VDSS IRB Member Responsibilities and Conflicts of Interest

Guidance Statement

VDSS will establish an institutional review board (IRB) to meet regulatory requirements, protect human subjects, and facilitate research. Membership will follow 45 CFR 46.107, with members agreeing to specific IRB responsibilities.

A. Definitions

"Affiliated" means a VDSS or LDSS employee (or immediate family member) has a connection to the IRB.

"Alternate" is a member substituting for a primary IRB member (e.g., social worker, lawyer, ethicist). The alternate has comparable experience and votes when replacing a primary member.

"Non-scientist" means an IRB member who lacks professional scientific training and does not work in scientific areas or who has past scientific training but works only in non-scientific fields, viewing protocols from a non-scientist perspective.[1]

"Primary" is a regular IRB member listed on the OHRP registration.[2]

"Scientist" is an IRB member knowledgeable in the scientific method, through advanced training or current scientific occupation, likely viewing protocols from a scientist's perspective.

"Unaffiliated" means having no connection with VDSS or LDSS.

[1] The IRB Chairperson/Administrator will determine if a nominated member's primary area of work or study is scientific or non-scientific. See OHRP guidance on IRB membership and scientist/non-scientist definitions: http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-january-24-letter-attachment-b/index.html

[2] Consistent with OHRP guidance, members are only appointed as regular (primary) or alternate; non-voting members do not exist. See OHRP guidance on IRB and FWA registrations: http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html#

B. Membership

Member diversity ensures representation across professions, ethnicities, genders, and both scientific and non-scientific areas.

The VDSS IRB has at least five members including:

1. At least one scientist member.
2. At least one non-scientist member.
3. At least one member unaffiliated with VDSS and does not have a family member affiliated with VDSS. (Note: The IRB member may be both a non-scientist and non-affiliate at the same meeting.)
4. For studies involving vulnerable populations, at least one person knowledgeable about or representing the interests of the vulnerable group.
5. At least one member representing the participant perspective.

A member will not be designated as an unaffiliated member until he/she (or an immediate family member) has been unaffiliated with VDSS for at least three years. The IRB administrator documents membership and status changes.

Chairperson appointments: The Institutional Official (or their delegate) appoints the Chair for two years with automatic annual renewal. Members should be notified about term endings in writing. No justification is needed for term end notices (by either party).

General membership: The Institutional Official (or delegate) appoints members and alternates. Potential members may self-identify or be recruited. Terms last two years and end by written notice. No justification is needed for term end notices (by either party).

The VDSS IRB roster serves as the official documentation of membership appointment.

C. IRB Member Responsibilities

General Responsibilities

While serving, members must:

1. Complete all required VDSS human subject protections training and seek additional training as needed to maintain understanding of regulations.[3]
2. Complete assigned reviews promptly as directed by the Chairperson.

[3] VDSS offers free training through the Collaborative Institutional Training Initiative (CITI) program for its IRB members and for VDSS/LDSS employees and contractors who are conducting research for VDSS. Contact the IRB (irb@dss.virginia.gov) for more information. OHRP also offers free training resources on its Education & Outreach web page (https://www.hhs.gov/ohrp/education-and-outreach/index.html).

3. Review the agenda and materials before meetings to ensure familiarity and readiness to participate and contribute.
4. Speak freely to share views about studies and listen respectfully.
5. Participate openly in discussions, motions, or votes to approve, disapprove, modify, or table submissions during IRB meetings.
6. Maintain confidentiality of protocols, decisions, and discussions inside and outside meetings.
7. Work collegially with investigators and other IRB members to facilitate human subject protection oversight.
8. If an IRB member is also a researcher, their research must be ethical and adhere to IRB standards.
9. Declare conflicts of interest and recuse themselves from review when applicable.
10. Attend 75% of meetings and notify the chair when unavailable. Meetings may be held via teleconference/web conference if needed.
11. As an alternate member, attend at least 2 meetings annually as a voting member.
12. Notify the Chairperson of resignation from the IRB.

