VIRGINIA DEPARTMENT OF
SOCIAL SERVICES

# Institutional Review Board:

## Summary and Procedures

(Updated 4/23/2026)

Completed by the
**Office of Research and Planning**

For questions or comments about this guidance document, contact
the IRB Chair/ Administrator at:

Virginia Department of Social Services (VDSS)

Office of Research & Planning
5600 Cox Road
Glen Allen, VA 23060
irb@dss.virginia.gov

NOTE: Over time, this document is being replaced by topic specific IRB guidance documents posted to the IRB webpage (https://dss.virginia.gov/research-and-planning/institutional-review-board-irb/). If there is a conflict between this document and any topic specific IRB guidance document, the topic specific guidance document takes precedence over this document.

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# VDSS IRB Guidance Summary

## I. Introduction

This section outlines the purpose, legal authority, and composition of the Virginia Department of Social Services (VDSS) Institutional Review Board (IRB).

### A. Purpose of the IRB

The IRB is designated to review and approve research involving human subjects prior to the initiation of such research, and to conduct periodic reviews of such research.[1] The IRB has authority to approve, disapprove, or require modifications of research activities.[2] The IRB may work in conjunction with other IRBs; however, it independently reviews research projects. Research approved by the IRB may be subject to further appropriate review and approval or disapproval by VDSS officials. However, those officials may not approve the research if it has not been approved by the IRB.[3] VDSS Human Subject Research regulations and guidance documents apply to:

- The Virginia Department of Social Services (VDSS),
- Local Departments of Social Services (LDSS),
- All facilities licensed by VDSS, and
- All contractors who propose, authorize, or conduct human research with VDSS funds.

### B. Authority and Responsibility of the IRB

The VDSS IRB operates under a federal-wide assurance[4] (FWA00010976) and complies with the requirements in Title 45 Code of Federal Regulations (CFR) part 46. The FWA is an agreement between the VDSS Commissioner and the U.S. Department of Health and Human Services (DHHS) outlining the IRB's responsibilities in ethical research involving human subjects. These principles are outlined in the report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (aka the "Belmont Report").[5] The FWA is required for institutions involved in federally-supported human subjects research.

Additionally, the IRB follows the Virginia Administrative Code 22VAC40-890 et seq. The IRB can determine if a project is human subjects research. The IRB reviews proposed research conducted or authorized by VDSS; the regulation applies to research conducted by local departments of social services, licensed facilities, and contractors on behalf of VDSS.[6,7]

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[1] 45 CFR 46.103(b) & COV 63.2-218
[2] 45 CFR 46.109(a)
[3] 45 CFR 46.112
[4] 45 CFR 46.103
[5] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
[6] COV 63.2-218; 22VAC40-890-20
[7] 22VAC40-890-20. Under 22VAC40-890-60B, "local departments, facilities, or contractors collaborating with another

The IRB reports to the VDSS Commissioner. The Director of Research and Planning oversees the IRB. The IRB chair is a staff member. Annually, the IRB reports reviewed studies, approvals, and deviations from the approved protocol to the Commissioner, the Governor, and the Virginia General Assembly.[8]

### C. Board Membership

The IRB shall have at least five members, appointed by the VDSS Commissioner.[9] Members shall have diverse backgrounds for comprehensive review; at least one shall focus on non-scientific or ethical concerns.[10] Members shall ensure competent review of human research.

The IRB may invite subject matter experts to assist in reviewing studies with complex issues requiring expertise beyond the IRB. These individuals cannot vote.

The IRB is responsible for determining conflicts of interest. The IRB reviewer shall not be directly involved in the proposed human research project or have approval authority over the proposed research. Members shall not review projects where they have a conflict of interest; they may provide information requested by the IRB.[11] If the IRB member has a conflict of interest and must recuse themself, an alternate member shall be assigned to review the project.

The IRB roster is on the IRB webpage.[12]

## II. IRB Guidance Summary

This section summarizes IRB guidance and requirements for reviewing human subjects research. Guidance documents and forms are on the IRB webpage. It also covers informed consent and release of client records.[13]

### A. Criteria for IRB Approval of Research

VDSS, local DSS, licensed facilities, or contractors cannot conduct or authorize human subjects research unless approved by the VDSS IRB. The IRB considers. The IRB considers:

1. Utility and necessity of the research,
2. Appropriate methodology for the study,
3. Whether risks are outweighed by the potential benefits (risk level),
4. Whether the rights and welfare of participants are adequately protected,
5. Whether the informed consent process (including written consent forms) is adequate and appropriate based on the participant's education, reading level, and language fluency,
6. Whether the research personnel, especially the principal investigators, are competent and

organization on a research project may instead elect to utilize that organization's research review committee."
[8] COV 63.2-218
[9] 45 CFR 46.107(a)
[10] 45 CFR 46.107(b)
[11] 45 CFR 46.107(e)
[12] https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/irb-membership/
[13] https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/policies-and-procedures/

qualified, and

7. Whether the participant selection criteria are equitable.

The IRB (or reviewers for expedited reviews) will consider proposals within 30 calendar days of receiving a complete application.[14] It will notify investigators in writing of approval, disapproval, or required modifications to secure IRB approval within seven business days. No personal identifiers of participants shall be discussed during review.

Investigators must include procedures for handling participant complaints. All complaints shall be referred to the IRB to assess for violations of approved research.

