VIRGINIA DEPARTMENT OF
SOCIAL SERVICES

Institutional Review Board:

Guidance Summary

(Updated 12/7/2016)

Completed by the
Office of Research and Planning

Specific guidance documents are available on the IRB web page http://www.dss.virginia.gov/about/irb.cgi.

Table of Contents

For questions or comments about this manual, contact:

IRB Chair & Administrator irb@dss.virginia.gov
Virginia Department of Social Services (VDSS)
Office of Research & Planning
801 East Main Street, 15th Floor
Richmond, VA 23219

NOTE: Over time, this document is being replaced by topic specific IRB guidance documents posted to the IRB webpage[1]. 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.

[1] http://www.dss.virginia.gov/about/irb.cgi

VDSS IRB Guidance Summary

I. Introduction

This section describes the purpose of the VDSS Institutional Review Board (IRB), provides citations for its legal authority, and briefly describes the composition of the IRB.

A. Purpose of the VDSS Institutional Review Board

The Institutional Review Board (IRB) at the Virginia Department of Social Services (VDSS) 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[2]. The IRB has authority to approve, disapprove, or require modifications of research activities[3]. 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[4]. 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 authorize, conduct, or propose to conduct any human research using VDSS funds.

B. Authority and Responsibility of the IRB

The VDSS IRB operates under a Federal Wide Assurance[5] (FWA00010976) and complies with the requirements in Title 45 Code of Federal Regulations (CFR) part 46. A FWA is an agreement between the VDSS Commissioner and the Department of Health and Human Services (DHHS) outlining the responsibilities of the IRB in upholding the ethical principles of 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, known as the "Belmont Report." The FWA is required for any institution that participates in federally supported human subjects research.

In addition, the IRB operates in accordance with the Virginia Administrative Code 22VAC40-890 et seq. The VDSS IRB provides review of proposed research conducted or authorized by VDSS, any

[2] 45 CFR 46.103(b) & Code of Virginia 63.2-218
[3] 45 CFR 46.109(a)
[4] 45 CFR 46.112
[5] 45 CFR 46.103

agency or facility licensed by VDSS, or any local department of social services[6]. The IRB is authorized to determine if a proposed project is human subject research; and to review and approve any human research proposed, authorized, or conducted by VDSS, by any local DSS, by any facility licensed by VDSS or by any contractor[7].

The IRB reports to the VDSS Commissioner. The Director of the VDSS Research and Planning Division is responsible for IRB oversight and resource support. The IRB chair/administrator is a staff member in the Research and Planning Division. The IRB submits to the Governor, the General Assembly, and the Commissioner, at least annually, a report on the human research projects reviewed and approved by the committee and reports any significant deviations from the proposals as approved[8].

C. Board Membership

The IRB shall have at least five[9] members, appointed by the VDSS Commissioner. IRB members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. At least one member shall be an individual whose primary concerns are in non-scientific or ethical areas[10].

Members shall ensure the competent, complete and professional review of human research. No member of the IRB shall be directly involved in the proposed human research project or have administrative approval authority over the proposed research, except in connection with her responsibilities as a member of the IRB.

No member shall participate in an initial or continuing review of any project in which they have a conflicting interest[11]. Members may provide information requested by the IRB. The IRB is responsible for determining whether a member has a conflict of interest. To maintain the IRB size, alternate members may be appointed to review a project where a member has a conflicting interest.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote. The member roster is available on the IRB webpage[12].

---

[6] Code of Virginia 63.2-218
[7] 22VAC40-890-60A
[8] Section 63.2-218
[9] 45 CFR 46.107
[10] 45 CFR 46.107(b)
[11] 45 CFR 46.107(e)
12 http://www.dss.virginia.gov/about/irb.cgi

II. IRB Guidance Summary

This section summarizes IRB guidance for review of human subjects research. S**pecific guidance documents and submission forms can be found on the IRB web page**[13]. This section also discusses the requirements for informed consent and release of client records for research purposes.

