Chair or IRB administrator, though limited review, may determine that an activity is not reviewable research and may inform the researcher of such a determination. Such determinations will be filed as responses to queries in the URIRB's email records. At the Chair's discretion, he or she may elect to report to the convened URIRB a determination that an activity is not reviewable research. The URIRB Chair may use such instances as opportunities to document determinations that he or she may think to be of interest to the convened board.

i. Develop and maintain a system of educating and training University researchers on the protection of human subjects of research.

j. Serve as the University's administrator for the Collaborative Institutional Training Initiative (CITI) program.

k. Serve as a resource for the University of Richmond research community on the protection of human subjects. Make presentations to university groups as requested (when feasible).

9. Report the findings and actions of the URIRB to the Provost and the President as appropriate. Any reports of noncompliance, adverse events, or other matters of importance will be made to the appropriate University of Richmond officials (e.g., the offices of the Provost, research integrity, compliance, general counsel, foundation, corporate and government relations, and the President).

10. The URIRB chair will report all serious or continuing noncompliance, and all instances of serious unanticipated problems or adverse events, to OHRP. URIRB will also report to OHRP if it suspends or terminates any study or any part of a study.
11. Other duties as assigned by the President, the Provost, or the Board.

Records of the URIRB. The URIRB Chair maintains the records of the IRB proceedings. Records must be retained at least three years from the date of project completion, as required by 45 CFR 46.115 (b) except in those instances specified elsewhere in this chapter. The University of Richmond URIRB will comply with the records required in 45 CFR 46.115 (b) that are detailed there.