The IRB shall conduct continuing review of research at intervals appropriate to its risk level, but no less than once annually. The IRB (or assigned third party) shall have authority to observe the consent process and the research.[15] Investigators must submit a research summary report to the IRB after completion of the study.[16]

### B. Key Determinations for Human Subjects Research Review

Research conducted by VDSS or in collaboration with the LDSS, licensed facilities, contractors, or outside investigators using VDSS resources, must be reviewed and approved by the IRB. Federally supported research involving DSS clients and/or their data must also be approved by the VDSS IRB.

Not all research needs IRB review. This section explains how to determine the need, based on four key questions:

Question 1: Does the project involve human subjects?

Question 2: Is the project considered research?

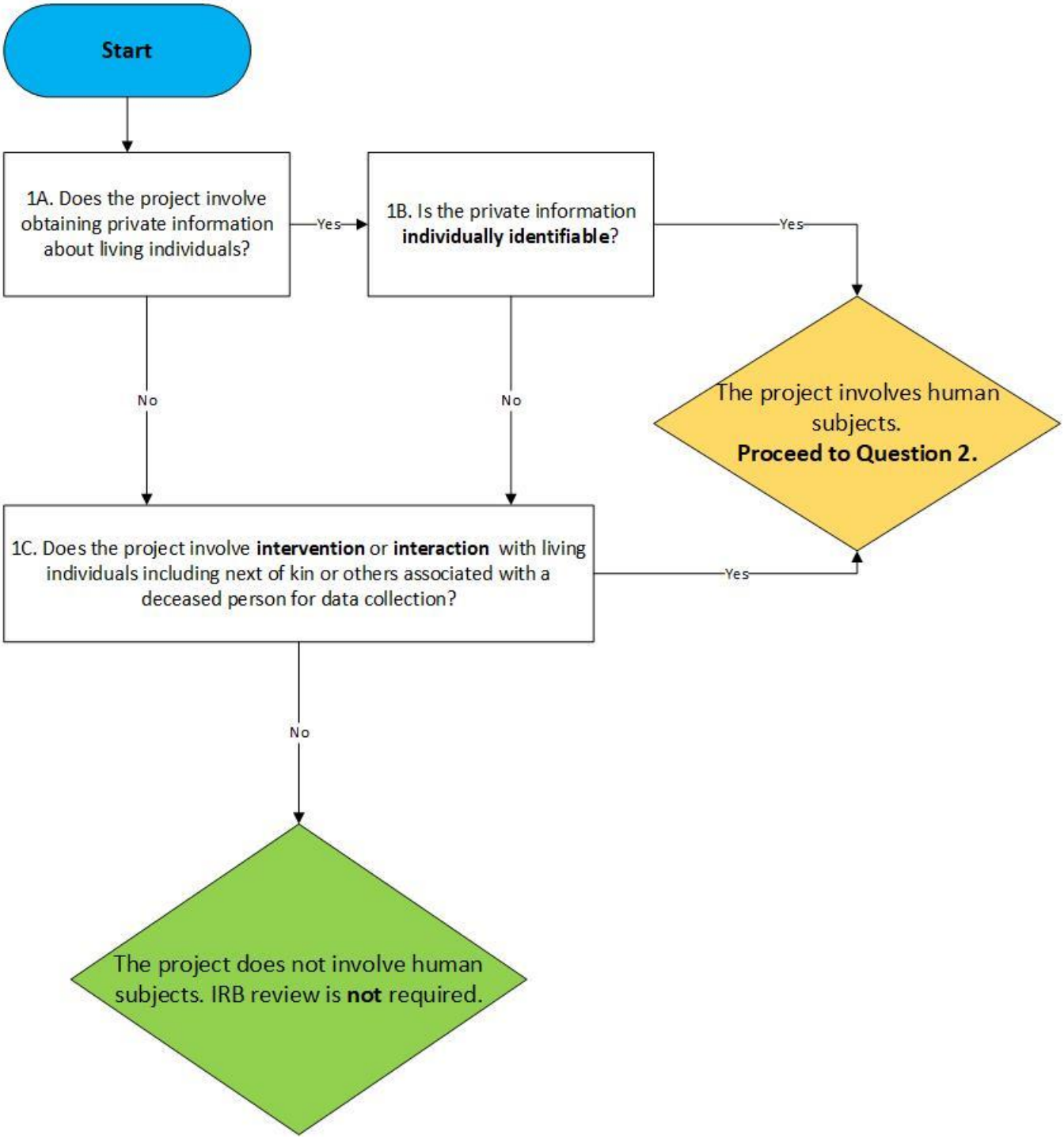
Question 3: Does the project qualify for exemption determination?

Question 4: Does the project qualify for expedited review?

Each question is outlined in flow charts 1 through 4 below and is followed by a brief description. For additional guidance, refer to decision charts developed by the U.S. Office for Human Research Protections (OHRP).[17]

[14] 22VAC40-890-70C
[15] 45 CFR 46.109(e)
[16] 22VAC40-890-90B
[17] https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

***Question 1. Does the Project Involve Human Subjects?***



### 1A. Does the Project Involve Obtaining Private Information About Living Individuals?

*Private information* is (1) information provided for specific purposes with reasonable expectation of confidentiality (e.g., family history, medical information), or (2) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

### 1B. Is the Private Information Individually Identifiable?

*Individually identifiable* means private information is recorded so that (1) the subject's identity can be ascertained (e.g., name, SSN, address), or (2) it may be readily inferred from the data.