A. Criteria for IRB Approval of Research

No human subjects research shall be conducted or authorized by VDSS, local departments of social services, VDSS-licensed facilities, or VDSS-authorized contractors unless the VDSS IRB has reviewed and approved the proposed human subjects research project. The IRB must give consideration to:

1. The necessity and utility of the research;
2. The adequacy of the description of potential benefits and risks involved and the appropriateness of the research methodology;
3. risk level of the proposed research;
4. Whether the risks to the participants are outweighed by the potential benefits to them;
5. Whether the rights and welfare of the participants involved are adequately protected;
6. Whether the voluntary informed consent is obtained by methods (including the written consent form) that are adequate and appropriate considering the participants' educational level and language of greatest fluency;
7. Whether individuals proposing to supervise or conduct the research are competent and qualified; and
8. Whether the criteria for selection of participants are equitable.

The IRB (or designated reviewers in the case of expedited reviews) will consider research proposals *within 30 days*[14] after receiving a complete application. The IRB will notify investigators in writing of its decision to approve or disapprove the proposed research or of modifications required to secure IRB approval *within seven business days* of the IRB review. No personal identifiers of present or potential participants shall be presented or discussed during the IRB review of research projects.

Investigators must include a written description of the procedure to be followed when a participant has a complaint about a research project in which she/he is participating or has participated. All complaints shall be referred to the IRB to determine if there has been a violation of the research as approved by the IRB.

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to

[13] http://www.dss.virginia.gov/about/irb.cgi
[14] 22VAC40-890-70C

the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research[15]. Investigators must also submit to the IRB a report summarizing results of the research after its conclusion[16].

B. Key Determinations for Human Subjects Research Review

Research to be conducted by VDSS, local departments of social services (LDSS), outside investigators in collaboration with VDSS, LDSS, facilities licensed by VDSS, VDSS contractors, or by outside investigators using VDSS resources, is subject to IRB review. In addition, research to be conducted or supported by a federal department or agency involving VDSS clients must be reviewed and approved by the VDSS IRB.

Not all research requires IRB review. This section covers the process for determining the need for IRB review. The decision-making process can be divided into four key questions:

Question 1: Does the project involve human subjects?

Question 2: Is the project considered research?

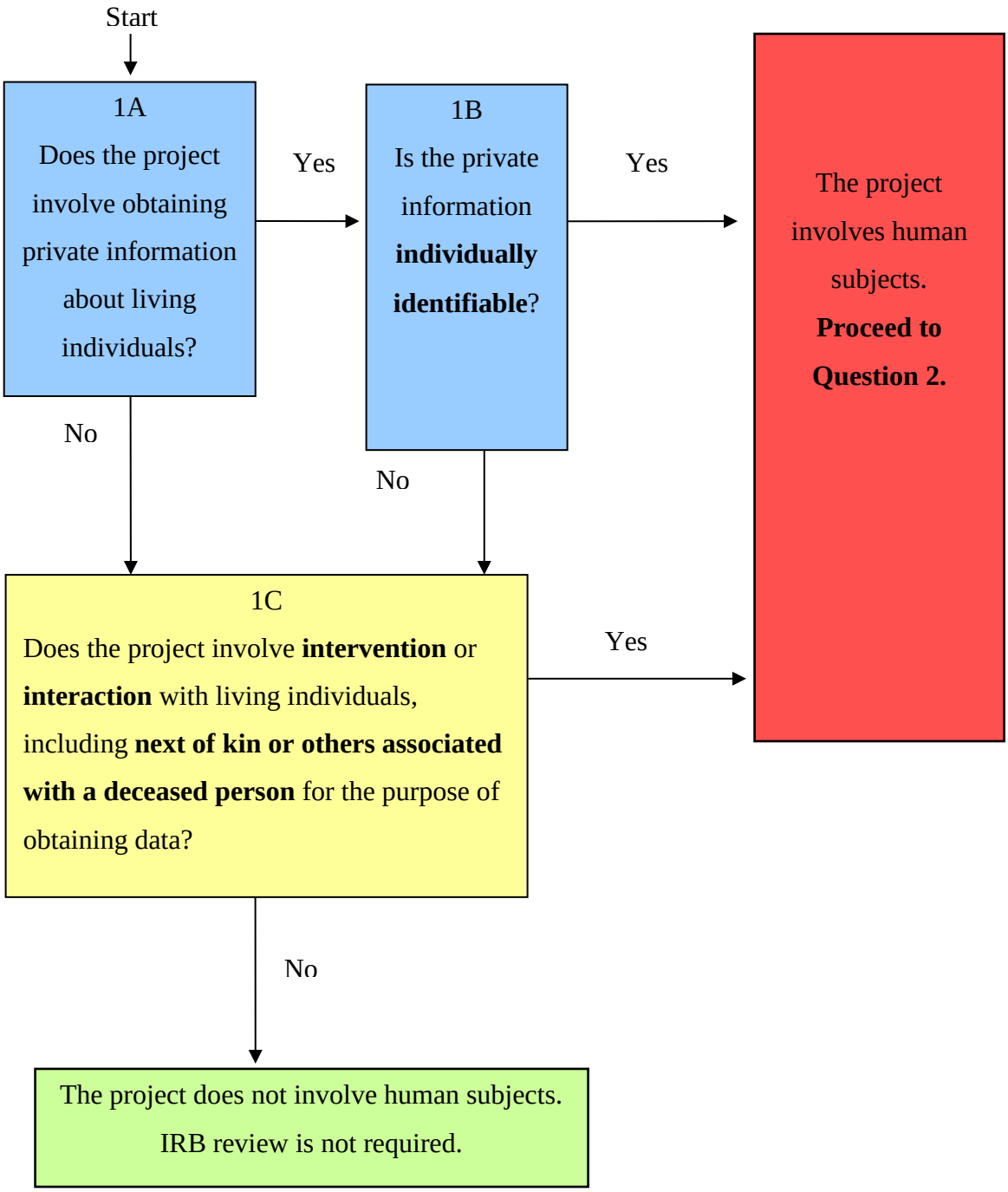
Question 3: Does the project qualify for exemption determination?