Responsibilities of IRB Primary Reviewers

During **Full Board Reviews**, the Primary Reviewer must:

1. Conduct a full review of all materials related to the assigned protocol.
2. Contact the Chairperson if additional expertise/consultation is needed.
3. With the Secondary Reviewer and/or Chairperson, request clarification or additional information from the Principal Investigator before IRB review. The Primary Reviewer, in coordination with the IRB Chairperson, should work with the Principal Investigator (or designee) to revise documents (e.g., protocol, consent forms, questionnaires, advertisements) prior to the meeting to facilitate review.
4. Request (with the Chairperson) that the Principal Investigator (or designee) attend or be available to answer questions during the IRB meeting.
5. Prepare and lead the discussion of the protocol and present their decision on whether the research meets IRB approval criteria.
6. Coordinate review comments/questions with the secondary reviewer, if appropriate.
7. Present specific written recommendations for IRB action, including changes and/or questions to the Chairperson, prior to the IRB meeting.
8. Using track changes (in Word) and comments, record required or recommended changes and text edits directly on the relevant submission forms and documents.

During **Expedited Reviews**, the Primary Reviewer must:

1. Conduct a complete review of all materials related to the assigned protocol.
2. Work with the Principal Investigator (or designee) to obtain clarifications, modifications, and necessary changes for thorough review to determine if the research meets IRB approval criteria.

3. If the reviewer determines whether a study qualifies for exemption or should receive a full board review, refer the matter to the IRB for further discussion.

During **Exempt Reviews**, the Primary Reviewer must:

1. Conduct a complete review of all materials related to the assigned protocol.
2. Work with the Principal Investigator (or designee) to obtain clarifications, modifications, and necessary changes to determine if the research qualifies for exemption.
3. If exempt criteria are not met, change the review category to expedited when appropriate and continue the review. Additionally, studies may be referred to the IRB for informal discussion or full review.

Responsibilities of IRB Secondary Reviewers

During **Full Board Reviews**, the Secondary Reviewer must:

1. Conduct a full review of all materials related to the assigned protocol.
2. Work with the Primary reviewer prior to the IRB meeting as needed to complete the review.
3. Contact the Chairperson if additional expertise/consultation is necessary.
4. Prepare and lead the discussion of the informed consent or alternative document/request and recruitment procedures.
5. Discuss pertinent review comments/questions with the primary reviewer, if appropriate.
6. Present specific written recommendations for IRB action, including changes/questions to the Chairperson, before the IRB meeting.
7. Record required or recommended changes and text edits directly on the relevant submission forms and documents using track changes or comments.
8. A secondary reviewer may assist in expedited protocol review when additional expertise is needed, provided the research does not exceed minimal risk criteria. A third reviewer or consultant may assist in full board protocol review based on content expertise needs.

D. Member Compensation

VDSS does not provide financial compensation for IRB service.

E. Member Liability

IRB members, as VDSS employees or agents acting per regulations and VDSS IRB Guidance, are covered by Virginia's General Liability Self-Insurance program, protecting all State committee members.[4]

[4] Code of Virginia § 2.2-1837. Risk management plan for public liability

F. Alternate Members

Alternates, if appointed, are designated for specified member(s) by the Chairperson. If both the alternate and the member attend a meeting, only one may vote. Attendance and votes are recorded in the meeting minutes. Experienced alternates may conduct expedited or exempt reviews.

G. Evaluation of Members and Chairpersons

Members and the Chairperson will be evaluated at least every two years to assess if responsibilities are met. Data will be collected on reviews completed and meetings attended. The Chair reviews evaluations, follow-up actions, and IRB rosters to ensure appropriate expertise and diversity.

Beyond formal evaluations, the Chairperson can review IRB member performance and make recommendations to the Institutional Official regarding appointments and terminations. Members may appeal membership decisions to the VDSS Research and Planning Director.

H. IRB Member Conflict of Interests

IRB members involved in the research project's design, conduct, or reporting will not participate in reviews or determinations except to provide information. VDSS grant administrators cannot perform reviews or be involved in other IRB operations.

Members or ex-officio members (e.g., ORP Director, VDSS Commissioner, Division of General Services, HHS Secretary) cannot serve on the IRB.

A conflict of interest exists if the member, spouse, or dependents have financial interests related to the research, sponsor, product, or service. Members should also consider non-financial conflicts with investigators or the study that may affect objectivity, such as moral objections or hierarchical relationships.

Members holding a financial or non-financial conflict of interest with the study or investigators shall:

1. Announce a conflict and disqualify themselves from accepting or participating in a convened IRB review, except to provide information on request.
2. Leave the meeting during discussion and voting on any motion to approve, require changes, or disapprove, as a person with a conflict cannot be counted towards a quorum. If quorum is lost, the protocol is tabled. Members who dismiss or are absent will be noted in the minutes.
3. If a member is unsure about a potential conflict of interest, discuss this with the Chairperson. The recommendation would be to recuse oneself if the presence (or appearance) of a potential conflict is unclear.