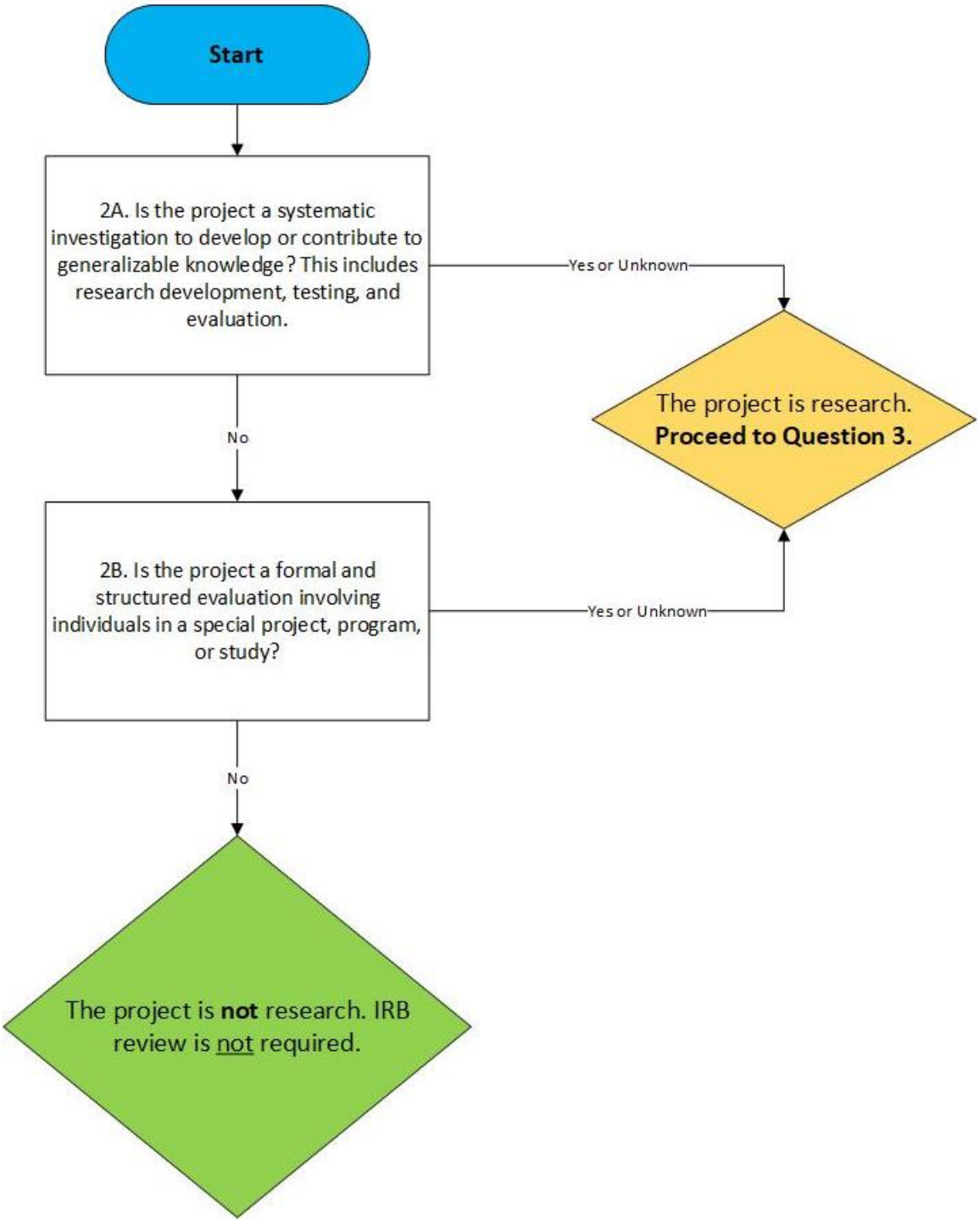
### 1C. Does the Project Involve Intervention or Interaction with Living Individuals for Data Collection?

*Intervention* includes physical procedures and manipulations of the subject or their environment. *Interaction* includes communication or interpersonal contact with the subject or with others (e.g., relatives, caseworker) about the subject.

If "Yes" to any of the above questions, proceed to Question 2: Is the Project Considered Research?

If all answers are "No," the project involves no human subjects and does not require IRB review.

***Question 2. Is the Project Considered Research?***



### 2A. Is the Project a Systematic Investigation to Develop or Contribute to Generalizable Knowledge?

The main criterion for research is the activity's purpose or intent. The project is research if its primary purpose is to gain knowledge generalizable to other populations or settings. If activities include research development, testing, or evaluation aimed at generalizable knowledge, the project is research.[18]

ORP developed an online tool to help investigators determine whether their data project meets the federal definition of "human subjects research" (or "human research"). If a project is not human research, IRB review is not required. The *Human Research Determination – Decision Assistance Tool* is on the IRB web page, under **Resources for Investigators**.[19]

### 2B. Is the project a formal and structured evaluation involving individuals in a special project, program or study?

The *VDSS Administrative Code* defines "human research" as **"…**any systematic investigation, including research development, testing, and evaluation, utilizing human subjects that is designed to develop or contribute to generalized knowledge."[20] Evaluation of social services may or may not be research. A program evaluation isn't research if it assesses a program's success and is part of normal operations like management reporting or quality assurance or improvement. If the purpose is to develop or contribute to generalized knowledge, it is research. Some evaluation research may qualify for exemption (see Question 3).