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.

[15] 45 CFR 46.109(e)
[16] 22VAC40-890-90

Question 1: Does the Project Involve Human Subjects?



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

Private information is defined as (1) information which has been provided for specific purposes by an individual which he can reasonably expect will not be made public (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 that private information is recorded in such a way that (1) the identity of the subject is or may be ascertained by the investigator (e.g., name, SSN, address), or (2) the identity of the subject may readily be inferred from the information obtained.

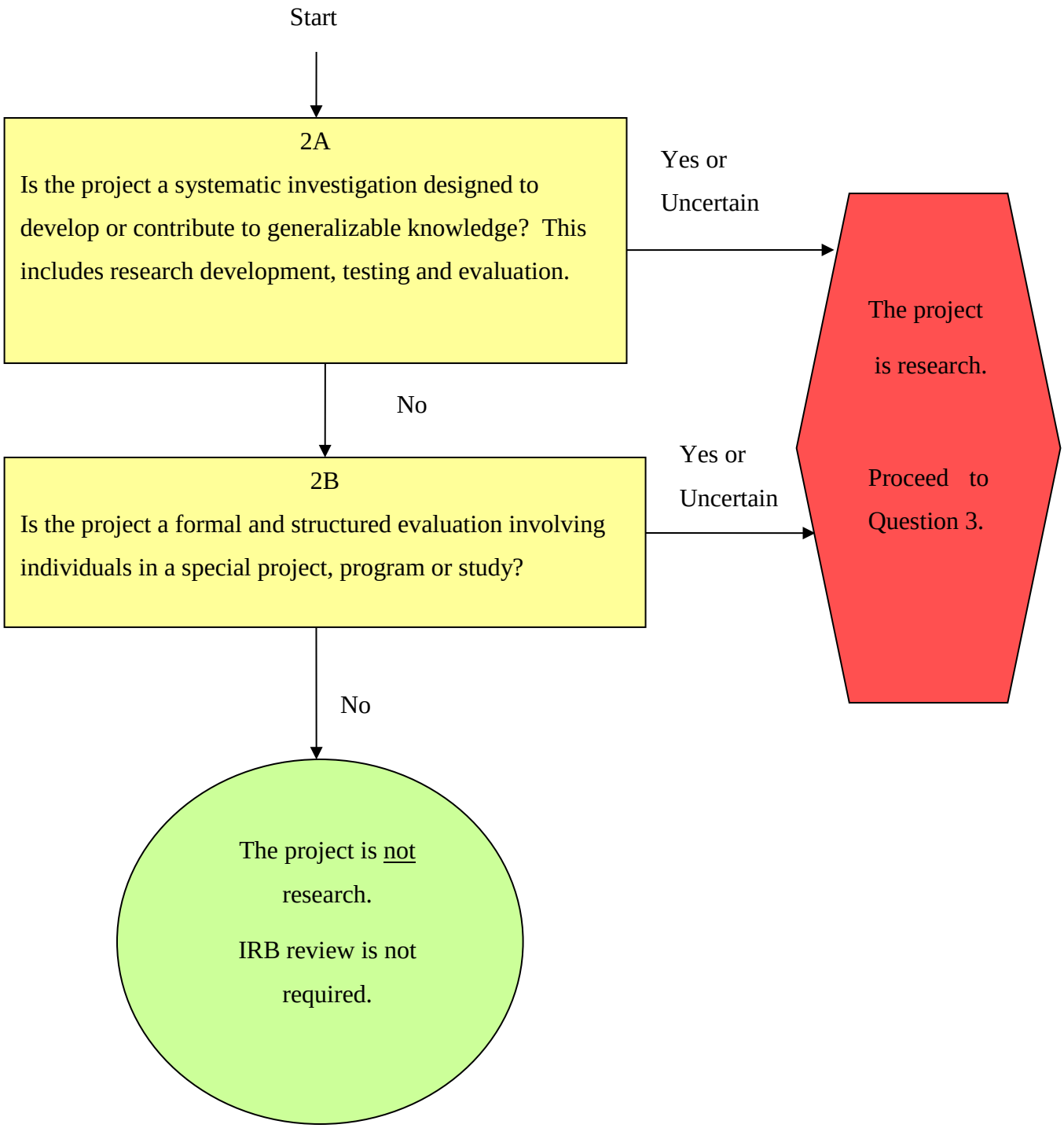
1C. Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?

Intervention includes physical procedures by which data are collected and manipulations of the subject or the subject's environment. *Interaction* includes communication or interpersonal contact with the subject or with others in regard to the subject (e.g., relatives, caseworker).

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

If "No" is the answer to all three of the above questions, then the project does not involve human subjects and does not need to be reviewed by the IRB.

Question 2: Is the Project Considered Research?



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

The main criterion for determining whether a project is research is the purpose or intent of the activity. The project is research if its primary purpose is to gain knowledge that is generalizable to other populations and/or other settings. If any of the project's activities include research development, testing or evaluation and are designed to yield knowledge that can be generalized or applied to other populations and/or settings, then the project is research[17].

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

