

4 Institutional Review Board

The University of Virginia has established Institutional Review Boards (IRBs) to ensure the protection of human subjects in research conducted under the auspices of the University of Virginia. All non-exempt human subject research conducted under the auspices of the University of Virginia must be reviewed and approved by a University of Virginia IRB or another designated IRB prior to the initiation of the research unless it has been determined that the University of Virginia is not engaged in the research (See Section 1.11.1).

4.1 IRB Authority

The IRB derives its authority from University of Virginia policy, as cited in Section 1.2 above. Under the federal regulations, IRBs have the authority:

1. To approve, require modifications to secure approval, or disapprove all human subjects research activities overseen and conducted under the auspices of the University of Virginia;
2. To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
3. To conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year;
4. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
5. To observe, or have a third party observe, the consent process; and
6. To observe, or have a third party observe, the conduct of the research.

The IRB functions independently. Attempts to coerce or otherwise unduly influence the actions of the IRB are forbidden by policy, and are to be reported as described in Section 4.7. Likewise, the IRB must remain free from the influence of financial and other organizational interests. No individual with responsibility for the business and financial interests of the organization may serve on the IRB.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the organization. However, those officials may NOT approve research if it has not been approved or has been disapproved by the IRB. Reviewing officials may strengthen requirements and/or conditions, or add other modifications before approval or may require approval by an additional ancillary committee. Previously approved research proposals

and/or consent forms must be re-approved by the IRB before initiating any changes or modifications that result from such additional reviews/approvals.

4.2 Roles and Responsibilities

4.2.1 Chair of the IRB

The University of Virginia Institutional Official (IO), in consultation with the [Director of the HRPP Office], appoints a Chair and Vice Chair(s) of the IRBs to serve for renewable [5 year] terms. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chair should be a highly respected individual, from within the University of Virginia, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the research community falls primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial and immune to pressure by administration, the investigators whose research plans are brought before it, and other committees and professional and nonprofessional offices/sources.

The IRB Chair is responsible for conducting the meetings reviews, and may serve as signatory for correspondence generated by the IRB.

The IRB Chair is authorized to take immediate action to suspend a study or studies if information is presented regarding subject safety or for any other reason where such action would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.

The IRB Chair may designate other experienced IRB members to perform duties such as expedited reviews and other IRB functions.

The IRB Chair advises the Institutional Official and the IRB Directors about IRB member performance and competence.

The performance of IRB Chair will be reviewed on an annual basis by the Institutional Official in consultation with the IRB Directors. Feedback from this evaluation will be provided to the Chair. If the Chair is not acting in accordance with the IRB's mission, or following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she may be removed.

4.2.2 Vice Chair of the IRB

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as the Chair.

The performance of IRB Vice Chair will be reviewed on an annual basis by the [Director of the HRPP/IRB Manager] in consultation with the Institutional Official. Feedback from this evaluation will be provided to the Vice Chair. If the Vice Chair is not acting in accordance with the IRB's mission, or following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Vice Chair, he/she may be removed.

4.2.3 IRB Members

The role of an IRB member is to ensure that human research activities comply with federal regulations, state and local laws, and organizational policies and procedures, by:

1. Completing member education and training, both initial and on-going (See Section 3.1).
2. Maintaining the confidentiality of IRB deliberations and research review by the IRB.
3. Conducting and documenting reviews of assigned research in a timely fashion.
4. Attending IRB meetings as scheduled.

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform an IRB Office staff member.

If an IRB member is to be absent for an extended period of time, he or she must notify the IRB at least 30 days in advance so that an appropriate alternate/replacement can be obtained. If the member has a designated alternate, the alternate can serve during the primary member's absence.

5. Recusing self from final deliberations and vote when s/he has a conflict of interest (Refer to section 21.2 for IRB Member conflict of interest policies).
6. Participating in subcommittees of the IRB if requested and available.
7. Conduct themselves in a professional and collegial manner.

The performance of IRB members will be reviewed on an annual basis by the IRB Chair and the IRB Director. IRB members will receive formal documented feedback on the results of this review. Members who are not acting in accordance with the IRB's mission or not following policies and procedures or who have an undue number of absences may be removed.

4.2.4 Alternate members

The appointment and function of alternate members is the same as that for primary IRB members. An alternate's expertise and perspective should be comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.

The IRB roster identifies the primary member(s) or class of members (e.g., physician scientist) for whom each alternate member may substitute. The alternate member will not be counted toward meeting quorum as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

Experienced alternate members may be designated by the Chair to conduct expedited reviews.

4.2.5 Subcommittees of the IRB

The IRB Chair, in consultation with the IRB Director, may designate one or more other IRB members to a subcommittee of the IRB to perform duties, as appropriate, and undertake other IRB functions, and to make recommendations to the IRB (e.g., to supplement the IRB's initial review, continuing review, review of modifications, and/or review of reports of unanticipated problems or of serious or continuing non-compliance). The IRB Chair, in consultation with the IRB Director, will appoint IRB members to serve on each IRB Subcommittee created under this Section. The number and composition of the IRB Subcommittee members shall depend on the scope of duties delegated by the IRB Chair to such IRB Subcommittee (e.g., making recommendations, conducting an inquiry, etc.). Any such Subcommittee cannot approve research that requires approval at a convened IRB meeting.