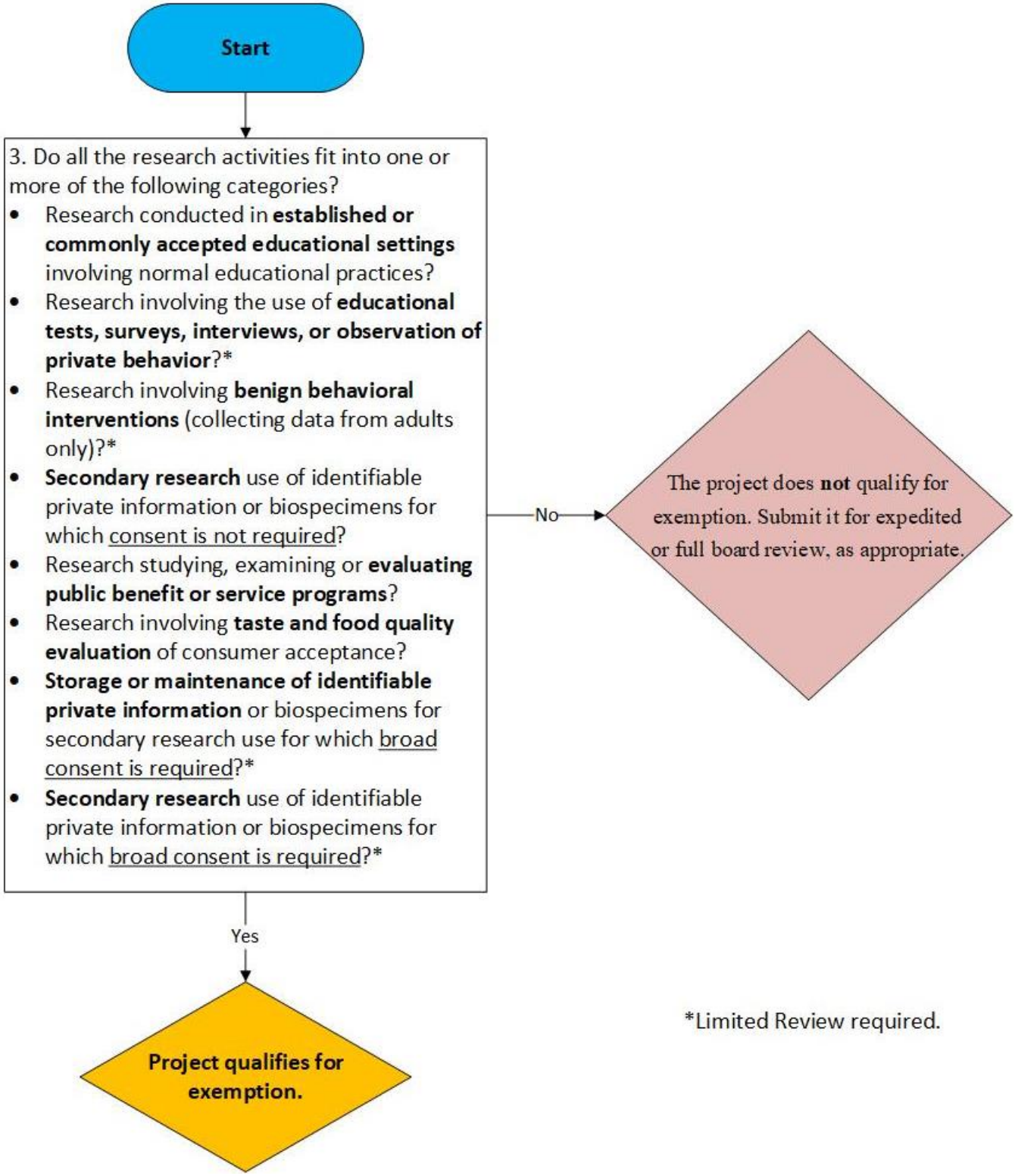
Investigators should consider if consent forms protect subjects. The IRB chair or coordinator can advise if review is needed. If activity is human research or unclear, submit protocol to IRB. Proceed to Question 3 to determine if your protocol requires exemption, expedited, or full review.

Certain human research is exempt under federal regulations.[21] If believed applicable (i.e., all study activities must fall under one or more exemption category), submit the study to the IRB for exemption determination (see Question 3).

The IRB Chair will decide on exemption within 30 days of complete submission. All decisions will be communicated to the Investigator in writing within seven business days after review.

[18] *45 CFR 46.102(d)*
[19] https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/policies-and-procedures/
[20] *22 VAC40-890-10*
[21] 45 CFR 46.104(d)

***Question 3. Does the study qualify for Exemption?***



The exemption process aims to ensure review by knowledgeable persons and that all research activities are exempt for project submission. If any activity is not exempt, the whole project is not exempt.

**3A. Does the research qualify for Exemption from IRB review?**
All research activities in the research study must qualify under one or more of the following categories to be Exempt:

- Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices (§46.104(d)(1))
- Category 2: Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior (§46.104(d)(2)); a limited review may be required.
- Category 3: Research involving benign behavioral interventions (collecting data from adults only) (§46.104(d)(3)); a limited review may be required.
- Category 4: Secondary research use of identifiable private information or biospecimens for which informed consent is not required (§46.104(d)(4))
- Category 5: Research studying, evaluating, or examining public benefit or service programs? (§46.104(d)(5))
- Category 6: Research involving taste and food quality evaluation of consumer acceptance studies (§46.104(d)(6))
- Category 7: Storage or maintenance of identifiable private information or biospecimens for secondary research use for which broad consent is required (§46.104(d)(7)); a limited review is required.
- Category 8: Secondary research use of identifiable private information or biospecimens for which broad consent is required (§46.104(d)(8)); a limited review is required.