The *VDSS Administrative Code*[18] defines "human research" as **"…**any formal and structured evaluation involving individuals in a special project, program, or study." Evaluations of ongoing social services programs may or may not constitute research. A program evaluation is **not** considered research if the purpose of the evaluation is to assess the success of a specific program in achieving its objectives and is part of normal social service program operations, such as management reporting or quality assurance or improvement activities. However, if the purpose of a program evaluation is to develop or contribute to generalized knowledge, the project is considered research. In some instances, evaluation research may qualify for exemption determination (see Question 3).

Investigators should also consider whether the use of consent forms would help protect human subjects. The IRB chair or administrative coordinator is always available to provide guidance for determining if IRB review is required. If the proposed activity is considered human research or if it is not clear, you will need to submit the research protocol to the IRB for review. Proceed to Question 3 to determine if your protocol should be submitted for exemption determination, expedited or full board review.

Certain research activities involving human subjects have been given exemptions through federal regulations[19]. If an investigator believes the proposed research is addressed under one of the exemption categories, the protocol should be submitted to the IRB for exemption determination (see flow diagram, question 3).

The decision to approve or disapprove a project submitted for exemption determination will be made by the Chair of the IRB *within 30 days after submission of a complete application.* All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the Principal Investigator (PI) in writing *within seven business days* after review.

---

[17] *45 CFR 46.102(d)*
[18] *22 VAC40-890-10*
[19] 45 CFR 46.101(b)

Question 3: Does The Project Qualify for Exemption Determination?