4.3 IRB Membership

The structure and composition of the University of Virginia IRB is appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at the University of Virginia.

The IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in University of Virginia research.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities. The University of Virginia has procedures (See Section 7.4.1.1) that specifically outline the requirements of research plan review by individuals with appropriate scientific or scholarly expertise. A member of the IRB may fill multiple membership position requirements for the IRB.

Individuals from University of Virginia Office of Sponsored Programs, ResearchNET: (office of research development), Strategic Corporate Partners or the Licensing and Ventures Group may not serve as members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may provide information to the IRB and attend IRB meetings as invited guests.

4.4 Composition of the IRB

7. The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the organization.
8. The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

9. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of organizational commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.
10. If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in working with these subjects.
11. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the organization's consideration of qualified persons of both sexes, so long as no selection is made to the IRB solely on the basis of gender. The IRB shall not consist entirely of members of one profession.
12. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
13. The IRB includes at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.
14. The IRB includes at least one member who represents the general perspective of participants.
15. One member may satisfy more than one membership category.
16. The IRB Chair and Vice-Chairs are voting members of the IRB.
17. The Directors and staff of University of Virginia IRB Offices may be voting members of the IRB.

On an annual basis, the IRB Chairs and Directors shall review the membership and composition of the IRB to determine if they continue to meet regulatory and organizational requirements. Members will receive documented feedback on their performance as reviewers following this annual review.

4.4.1 Appointment of Members to the IRB

When the IRB Chair, Vice Chair and/or the Director of the IRB Office, identifies a need for a new, replacement, or alternate member, they send the names of candidates to the Institutional Official. Department Chairs and others may forward nominations to the Institutional Official, or to the IRB Chair or office staff.

The final decision in selecting a new member is made by the Institutional Official, in consultation with, the IRB Chair and the Director or designee of the IRB Office.

Appointments are made for a one or three year terms depending on the position. Certain positions (e.g. study coordinator, medical student) are not renewable. Other appointments are made for a renewable three-year period of service. Any change in appointment, including

reappointment or removal before the end of a member's term, requires written notification. Members may resign by written notification to the IRB Chair or Director.

On an annual basis, the IRB Chair and the Director or their designee of the IRB Office reviews the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

4.4.2 IRB Registration Updates

Changes in IRB membership will be reported to FDA and OHRP as follows:

1. A University of Virginia decision to disband a registered IRB that it is operating will be reported in writing within 30 days after permanent cessation of the IRB's review of DHHS-conducted or –supported research.
2. If an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA, it must report this within 30 days of the change.
3. Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB Chair,
4. To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by DHHS or regulated by FDA.
5. Within 90 days of a change in the membership roster if that IRB is designated under an FWA.

4.5 Use of Consultants

When necessary, the IRB Chair or the Director may solicit individuals from the organization or the research community with competence in special areas to assist in the review of issues or research plans, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. The IRB Office will ensure that all relevant materials are provided to the outside reviewer prior to the convened meeting.

Written statements from consultants will be kept in the IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the study records.

The IRB Director reviews the conflicting interest policy for IRB members with consultants and consultants must confirm that they do not have a conflict of interest prior to review. Individuals who have a conflicting interest or whose spouse or immediate family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

The consultant's findings will be presented to the convened board for consideration either in person or in writing. If in attendance, these individuals will provide consultation and may assist in the deliberation, but may not participate in the vote.

Ad hoc or informal consultations requested by individual members (rather than the convened board) will be processed by the IRB Office in a manner that protects the investigator's confidentiality and is in compliance with the IRB conflict of interest policy.

4.6 Liability Coverage for IRB Members

The University of Virginia, as an authorized agency of the Commonwealth of Virginia, participates in the Commonwealth's self-insured program which provides insurance coverage for employees and any other person authorized to act on behalf of University of Virginia for acts or omissions within the scope of their employment or authorized activity.

4.7 Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the IRB Director or Institutional Official (IO), depending on the circumstances. The IO will ensure that a thorough investigation is conducted and if the allegation is determined valid, that corrective action is taken to prevent additional occurrences. In the event that the allegation is regarding the IO, the matter will be referred to Provost for investigation and any necessary action.

Undue influence means attempting to interfere with a normal functioning and decision making of the IRB or to influence an IRB member or staff, or any other member of the research team outside of the establish processes or normal and accepted methods in order to obtain a particular result, decision or action by the IRB or one of its members or staff.

The IO ensures that a thorough investigation is conducted, and if the allegation is determined valid, that corrective action is taken to prevent additional occurrences. In the event that the allegation is regarding the IO, the matter is referred to the Provost for investigation and any necessary action.