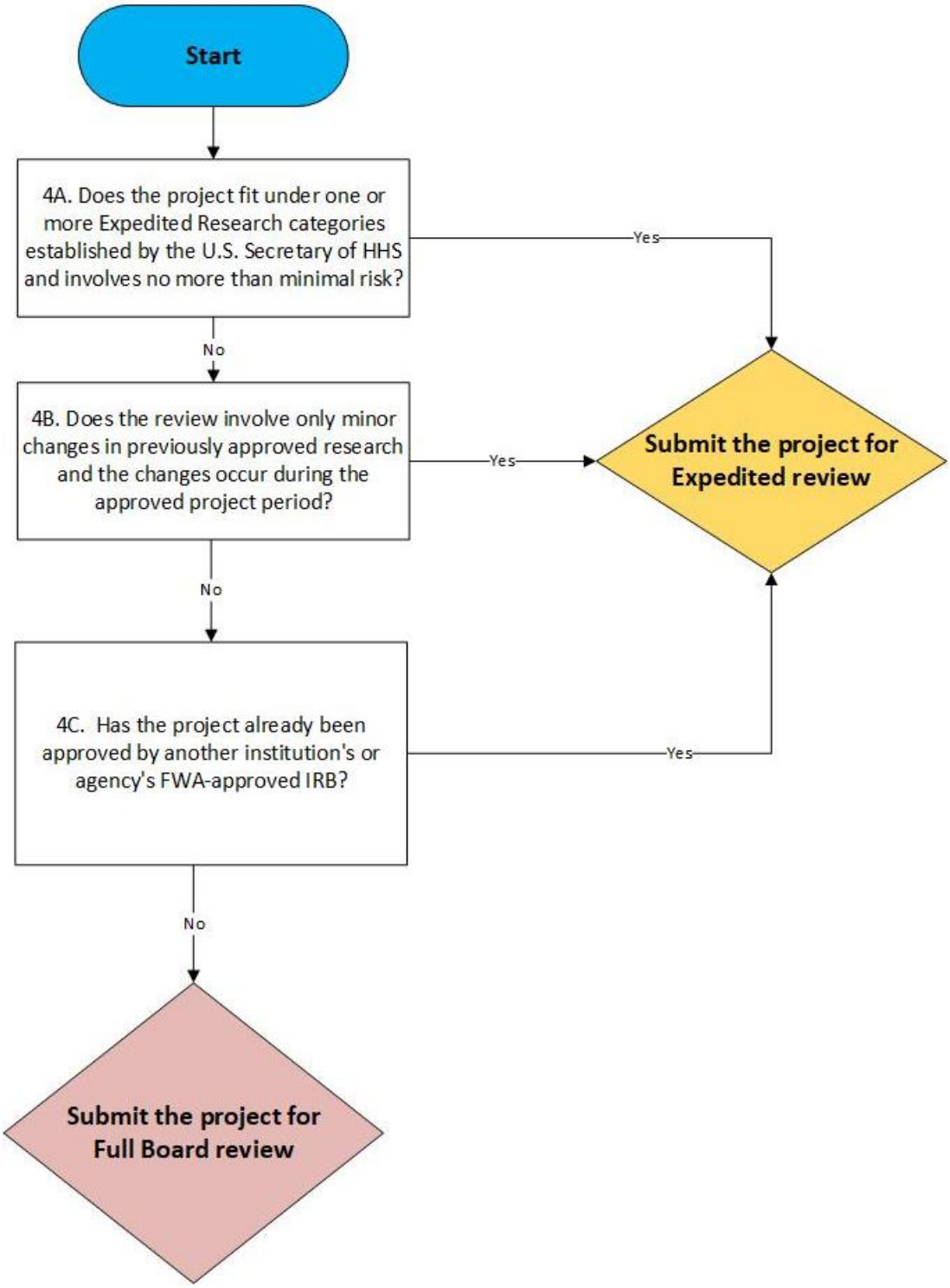
For more information about limited reviews, see section "Limited Review" on page 14.

***Does the research involve vulnerable persons?***

The IRB must determine subject selection is equitable.[22] considering research purpose, setting, and special issues involving vulnerable groups like children,[23] prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

[22] 45 CFR 46.111(a)(3)
[23] Age of majority means persons 18 years of age, Code of Virginia §1-204.

***Question 4. Does the Project Qualify for Expedited Review?***



### 4A. Does the project fit under one or more Expedited Research categories established by the U.S. Secretary of HHS and involve no more than minimal risk?

Per the U.S. Department of Health and Human Services (HHS), research that (1) presents no more than minimal risk to human subjects, and (2) involves a limited set of activities, may be reviewed by the IRB through expedited procedures.[24] These activities include, but are not limited to:

a) Collection of data from voice, video, digital, or image recordings for research purposes,

b) Research on individual or group characteristics or behavior (e.g., perception, cognition, motivation, identity, language, communication, cultural beliefs/practices, and social behavior),

c) Research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methods (some categories may be exempt),

d) Research where:

1) Enrollment of subjects is permanently closed, all subjects have completed all research interventions, and the research remains active only for long-term follow-up of subjects; or

2) Subjects have been enrolled and no additional risks identified; or

3) Remaining research activities are limited to data analysis.

e) Continuing review of ongoing research posing no more than minimal risk to subjects and no additional risks have been identified.