3A

Do **all** of the project's research activities fit into one or more of the following categories?

- Conducted in established educational settings?
- Involve the use of educational tests, survey/interview procedures, or observation of public behavior?
- Involve the collection or study of **existing** data, documents or records that are publicly available **or** recorded in such a manner subjects cannot be identified?
- Conducted by, or subject to approval of, federal department or agency heads, and study or evaluate:
  - public benefit and service programs;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in/alternatives to those procedures or programs; or
  - possible changes in methods or levels of payment for benefits or services under those programs.

No

The project does **not** qualify for exemption Determination.

Submit the project for expedited or full board review, as appropriate

Yes

The project <u>qualifies</u> for exemption Determination.

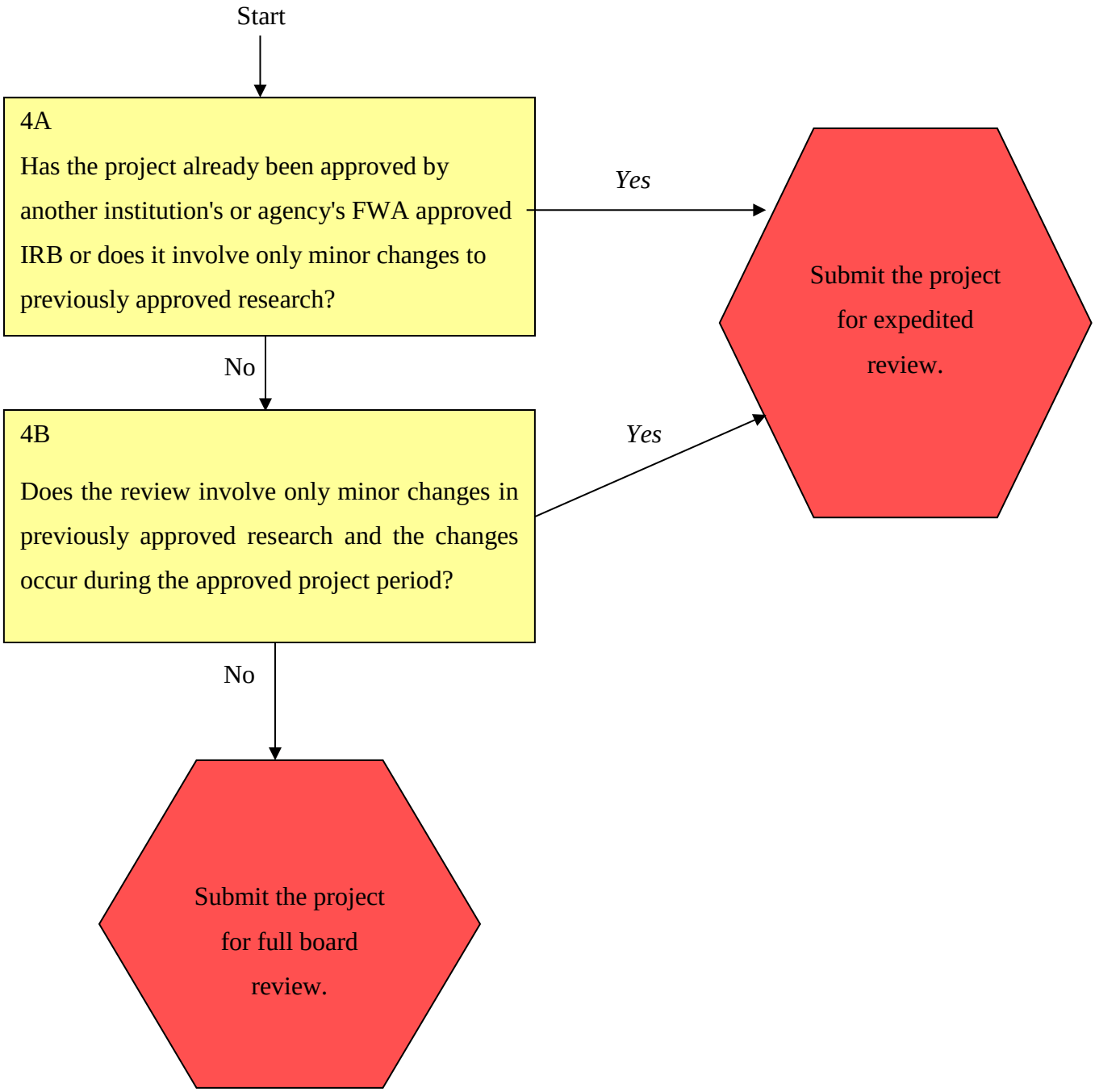
The purpose of the exemption determination process is to: 1) ensure review by a person(s) knowledgeable and experienced with federal and state IRB regulatory requirements; and 2) provide assurance that a particular research project does indeed satisfy criteria for exemption. **All** research activities in a project must be exempt in order for the project to be submitted for exemption determination. If even one activity is not exempt, the entire research project is not exempt.

