

VDSS IRB Guidance Document:
Member Responsibilities and Conflicts of Interest

Guidance Statement

VDSS will constitute a sufficient IRB to effectively fulfill regulatory requirements, protect human subjects, and facilitate research. IRB membership will be constituted in accordance with regulatory requirements defined in 45 CFR 46.107. IRB members agree to carry out specific responsibilities related to their IRB roles.

A. Definitions

Affiliated means a VDSS or LDSS employee (or a member of that person's immediate family) is considered affiliated.

Alternate means a member who substitutes for a primary IRB member or a category of member (examples: social worker, lawyer, research methodologist, ethicist, etc.). Each alternate IRB member has experience, expertise, background, professional competence and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace; an alternate member votes on IRB actions when serving as a replacement for a primary IRB member.

Non-scientist¹ means an IRB member who lacks professional scientific training and does not work in scientific areas **or** who may have past scientific training but who has worked only in areas that do not exercise that training, and might thus be inclined to view a research protocol primarily from the viewpoint of a non-scientist.

Primary means an IRB member who is a regular member of the IRB and is listed as a regular member on the Office for Human Research Protections (OHRP) IRB registration².

Scientific means an IRB member who is professionally conversant with the scientific method (either by virtue of advanced training or by current occupation in scientific fields), and who might thus be inclined to view a research protocol primarily from the viewpoint of a scientist.

Unaffiliated means an IRB member has no affiliation with VDSS or a LDSS.

NOTES:

1. The determination of whether the nominated IRB member's primary concerns are in scientific or non-scientific areas will be made by the IRB Chairperson/Administrator at the time when nominated for appointment.
2. Consistent with Office for Human Research Protections (OHRP) guidance, IRB members can only be appointed as either regular (primary) or alternate members. There is no category of non-voting member of the IRB.

¹ See OHRP guidance document entitled "*Attachment B: Recommendation on IRB membership and Definition of Non-scientist under 45 CFR 46 and 21 CFR 56*"

<http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-january-24-letter-attachment-b/index.html>

² <http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html#>

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B. Membership

Member Diversity (Scientific/Nonscientific and Overall)

Membership is selected to assure appropriate diversity, including representation by multiple professions, multiple ethnic backgrounds, both genders, and to include both scientific and non-scientific members.

The VDSS IRB has **at least five members** including:

1. at least one member whose primary concerns are in scientific areas
2. at least one member whose primary concerns are in nonscientific areas
3. at least one member who is not otherwise affiliated with VDSS (and who is not part of the immediate family of a person who is affiliated with VDSS). (**NOTE:** One IRB member may fulfill both criteria of non-scientist and non-affiliate at the same meeting).
4. When a study involves a population vulnerable to coercion or undue influence, the IRB will include at least one member who is knowledgeable about or experienced in working with such participants.
5. At least one member who represents the general perspective of participants.

A member will not be designated as an unaffiliated member until he/she or an immediate family member has been unaffiliated with VDSS for a period of three years. The IRB administrator is responsible for documenting changes in the IRB membership and/or member status changes.

Chairperson Appointments

The Institutional Official (or delegate) appoints the IRB Chairperson/administrator. The appointment is for a three year term with an automatic annual renewal. Ending of a term should be accompanied by written notice. Justification is not required for notice of the Chairperson's term end (by either party).

General Membership Appointments

The institutional signatory official (or delegate) appoints the general members and alternate members. Potential members may self-identify to the IRB Chairperson and/or the Chairperson will recruit potential members. Appointments are for a three year term and should be ended by written notice. Justification is not required for notice of membership term end (by either party). The VDSS IRB roster serves as the official documentation of membership appointment.

C. IRB Member Responsibilities

General Responsibilities

While serving an IRB appointment, members have the following responsibilities:

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1. complete all required VDSS human subject protections training and seek additional training where necessary to maintain an effective understanding of human subject protection regulations³,
2. complete assigned reviews in a timely fashion as assigned by the Chairperson,
3. review meeting agenda prior to the convened meeting, ensuring that all materials are reviewed for familiarity of protocol and be prepared to participate and contribute to discussion,
4. speak freely to discuss their point of view and listen respectfully regarding studies under review,
5. participate openly in appropriate discussions, and motioning and/or voting to approve, disapprove, require modifications, or table each submission during the IRB meetings,
6. maintain confidentiality of protocols, decisions, and discussions both inside and outside of meetings,
7. work collegially with investigators and other IRB members to facilitate human subjects' protections,
8. if an IRB member is also a research investigator, research conducted must be ethical and must maintain IRB studies in good standing,
9. announce conflicts of interest with research under review and recuse themselves from the review of studies where conflicts of interest exist or may appear to exist,
10. as a primary member, attend 75% of scheduled meetings and notify chairperson when unavailable to attend meetings or conduct reviews. Meetings can be attended via teleconference/web conference if necessary,
11. as an alternate member, attend at least 2 meetings per year as either a voting or non-voting member,
12. provide prior notice of intention to resign from the IRB to the Chairperson.

The Responsibilities of IRB Members serving as Primary Reviewer Include:

Full Board Reviews

1. conducting a full and thorough review of **all materials** related to the assigned protocol,
2. contacting the Chairperson if additional expertise/consultation may be necessary,
3. requesting (along with the Secondary Reviewer and/or Chairperson) additional information from the Principal Investigator such as documents, or clarification prior to the IRB review. In coordination with the IRB Chairperson, the Primary Reviewer should work with the Principal Investigator to revise documents (protocol, consents, and advertisements) prior to a meeting to facilitate review,
4. requesting (along with the Chairperson), that the Principal Investigator (or designee) attend or be available during the IRB meeting to aid in the review,

³ Free training options may include: 1) the Annual Virginia IRB Consortium Conference; 2) OHRP' recorded lectures "Luminaries" Lecture Series"; 3) OHRP "Education & Outreach Archived Materials"; and 4) OHRP conferences, workshops, and other educational events.