The HHS Secretary will evaluate the list at least every eight years and amend the list as appropriate. A copy of the full list is available from the Office for Human Research Protections.

### 4B. Does the review involve only minor changes to previously approved research, occurring during the approved project period?

Minor changes to previously approved research, that occur during the approved project period, may be reviewed under expedited procedures.[25] When the project's activities have not been reviewed by another IRB and all activities entail more than minimal risk to human subjects in one or more of the qualifying categories, however, the project must be reviewed at a convened meeting of the IRB.

### 4C. Has the project already been approved by another institution's or agency's IRB?

State regulations permit expedited review for research already approved by another IRB if activities fit within one or more Expedited categories and involve no more than minimal risk.[26]

If VDSS is participating in a cooperative project with the other institution/agency, the IRB may enter a reliance (or authorization) agreement with the other institution/agency and rely on their IRB's review and approval of the project. Refer to guidance on Reliance Agreements (under "Policies and Procedures") for more details.

[24] 45 CFR 46.110(a)
[25] 45 CFR 45.110(b)(2)(ii)
[26] 22VAC 40-890-80

### C. Additional Protections for Children as Research Subjects

This section applies to all research involving children, defined as persons under the age of majority.

*Assent* is a child's affirmative agreement to participate in research.

*Permission* is the parent's or guardian's agreement for the child's research participation. *Parent* means a biological or adoptive parent. *Guardian* means an individual authorized under law to consent for the child's medical care.

Per 45 CFR 46, Subpart D, research involving children as subjects is allowed under the following circumstances:

1. Exempt research activities. Most research exempt under 45CFR 46.104(d) (i.e., Categories 1, 4-8) is allowed when they involve children.[27] Exemptions under Categories 2 and 3 are allowed in the following ways:
   - Use of educational tests, surveys, interviews or observation of public behavior (Category 2) is exempt when (i) disclosure of the subject's responses would not reasonably place the child at risk, or (ii) information is recorded so that the child's identity cannot be readily ascertained. When the child's identity can be readily ascertained, the research is not exempt and requires IRB review.
   - Educational tests and observations of public behavior only when the investigator does not participate in the activity being observed. Otherwise, the research is not exempt and requires IRB review.
   - Research using benign behavioral interventions (Category 3) and involving children as subjects are not exempt and require IRB review.
2. Research involving no more than minimal risk to children. The IRB must determine whether the research presents no more than minimal risk and that there are adequate provisions for soliciting the child's assent and permission from their parents or guardians.
3. Research involving greater than minimal risk but offering potential direct benefits to children. The IRB must determine that the risk is justified by the anticipated benefits to the child; that the anticipated benefit-to-risk is at least as favorable as with available alternative approaches; **and** that there are adequate provisions for soliciting the child's assent and permission from their parents or guardians.

The IRB web page has more detailed guidance about obtaining consent from parents, guardians, or legally authorized representatives (LAR) for children and youth in Virginia's foster care system.[28]

### D. Informed Consent

Voluntary informed consent[29] signed by the participant or by the participant's legally authorized

[27] 45 CFR 46.104(b)(3)
[28] Guidance on Informed Consent for Children in Foster Care (in the "Children as Research Participants" section)
[29] 45 CFR 46.116

representative is required for all human research projects. The IRB may waive or alter the basic elements of informed consent[30] if:

1. The research involves no more than minimal risk to participants; and
2. The waiver or alteration will not adversely affect the participant's rights and welfare; and
3. The research cannot practicably proceed without the waiver or alteration of informed consent; and
4. If appropriate, the participants will be provided with additional pertinent information after participation.

The IRB may waive signed consent if the only record linking participant and research is the consent form and the main risk is confidentiality breach. The IRB may require the researcher to give a written explanation to participants. Participants shall be asked whether they want documentation linking him to the research, and the subject's wishes shall govern.

### E. Release of Client Records for Research Purposes

Client records may be released for research purposes if the following conditions are met:

1. For public assistance and social services, the Commissioner, the division director, or their designee(s) authorizes the plan and release of client records; or
2. For child support enforcement, the Commissioner, the Director of Child Support Enforcement, or their designee(s) authorizes the plan and release of client records; and
3. The requestor has entered into a data use and information exchange agreement with the Department or agency stipulating conditions of use for client records or information.

Confidentiality of data used in research involving public assistance, child support, and social services is governed by 22VAC40-910-50.

## III. IRB Procedures

This section summarizes IRB operation, meetings, documentation, and approval procedures. More detailed guidance is available at https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/policies-and-procedures/.

### A. Board Meetings

The VDSS IRB will meet at least annually and more often as needed. The IRB Chair will distribute meeting times, locations, and study materials before meetings.

The federal Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services recognizes IRB meetings via phone and video if:

1. Each IRB member has received all pertinent materials before the meeting, and

[30] 45 CFR 46.117(c)

2. Each participant can actively and equally discuss all protocols.

Minutes must document the two conditions above; meetings follow Robert's Rules of Order.

### B. Majority Vote

A quorum, or majority, of the IRB's members shall be present to conduct a review. Voting members must include at least one non-scientist. For example, with ten eligible voting members, six (including one nonscientist) must be present to vote. A decision – approved, approved with conditions, not approved, or tabled -- requires a simple majority vote.

### C. Initial Review and Exemption Determination

Researchers/investigators who determine a project involves human subjects must request an initial review by the IRB (either expedited or full board) or a determination that the research is exempt from IRB review.

