VDSS IRB Guidance Document: Reliance Agreements

This Guidance Document applies to:

1. Virginia Department of Social Services (VDSS),
2. Local Departments of Social Services (LDSS),
3. Any agency or facility licensed by VDSS, and
4. VDSS contractors

Definitions

"Authorization Agreement" is a contract between institutions with registered federal wide assurances[1] to review or rely on each other's IRB.

"Cooperative research" means projects under federal human subjects protection policy[2] involving multiple institutions, each responsible for protecting human subjects' rights and welfare.

"Engagement in Research" means employees or agents who (i) interact with living individuals, (ii) obtain private identifiable information for research, or (iii) obtain informed consent from individuals.

"Local context" refers to specific state or local laws or regulations as well as customs or practices of a particular area or community or research site that may affect the research process. It also includes factors associated with research participants (e.g., participants' race, culture and language, geography).

"Non-VDSS institution" means an institution or its employees/agents not under VDSS authority and involved in VDSS-involved or supported human subjects research.

"Relying Institution" is an institution that delegates IRB review to another IRB in multi-site research.

"Reviewing IRB" is an IRB that reviews multi-site research for another institution's IRB.

"Reliance Agreement" is a contract between IRBs for multi-institutional human subjects research seeking to use a single IRB. These agreements cover oversight, investigator roles, and institutional requirements.

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[1] An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements in the regulations for the protection of human subjects at 45 CFR part 46. The federal wide assurance (FWA) is the only type of assurance of compliance accepted and approved by the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (HHS).

[2] 45 CFR 46.114

A. Overview of IRB Reliance Agreements

VDSS promotes agreements where an IRB relies on another's review, reducing duplication and increasing efficiency by designating a single IRB for multi-institutional projects. HHS regulations permit institutions in multi-institutional studies to use reasonable joint or cooperative review methods.[3]

In cooperative research, each institution is responsible for safeguarding human subjects' rights and welfare. Reliance agreements generally cover a specific protocol with a qualified IRB[4] of a collaborating institution.

The VDSS Commissioner can decide to have VDSS review or rely on another IRB. The Commissioner executes Memorandums of Understanding (MOUs) and IRB Authorization Agreements (IAAs), or reliance agreements; he/she can delegate this authority to General Services for minimal risk research.

VDSS will consider these criteria when deciding whether to review or rely on another IRB:

a) **Accreditation status**: Whether the other IRB's policies meet VDSS standards; accreditation by AAHRPP presumes compliance, but accreditation status alone does not determine reliance.
b) **Study risk level**: 1) risk to subjects is minimized, 2) risks are reasonable relative to benefits, and 3) subject selection is equitable.
c) **Funding source**: VDSS generally will not defer review if it is the primary grantee.
d) **Location**: if research activities differ between sites, and most research activities occur at VDSS, VDSS will generally serve as the reviewing IRB.
e) **Personnel**: VDSS considers the PI's primary affiliation, his/her ability to coordinate and oversee study activities, and expertise of research personnel.
f) **IRB expertise**: VDSS considers the types of IRB expertise required.

The VDSS IRB administrator will ensure agreement documents are signed by the Commissioner (or designee, such as General Services) and kept on file. The VDSS IRB administrator will facilitate communication with involved institutions.

B. Requirements when VDSS relies on another IRB

Step 1: PI contacts VDSS IRB administrator to confirm reliance is possible. Send an email to irb@dss.virginia.gov that includes the following information:

- VDSS PI's name
- Study Summary

[3] Ibid
[4] The IRB must hold a FWA on file with OHRP in HHS.

- Role of each institution in the research collaboration
- Name of the reviewing IRB site

Step 2: Obtain Institutional Reliance Agreement

Once the VDSS IRB administrator confirms reliance, the VDSS IRB will collaborate with the VDSS investigator to establish signed agreements. The VDSS PI must contact the other institution's PI to confirm IRB willingness and obtain their reliance agreement. Contact the VDSS IRB Administrator to obtain a copy of the Reliance Agreement template. Each institution completes the Agreement to formalize reliance. Steps 3 and 4 must be completed before the VDSS PI starts the study.

Step 3: Ensure consent documents, as appropriate, include local context requirements

Local context reviews are essential to ensure that the research is conducted in accordance with the local laws and that the research is sensitive to the local community's needs and concerns.

