This Guidance Document applies to[1]:

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: means a contract between institutions that hold a Federalwide Assurance (FWA) to review for or rely on the IRB of the other institution.

Cooperative research: means those projects covered by federal *Protection of Human Subjects* policy[2] which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the policy.

Engagement in Research: means an institution's employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

Non-VDSS Institution: means an institution (or an employee or agent of the institution) not under the authority of VDSS for the purpose of conducting or authorizing human subjects research.

Relying Institution means an institution that cedes IRB review to another institution's IRB that is engaged in a multi-site research study.

Reviewing IRB means an IRB that reviews multi-site research on behalf of another institution's IRB engaged a research study.

Reliance Agreement: means a contract between IRBs for human subjects research studies involving more than one institution and those institutions seek to use a single IRB. These agreements vary from institution to institution and cover topics related to IRB oversight, investigator responsibilities and other institutional requirements.

Overview of IRB Reliance Agreements

VDSS promotes and engages in agreements by which an IRB relies on the review conducted by another entity. These agreements vary in scope, terms, and terminology. These agreements are designed to reduce duplication and increases efficiency by designating a single IRB review when multiple (two or more) institutions and their IRB are involved in a research project.

The Department of Health and Human Services regulations[3] permit institution involved in multi-institutional studies to use reasonable method of joint or cooperative review. In the conduct of

[1] Code of Virginia §63.2-218 and 22VAC40-890-20
[2] 45 CFR 46.114
[3] 45 CFR 46.114

cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects.

Generally, the scope of a VDSS reliance agreement will be limited to a specific protocol/research plan with a collaborating institution that has a qualified IRB[4].

The VDSS Commissioner is vested with the authority to make the decision whether or not to review for or rely on another IRB. The Commissioner may execute Memorandums of Understanding (MOUs), Authorization Agreements (IAAs) and/or reliance agreements on VDSS's behalf and may delegate this authority. For minimal risk research, the Commissioner has delegated this authority to General Services, in consultation with the VDSS IRB administrator.

In deciding whether or not to review for or rely upon another IRB, VDSS will consider the following criteria:

A. **Whether other IRB's policies and procedures meet VDSS standards**. If the other IRB is accredited by the Association for the Accreditation of Human Research Protections Programs, Inc., then it will be presumed that VDSS standards are being met. However, accreditation status does not in itself necessarily suffice as a basis for VDSS decision; nor does a lack of accreditation necessarily mean VDSS will not rely on another IRB.
B. **Risk level of study**: 1) risks to subjects are minimized; 2) risks to subjects are reasonable in relation to anticipated benefits; and 3) selection of subjects is equitable.
C. **Source of funding**. In general, VDSS will not defer review if it is the prime grantee.
D. **Location of human research activities**. If research activities are not the same at both or all institutions and most human subjects research will occur at VDSS facilities; in general, VDSS will serve as the reviewing IRB.
E. **Personnel involved**: VDSS will consider: 1) PI's able to provide appropriate coordination and oversight of the study activities; 2) the expertise of study personnel; 3) PI's primary affiliation.
F. **IRB expertise**: VDSS will consider the type(s) of IRB expertise needed to appropriate conduct the review.

The VDSS IRB administrator will ensure that any required agreement documents are appropriately signed by the Commissioner/designee/VDSS Division of General Services for both or all institutions involved and is kept on file for reference and review. The VDSS IRB administrator will facilitate communication with the relying or reviewing institution about VDSS IRB actions on the Human Subjects Research that is subject to the agreement.

I. What is required when VDSS relies on another IRB

Step 1: The Principal Investigator (PI) must contact the VDSS IRB administrator to confirm that reliance is possible.

Send an email to irb@dss.virginia.gov that includes the following information:

[4] The IRB must hold a "Federalwide Assurance" on file with the Office for Human Research Protections, U.S. Department of Health & Human Services

- VDSS PI's name
- Study Summary
- Role of each institution in the research collaboration
- Identify the name of the reviewing IRB site

Step 2: Obtain Institutional Reliance Agreement

Once the VDSS IRB administrator confirms VDSS is willing to rely, the VDSS IRB will work with the VDSS investigator to establish the appropriate signed agreements. The VDSS PI should contact the PI of the other institution to (a) confirm that their IRB is willing to review for VDSS and (b) obtain a copy of their IRB reliance agreement. The Agreement is completed by each institution and formalizes the IRB reliance arrangement between institutions. Completion of Steps 3 and 4 below are also required in order for the VDSS PI to commence the study.