3A. Does the research involve vulnerable persons?

The IRB shall determine that selection of subjects is equitable[20]. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children[21], prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

[20] 45 CFR 46.11(a)(3)
[21] Age of majority means persons 18 years of age, Code of Virginia §1-204

Question 4: Does the Project Qualify for Expedited Review?



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

State regulations allow research projects that have already been reviewed and approved by the IRB of another institution or agency to undergo expedited review[22]. If the project has been reviewed and approved by another IRB and/or all activities involve no more than minimal risk to human subjects in one or more of the qualifying categories, then the investigator should submit the protocol for expedited review.

An IRB reliance agreement may be possible. The PI should review the reliance agreement guidance document posted the VDSS IRB web page and contact the IRB chair for further information about reliance agreements.

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

Research project that involve only minor changes in previously approved research, where the changes occur during the approved project period, may undergo expedited review[23]. Where the project has not been reviewed by another IRB and/or all activities involve do involve more than minimal risk to human subjects in one or more of the qualifying categories, however, the project must be submitted to the IRB for full board review.

C. Additional Protections for Children Involved as Subjects in Research

This section applies to all research involving children as research subjects. *Children* are persons who have not yet attained the age of majority.

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

Permission means the agreement of the parent(s) or guardian of the child to allow the child to participate in research. *Parent* means a child's biological or adoptive parent. *Guardian* means an individual authorized under state or local law to consent on the child's behalf to general medical care.

All studies involving children, and not otherwise exempt, require IRB review in accordance with 45 CFR 46, Subpart D, which permits three categories of research involving children as subjects. We present the two categories most relevant to research involving VDSS clients here:

1. Where children will be involved as research subjects the use of survey or interview procedures is eliminated from the exemptions at 45CFR 46.101(b)(2), and so is research involving the observation of public behavior if the investigators participate in the activity being observed[24].

[22] 22VAC 40-890-80
[23] 45 CFR 45.110(b)(2)
[24] 45 CFR 46.401(b)

Specifically, surveys, interviews and observation of public behavior involving children must be reviewed under either the expedited or full board IRB procedures.

2. Research not involving greater than minimal risk to the children. To approve, the IRB must determine that the research presents no greater than minimal risk to the child and that adequate provisions are made for soliciting the assent of the child and the permission of the parent(s) or guardian.
3. Research involving greater than minimal risk but presenting the prospect of direct benefit to the children. To approve, 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 adequate provisions are made for soliciting the assent of the child and the permission of the parent(s) or guardian.

D. Informed Consent

Voluntary informed consent[25] signed by the participant or by the participant's legally authorized representative is required for all human research projects. The IRB may waive or alter the basic elements of informed consent[26] if:

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

The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all participants if the IRB finds that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The IRB may require the investigator to provide these participants with a written statement explaining the research. Each participant shall be asked whether she/he wants 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:

[25] 45 CFR 46.116
[26] 45 CFR 46.117(c)

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

The confidentiality of human research activities involving public assistance, child support enforcement, and social services programs and clients is governed by 22VAC40-910-50 (Release of client records for research purposes).

III. Institutional Review Board Procedures

This section summarizes the operation of the IRB, meetings, documentation required for IRB reviews, and procedures for approval of research. Specific guidance documents are available on the IRB web page http://www.dss.virginia.gov/about/irb.cgi.