- The investigator shall submit the *Request for Initial Review* form if the project is likely to need an Expedited Review or a Full Board Review.
- If the investigator believes that the project's activities will qualify the study for exemption from IRB review, he/she shall submit the *Exemption from IRB Review Request Form.*
- If a waiver of informed consent or written informed consent is needed, the investigator shall submit the *Request for Waiver of Informed Consent* form along with their initial review application.

IRB request forms are on the IRB web page under **Forms**. Along with the request form, the investigator shall submit materials that provide sufficient information about the study, including the study's purpose, study population, risks and potential benefits, informed consent process, and safeguards to protect participants and their data. A checklist of required materials is on the IRB Policies and Procedures web page, under **Resources for Investigators**, and included in Appendix A. Submit applications to the IRB (irb@dss.virginia.gov).

Full board reviews require the full participation of the IRB (i.e., voting members who are not recused due to conflict of interest). Expedited reviews are conducted by the IRB Chairperson and one other member of the IRB. The IRB Chair or Administrator will determine if the research qualifies for exemption. Waivers of informed consent are reviewed along with the initial request. The IRB considers requests within 30 days of **when the complete application is received** and informs the investigator of decisions in writing within 7 days of review.

### D. Limited Review

***What is a limited IRB review and when is it required?***

A 'limited IRB review" is a specialized type of review for certain categories of low-risk research that would otherwise be exempt from full IRB review. The specific purpose of a limited review is to ensure that adequate measures are in place to protect the privacy of research subjects and maintain the confidentiality of their data.

The 2018 Common Rule requires limited IRB review for four specific exemption categories:

- Research involving educational tests, surveys, or interviews where information is identifiable and disclosure could pose a risk of harm to subjects. (Category 2)
- Research involving benign behavioral interventions with adults where information is identifiable and disclosure could cause harm. (Category 3)
- Secondary research involving the storage or maintenance of identifiable private information or biospecimens collected with broad consent, to ensure proper consent and privacy protections are in place. (Category 7)
- Secondary research using identifiable private information or biospecimens collected with broad consent, to confirm the research aligns with the consent and that privacy and confidentiality are protected. (Category 8)

***What is considered during limited review?***

Limited IRB review is less extensive than a full review and is typically conducted by the IRB chairperson or one or more experienced members. The limited review can consider the following aspects of the study:

- Type of identifiers in the dataset
- Extent to which identifiable private information is will be de-identified; the risk of data being re-identified
- Justification/need for using identifiers to conduct the research
- Characteristics of the study population
- How the information will be used
- Overall sensitivity of the data; potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way not approved for the study
- Security controls in place to protect the confidentiality and integrity of the information
- Individuals or groups who will have access to the data
- Process for sharing the data
- Retention period for identifiable data

A handout from CITI summarizes key points about limited reviews.

### E. Continuing Review

The IRB must review ongoing studies at intervals appropriate to their nature and degree of risk, but at least once every 12 months from IRB approval. The PI must submit the *Continuing Review Form* to ensure compliance. The form must be received by the IRB before the expiration date. The IRB Chair will send a reminder to investigators about four weeks before expiration. It is the investigator's

responsibility to submit the Continuing Review Form before the expiration date. Research cannot continue without VDSS IRB approval.

### F. Review of Modifications to the Study

All modifications to currently approved studies must be reported to and approved by the IRB before implementation in the study.

A *minor modification* is a change to the study's inclusion criteria, procedures, or consent forms that do not significantly affect (1) the risk-benefit assessment and (2) the study's aims or design. Examples include changing the sample size; modifying study materials (e.g., consent forms, questionnaires) for clarity or accuracy (e.g., improving grammar, spelling or reading level; correcting typing errors); adding/deleting study sites; or changing principal investigator(s) or key research staff. These modifications are typically reviewed under expedited procedures by the IRB Chair.

A *major modification* significantly affects the risk-benefit assessment or substantially alters the study's aims or design. Examples include changes to inclusion/exclusion criteria; revised consent or procedures; adding sensitive questions; or changing the subject population. These modifications may require full board review and approval.

For both minor and major modifications, the investigator must submit a *Modification to Approved Study* form. The PI should reference the title of the study and, where applicable, attach the revised study materials and/or protocol. Use Track Changes in Microsoft Word to show text changes.

### G. Completion/Termination of the Study

All human research studies must close and submit a *Study Close-Out Report*. The report updates the IRB on study conduct, outcomes, new risks, safety issues, or problems since the last study renewal, and informs the IRB of the final disposition of research records and data.

The *Study Close-Out Report* must be submitted within 30 days of the end of the study. The form is on the VDSS IRB web page (https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/institutional-review-board-forms/). For more guidance, refer to "Study Closure" (https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/policies-and-procedures/).

### H. Unanticipated Problems and Adverse Events

The investigator of approved human subjects research is responsible for reporting any anticipated and unanticipated problems (including adverse events) occurring during or after the study.

Definitions

*Unanticipated problem*: An incident, event, experience or outcome that meets these criteria: 1) unexpected (in terms of nature, severity, or frequency); 2) related (or potentially related) to participation in research; and 3) places subjects or others at greater risk of physical, psychological, economic or social harm than previously known or recognized or results in harm. "Unanticipated problem" includes increased future risks. Examples include unintentional changes to the approved protocol, accidental data

breach, or unanticipated side effects of treatment.