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

Although 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, minor changes and/or additions may be made by the relying IRB (VDSS) to the recruitment and consent documents. Ideally, the PI at the reviewing institution should incorporate relying IRB changes into the documents prior to submitting the application packet to the reviewing IRB. See ICF Checklist at the end of this document.

Step 4: Obtain other necessary approvals

IRB approval is not the only approval necessary to conduct the research. The relying investigator and/or relying institution remain responsible for determining that necessary approvals are in place before the research proceeds.

II. What is required when another IRB relies on the VDSS IRB

When the non-VDSS organization wishes to rely on the VDSS IRB, this should be indicated in the IRB submission; (a completed reliance agreement request form should be included in the submission packet). The IRB will consider the request. If accepted, the VDSS IRB will work with the VDSS investigator to establish the appropriate signed agreements.

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

1) Describe the level of VDSS PI oversight of the research activities conducted at the non-VDSS institution.
2) Describe your understanding of the local research context of the non-VDSS organization or how the knowledge will be obtained (i.e., use of consultants).
3) Does the non-VDSS Institution have an FWA? If yes, provide the FWA Number and effective dates.
4) Describe the resources available at the non-VDSS institution to conduct the research.
5) If the research is ongoing at another institution (such as in the case of a multi-center study) provide a report on research results to date and summary of all

unanticipated problems and/or serious adverse events and other reportable adverse events.

6) If a VDSS researcher is the lead researcher of a multi-site study, applications should include information about the management of information that is relevant to the protection of human subjects, such as interim results and research plan modifications.

Step 2: The VDSS IRB administrator will review the material and make a recommendation to the VDSS Commissioner/designee/General Services regarding approval.

III. Dual IRB Oversight

In some cases, each institution may determine that all aspects of a study conducted at its institution will be overseen by the respective institutional IRB. The IRB administrator will make this determination on a case-by-case base. VDSS researcher/investigator, in coordination with the VDSS IRB administrator, is responsible for obtaining an IRB dual oversight agreement. VDSS researcher/investigator should contact the VDSS IRB administrator to obtain a copy of the *Dual IRB Oversight Template* and work with the IRB administrator to obtain appropriate signature(s) from the non-VDSS institution.

IV. VDSS Principal Investigator Responsibilities:

When collaborating with non-VDSS organizations, it is the responsibility of the VDSS principal investigator to work with the VDSS IRB administrator to ensure:

1) adequate resources will be available at the non-VDSS institution to conduct the research safely and effectively in full accordance with the approved research plan;
2) all persons interacting with human subjects and/or their identifiable data are adequately trained in the protection of human subjects, regardless of their employment status with VDSS;
3) any non-VDSS institution whose IRB is reviewing research that is associated with VDSS is registered with the U.S. Office for Human Research Protections;
4) the VDSS IRB receives complete reports of all IRB-reportable events occurring both at VDSS and the other sites engaged in the research;
5) applicable state law relative to research outside of Virginia is incorporated into the research design, especially as it applies to enrollment and informed consent; and
6) the consent documents fairly and accurately represent the involvement of VDSS in the research and the decisions of all responsible IRBs reviewing the research.

V. Notes:

1) Allowing another institution to rely upon the VDSS IRB requires knowledge of the local research context. VDSS will consider geographic proximity and similarities of communities in the decision to allow for a deferral and/or request information from the other organization pertaining to local context.
2) VDSS considers requests for IRB deferrals on a case-by-case basis.
3) VDSS has drafted its own *Reliance Agreement and Dual Oversight templates* (available by contacting the IRB administrator).

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 to 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 the consent forms. Adapt these changes as appropriate for the assent forms, information sheets and recruitment materials.

☐	**The Heading**: Add "Virginia Department of Social Services" as part of the heading in the consent form, assent form, or information sheet.
☐	**The 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.
☐	T**he Procedures Section** (or elsewhere as appropriate): State where the procedures for the study will take place at VDSS, if appropriate.
☐	**Contact Information**: In the section that provides information about whom to contact with questions about the study, provide the local VDSS PI's contact information. Important Note: You do not necessarily need to add VDSS IRB contact information. The participant may contact the reviewing IRB and be given VDSS IRB information as appropriate.
☐	**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 participants 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."

References

Engagement of Institutions in Research[5]
OHRP List of Approved Assurances[6]
OHRP Assurance Process[7]

[5] http://www.hhs.gov/ohrp/policy/engage08.html
[6] http://www.hhs.gov/ohrp/assurances/status/index.html
[7] http://www.hhs.gov/ohrp/assurances/assurances/file/index.html