A. Board Meetings

The VDSS IRB will convene at least once annually and will convene more often as needed. The IRB Chair will distribute information on the time and place of all IRB meetings and study materials for board review, prior to all meetings.

The federal Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services recognizes IRB meetings that are conducted via telephone calls and video conferences provided that:

1. Each participating IRB member has received all pertinent material prior to the meeting, and
2. Each participant can actively and equally participate in the discussion of all protocols.

In addition to the usual regulatory requirements, the minutes of such meetings must clearly document that the two conditions listed above have been met. Meetings will follow generally accepted practices for parliamentary procedures as outlined in Robert's Rules of Order.

B. Majority

For review purposes, a majority shall consist of the whole number greater than one-half of the number of regular members including at least one member whose primary concerns are in nonscientific areas. For example, if the board has ten members, 6, including one nonscientist, must be present for each vote. In order for research to be approved by the IRB, it must receive the approval of most of the members present at a meeting in which a majority exists.

Except for research projects that qualify for expedited review, the IRB is required to consider all requests *within 30 days* after submission. The IRB shall communicate decisions regarding approval, disapproval, or of required modifications to the PI in writing *within seven business days* of the IRB meeting when the submission is reviewed.

C. Requests for IRB Review

Researchers and managers who have reviewed the guidelines and have made the determination that a project does indeed involve human subjects and is considered research will need to make a request for IRB review. Requests for IRB review will fall into one of three categories:

1. Exemption Determination;
2. Expedited Review; or
3. Full Board Review.

Submit all applications to the IRB chair[27].

1) Exemption Determination

If the PI believes that the research project qualifies for exemption (see Question 3), the following documents should be submitted to the IRB:

☐ *Exemption Determination* form
☐ Study protocol(s), including sections on:
- Hypotheses
- Goal(s) of Study
- Background and Significance of Study
- Preliminary Progress/Data Report (if available)
- Research Method and Design, and
- Statistical Analyses Planned (or in progress).

☐ Letter(s) and other materials that will be supplied to study subjects
☐ Questionnaire(s) (when applicable)
☐ PI Curriculum Vitae (CV) or resume

Exemption determination requires the submission of *Exemption Determination* form and supporting documents. The decision to approve or not approve a project submitted for exemption determination will be made by the IRB Chair (or her/his designee) *within 30 days after submission*. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the PI in writing *within seven business days* following the exemption determination.

[27] irb@dss.virginia.gov

2) Expedited Review

Certain research activities involving human subjects qualify for an expedited review[28]. Documents that must be submitted by the PI in order to obtain *expedited* IRB review include:

- ☐ *Request for Initial Review* Form
- ☐ Study protocol(s), including sections on:
  - Hypotheses
  - Goal(s) of Study
  - Background and Significance of Study
  - Preliminary Progress/Data Report (if available)
  - Research Method and Design
  - Statistical Analyses Planned (or in progress)
- ☐ Informed Consent form(s), (when applicable);
- ☐ Informed Consent waiver, (when applicable);
- ☐ Letter(s) and other materials that will be supplied to study subjects
- ☐ Questionnaire(s) (when applicable)
- ☐ PI CV or resume
- ☐ IRB approval document(s) (if requesting expedited review because the study has been approved by another IRB)
- ☐ See *Request for Initial Review* Form other materials (when applicable)

Investigators must submit an electronic copy of the *Request for Initial Review* form and supporting documents. The decision to approve or not approve a project submitted for expedited review will be made by the IRB Chair (or her/his designee) and at least one additional member of the IRB *within 30 days after submission*. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the PI in writing *within seven business days* following the expedited review.

3) Full Board Review

The following is a checklist of documents that must be submitted in order to obtain IRB *full board* review and clearance:

- ☐ *Request for Initial Review* form
- ☐ Study protocol, including sections on
  - Hypotheses
  - Goal(s) of Study

[28] 45 CFR 45.110(b)(1)

- Background and Significance of Study
- Preliminary Progress/Data Report (if available)
- Research Method and Design
- Statistical Analyses Planned (or in progress)

☐ Informed Consent form(s), (when applicable);
☐ Informed Consent waiver, (when applicable);
☐ Letter(s) and other materials that will be supplied to study subjects
☐ Questionnaire(s) (when applicable)
☐ See *Request for Initial Review* Form other materials (when applicable)
☐ PI CV or resume

According to state regulations, the committee shall consider research proposals within 30 days after submission to the IRB. All IRB decisions regarding approval, disapproval, or required modifications will be communicated to the PI in writing *within seven business days* following the full board review.