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5. preparing for and leading the discussion of the protocol, the complete grant application (as applicable), and whether the research meets the criteria for IRB approval,
6. coordinating review comments/questions with the secondary reviewer, if appropriate,
7. presenting specific written recommendations for IRB action, including changes and/or questions to the Chairperson prior to the IRB meeting,
8. recording any scripted (specific) changes requested/required directly onto relevant documents to facilitate communication to investigators and accurately capture IRB requirements

For Expedited Reviews

1. conducting a complete review of **all materials** related to the assigned protocol,
2. working with the Principal Investigator or designee to obtain clarifications, modifications, and necessary changes for a thorough review in order to determine if the research meets the criteria for IRB approval,
3. the reviewer may determine a study meets the criteria for an exemption. Additionally, the reviewer may refer the study to the IRB for informal discussion or for full board review.

For Exempt Reviews

1. conducting a complete review of **all materials** related to the assigned protocol.
2. working with the Principal Investigator or designee to obtain clarifications, modifications, and necessary changes for a thorough review in order to determine if the research qualifies for exemption.
3. If exempt review criteria are not met, then changing the study review category to expedited review when appropriate and continues the review. Additionally, studies may be referred to the IRB for informal discussion or for full review.

The Responsibilities of IRB Members serving as a Secondary Reviewers include:

Full Board Reviews

1. conducting a full review of **all materials** related to the assigned protocol,
2. working with the Primary reviewer prior to the IRB meeting as needed to complete the review,
3. contacting the Chairperson if additional expertise/consultation may be necessary,
4. preparing for and leading the discussion of the informed consent document or alternative document/request and recruitment procedures,
5. discussing pertinent review comments/questions with the primary reviewer, if appropriate, and
6. presenting specific written recommendations for IRB action, including changes and/or questions to the Chairperson prior to the IRB meeting,

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7. recording any scripted (specific) changes requested/required directly onto relevant documents to facilitate communication to investigators and accurately capture IRB requirements

A secondary reviewer may be requested to assist in the review of an expedited protocol when the research appears to require additional subject matter expertise, but the research does not exceed minimal risk criteria. Similarly, a third reviewer or consultant may be requested to assist in the review of a full board protocol depending on the need for content expertise.

D. Member Compensation

VDSS does not provide financial compensation for service on its IRB.

E. Member Liability

IRB members function as employees or agents of VDSS. As such, when acting in accordance with federal, state, and local regulations and the VDSS IRB Written Guidance Documents, their actions are covered by the Commonwealth of Virginia's General Liability Self-Insurance program⁴. Among others, this program protects individuals serving on all State committees.

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 of these two may vote. In these cases, the minutes reflect who is in attendance and who will vote. Alternate members with adequate experience may be designated to conduct expedited and/or exempt reviews.

G. Evaluation of Members and Chairpersons

Members and Chairperson will be evaluated periodically and no less than every three years to determine if the responsibilities of the appointment are being sufficiently met. Data will be collected regarding numbers of reviews completed and meetings attended. The Chairperson will review member evaluation results and determine follow-up action as necessary. The Chairperson will review the IRB rosters to ensure the membership represents the expertise and diversity necessary to effectively review the research portfolio.

In addition to the formal evaluation process, the Chairperson has authority to review IRB member performance and make recommendations to the Institutional Official regarding membership appointments and terminations. Members have the right to appeal any membership decisions they believe have been determined unjustly to the VDSS Research and Planning Director.

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

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H. IRB Member Conflict of Interests

No IRB member involved in the design, conduct, or reporting of the research activity under review will participate in an exempt, expedited or full board review or determinations except to provide information. Additionally, individuals who are responsible for VDSS grant administration are not permitted to carry out day-to-day operations of the review process nor serve as members or ex-officio⁵ members (for example: ORP Director, VDSS Commissioner, a representative for VDSS Division of General Services, HHS Secretary, etc.) on the IRB. An IRB member is considered to have a conflicting interest⁶ when the member, the member's spouse, or any of the member's dependent children have any financial interest related to the research, sponsor, product or service being tested in the research. IRB members should also consider whether they have non-financial conflicts of interest with study investigators or the study itself that may impact objective review. Examples of non-financial conflicts held by members may include: philosophic or moral objection to the study itself, supervisory or subordinate positions relative to the principal investigator. Members holding a financial or non-financial conflict of interests with the study or investigators shall:

1. Announce the presence of a conflict and disqualify themselves from accepting a protocol review or participating in a convened IRB review, except to provide information on request
2. Leave the meeting during the discussion and the vote on any motion to approve, require changes, or disapprove the research in question (Note: When a person with a conflict of interest leaves the room he/she cannot be counted towards a quorum. If the quorum is lost, the protocol will be tabled. Those who dismiss/absent themselves during a meeting will be identified as doing so, in the minutes.)
3. If an IRB member is unsure whether he or she has an actual or perceived conflict of interests with the research under review, the general recommendation is to discuss with the Chairperson and request recusal from protocol review if the presence or appearance of conflict remains unclear.

⁵ An ex officio member is a member of a body (a board, committee, council, etc.) who is part of it by virtue of holding another office. The term is Latin, meaning literally "from the office", or "by right of office".

⁶ Virginia State and Local Government Conflict of Interests Act §2.2-3100 et seq. Also see Virginia Conflict of Interest and Ethics Advisory Council <http://ethics.dls.virginia.gov/>