While reliance on another IRB allows the VDSS IRB to accept the other IRB's review of science, procedures, methods, and consent documents, minor changes or additions may be made to recruitment and consent documents. Ideally, the reviewing PI should incorporate the relying IRB's changes before submitting the application. See Checklist at the end.

Step 4: Obtain other necessary approvals

IRB approval is not sufficient; the relying investigator and institution are responsible for ensuring all necessary approvals are obtained before research begins.

C. Requirements When Another IRB Relies on the VDSS IRB

When a non-VDSS organization wishes to rely on the VDSS IRB, it must indicate this in the IRB submission and submit a request. The IRB will review the request, and if accepted, the VDSS IRB will work with the VDSS investigator to establish signed agreements.

Step 1: The VDSS investigator, in coordination with the collaborating investigator, should address all the following when completing the VDSS IRB submission:

1) Describe the level of VDSS PI oversight of research activities at the non-VDSS institution.
2) Describe the local context of the non-VDSS Institution or how this knowledge will be obtained (e.g., consultants).
3) Obtain the FWA number and effective dates for the non-VDSS institution.
4) Describe resources available at the non-VDSS institution to conduct research.
5) If research is ongoing at another institution (e.g., multi-center study), provide a report of results to date and a summary of all unanticipated problems, serious adverse events, and reportable adverse events.

6) If a VDSS researcher leads a multi-site study, applications must include information on how information will be managed relevant to human subject protections, like interim results and plan changes.

Step 2: The VDSS IRB administrator reviews the material and recommends approval to the VDSS Commissioner/designee.

D. Dual IRB Oversight

In some cases, each institution may decide to oversee all study aspects via their IRB. The IRB administrator will decide case-by-case. The VDSS researcher/investigator, with the IRB administrator, must obtain a dual oversight agreement.

The VDSS investigator should contact the IRB administrator to get the *Dual IRB Oversight Agreement* and work to obtain signatures from the non-VDSS institution.

E. IV. VDSS Principal Investigator Responsibilities:

When collaborating with non-VDSS organizations, the VDSS principal investigator must work with the IRB administrator to ensure:

1. Adequate resources will be available at non-VDSS institutions to conduct research safely and effectively per approved plan.
2. All people interacting with human subjects or data are adequately trained in human subject protection, regardless of employment with VDSS.
3. Any non-VDSS institution IRB reviewing VDSS-related research must be registered with the U.S. Office for Human Research Protections.
4. VDSS IRB receives complete reports of all IRB-reportable events at VDSS and other research sites.
5. Applicable state laws outside Virginia must be incorporated into the research design, especially regarding enrollment and consent.
6. Consent documents must accurately represent VDSS involvement and IRB decisions in the research.

The VDSS IRB is willing to rely on other specified IRBs in limited circumstances. The reliance on another IRB means that the VDSS IRB will accept the review of the science, procedures and methods as well as the consent documents of the reviewing IRB. However, minor changes will likely be required for the recruitment and consent documents so that the participant will have the needed local context to be truly informed about the study.

Use the checklist below when modifying consent forms; adapt as appropriate for assent forms, information sheets, and recruitment materials.

	Heading: Add “Virginia Department of Social Services” as part of the heading in the consent form, assent form, or information sheet.
	Introduction: Identify the name of the VDSS Principal Investigator and her/his division in the introductory paragraph. For example, “Amy Freg, PhD and her associates in the Office of Research at VDSS and … [investigator at other named site] are conducting a research study.” The VDSS IRB does not require, and, in fact, discourages listing all investigators in the consent form.
	Procedures Section (or elsewhere as appropriate): State where the procedures for the study will take place at VDSS, if appropriate.
	Contact Information: Provide the local VDSS PI’s contact details for questions. Note: Adding VDSS IRB contact info is optional; participants may contact the reviewing IRB for VDSS IRB information.
	Financial Interests: If any members of the research team have a financial or other conflict of interest, this information should be added in the appropriate section of the consent form. If VDSS has a financial interest, this should also be added. See Recommended Consent Form Language in the “Consent Form Guidance Document”.
	Social Services Clients: If Social Services clients are a designated research participant group, ensure the following statement is included in the consent form, assent form, information sheet, and/or recruitment materials. "It is your decision whether or not to participate in the study. Your social services benefits will not change based on what you decide about the study."