*Adverse Event*: "Adverse event" and "unanticipated problem" are sometimes used interchangeably. The term "adverse event" is typically used in the context of a medical or clinical study and associated with the treatment (or withholding of treatment). A "severe adverse event" is an adverse event that results in physical injury, hospitalization, significant disability, serious psychological and emotional distress (suggesting need for professional counseling or intervention), or death.

All unanticipated problems and non-severe adverse events, occurring during approved studies, must be reported to the IRB. The PI must notify the VDSS IRB within ten business days of becoming aware of the event, submitting the Adverse Event Reporting Form. Severe adverse events must be reported **within 5 business days**.

If uncertain whether an event is adverse or unanticipated, the investigator should contact the IRB Chair for guidance. Unanticipated problems or adverse events may require protocol or consent modifications or corrective actions to protect the safety, welfare, or rights of subjects or others.

*Anticipated problem*: An expected event or issue related to research participation that poses a risk to subjects, usually noted in the consent form or protocol. (For example: The subject may feel "embarrassed" when disclosing sensitive information in a survey or interview or feel "discomfort" when asked to recall negative events from the past.) Anticipated problems need not be reported individually but can be summarized at continuation review or study end on the Continuation Review Form. If, during the study, expected events occur more frequently or severely than anticipated, it becomes an "unanticipated problem" and must be reported to the VDSS IRB within ten business days.

## I. Cooperative Research

Cooperative research projects involve more than one institution. When conducting cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. HHS regulations permit institutions in cooperative research to use reasonable joint or cooperative review methods or rely on the review of another IRB.[31]

VDSS promotes reliance agreements (also called "authorization agreements") where one IRB relies on another's review, reducing duplication and increasing efficiency by designating a single IRB for cooperative research (or multi-institutional) projects. VDSS may enter an agreement where they are authorized to rely on another institution's IRB or serve as the reviewing IRB for a joint project. Reliance agreements generally cover a specific protocol with a qualified IRB of a collaborating institution. For more information about reliance agreements, refer to the "Reliance Agreements" guidance on the IRB web page (https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/policies-and-procedures/).

[31] 45 CRF 46.114

# Appendix A. Checklist of Materials Required for IRB Review

## Overview

This guidance document outlines the materials investigators should assemble and include with their applications for IRB review in order to provide sufficient information for the IRB to make specific determinations regarding the risks, potential benefits, informed consent, and safeguards for human subjects. The *IRB submission forms provide additional guidance on what to include in the submission packet.*

## Initial Review (* if applicable)

The following materials are **required** for initial review of **all types of research**:

☐ *IRB Request for Initial Review Form* (must be signed by PI)

☐ Description of recruitment and screening procedures and/or materials (e.g., advertisements, email messages, telephone scripts)*

☐ Informed Consent documents(s) and/or description of procedures*

- If consent is not being obtained, submit the *Request for Waiver of Informed Consent Form*
- If using administrative data under Broad Consent procedures, attach a copy of the consent document.

☐ Study protocol/research plan/evaluation plan

☐ Evidence of review by another IRB to include approval notice*

☐ Request for VDSS IRB to defer to another IRB review*

☐ Survey, questionnaires, interview materials and/or other materials related to interactions/interventions with human subjects to include investigator-authored measures*

☐ Principal Investigator(s) curriculum vitae (CV) or NIH biographical sketch

☐ *Research Personnel Form* (NEW; eff. 7/1/2023)

☐ Documentation of completed Human Research Protection Training (e.g., training certification of completion) for PI and research personnel (NEW; eff. 7/1/2023)

☐ Investigator's response to IRB inquiries*

☐ Copy of grant, contract, or data sharing agreement; if administrative data is requested, list of data elements is needed

☐ Any additional pertinent documentation

## Sponsored Research

☐ Detailed Sponsor's Protocol/research plan/evaluation plan

☐ Relevant Grant Applications or Contracts

☐ For federally supported Multi-Center trials: Federally approved Consent Forms and Protocol/research plan/evaluation plan

**Exemption from IRB Review**
Many of the same materials requested for an Initial Review also apply to a Request for Exemption.

☐ *Exemption from IRB Review Request Form*; must be signed by the PI
☐ Study protocol/research plan/evaluation plan
☐ Survey, questionnaires, interview materials and/or other materials related to interactions/interventions with human subjects to include investigator-authored measures*
☐ Consent form and/or description of consent procedures (see notes above)
☐ PI's CV or biosketch
☐ Documentation of completed Human Research Protection training
☐ Copy of funded grant, contract or data sharing agreement
☐ Documentation of exemption determination from another IRB
☐ Any additional pertinent information

**Continuing Review**

☐ Continuing Review Form
☐ Any relevant multi-center reports*
☐ Currently approved and any proposed recruitment and screening materials*
☐ Currently approved and any proposed informed consent document(s)*
☐ Any additional pertinent documentation

**Modifications (Amendments) to Approved Research**

☐ *Modification to Approved Study Form*; must be signed by PI
☐ Relevant modified study documents
☐ Modified recruitment & screening materials, consent documents, data collection instruments, etc.; prefer version with edits shown (e.g., use Word Track Changes) or highlighted*
☐ Any additional pertinent documentation

**Responses to IRB Correspondence**

☐ Investigator's response to IRB inquiries
☐ Revised consent documents, screening and recruitment materials*
☐ All other modified study documents
☐ Any additional pertinent documentation

**Study Closure**

☐ *Study Close-Out Report*
☐ Summary of research findings in any of the following formats: written report or thesis, Powerpoint presentation, PDF copy of research article (or web link to online publication), report abstract.