D. Continuing Review

The IRB must conduct continuing review of ongoing studies at intervals appropriate to the nature and degree of risk, but not less than once every twelve months from the date of approval by the IRB. It is the PI's responsibility to submit the *Continuing Review* form to ensure conformity with the approved proposal. The Continuing Review form must be received by the IRB on or before the expiration date of the approved research. As a courtesy, the IRB Chair will send a reminder to investigators approximately four weeks prior to the expiration date. However, it is the responsibility of the Investigator to submit the Continuing Review form prior to the expiration date. The research cannot continue without VDSS IRB approval.

E. 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 defined as a change that (1) would not affect an assessment of the risks and benefits of the study, and (2) does not substantially change the specific aims or design of the study. Examples include: an increase/decrease in the proposed study sample size; changes in study materials (e.g., consent forms, questionnaires) that clarify statements or correct typographical errors; addition/deletion of study sites; and changes in the principal investigator(s) or other major study staff.

A *major* modification is defined as a change that either affects an assessment of the risks and benefits of the study or substantially changes the specific study aims or design. Examples include: revised consent or other study procedures; addition of potentially sensitive questions on research instruments; and changes in the subject population.

For both minor and major modifications, the PI is required to 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.

F. Completion/Termination of the Study

A study closure report is required for all human research studies. Among other reasons for closing out a study, the closure report updates the IRB on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal, and informs the IRB of the final disposition of research records and data.

Closure reports should be submitted to the IRB within *30 days* of study close-out by completing a *Study Closure-Out Report* form. The form can be found on the VDSS IRB web page[29] in the Forms section.

G. Unanticipated Problems and Adverse Events

The PI of approved research involving the use of human subjects is responsible for reporting any anticipated and unanticipated problems (including adverse events) that occur during the course of the research study and afterwards.

Definitions:

Unanticipated problem: Any incident, experience, or outcome that meets all of the following criteria: 1) unexpected (in terms of nature, severity, or frequency); 2) related or possibly related to participation in the research; and 3) produces an unfavorable, undesirable effect (outcome) on study participants or places subjects or others at greater risk of experiencing an unfavorable outcome. "Unanticipated problem" is a broad term that includes not only unfavorable outcomes that have occurred and were not expected, but also the development of increased risk of unfavorable outcomes occurring in the future. An example is an accidental or unintentional change to the IRB approved protocol or accidental disclosure of identifying information.

Adverse Event: An undesirable effect on the rights, safety or welfare of study participants. This includes any incident resulting in possible physical, psychological, or emotional harm or injury to the subject. It also includes any breach of confidentiality (e.g., disclosure of personally identifying information) that is possibly damaging to the participant's rights, employment, financial standing or reputation. "Adverse event" and "unanticipated problem" are sometimes used interchangeably. The investigator is required to report the adverse event to the VDSS IRB within ten business days of when this finding is noted. 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.

[29] http://www.dss.virginia.gov/about/irb.cgi

All *unanticipated* events, including adverse events, occurring during the course of currently approved studies must be reported to the IRB. The PI is required to immediately notify the VDSS IRB *within ten business days* after the event becomes known to the Investigator; the PI should complete and submit the *Adverse Event Reporting Form*. Severe adverse events should be reported *within 5 business days* to the VDSS IRB. If the Investigator is not certain whether an event qualifies as an adverse or unanticipated event, she/he should contact the IRB Chairperson for further guidance. Unanticipated problems and/or adverse events will warrant consideration of making substantive changes in the research protocol or informed consent procedure or taking other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

Anticipated problem: an expected event or problem, related to participation in the study and posing a risk to the study's subjects that is usually noted in the consent form and/or study protocol. (For example: The "subject may feel uneasy" or "embarrassed" while responding to a survey or disclosing sensitive information during the study.) Anticipated problems need not be reported to the VDSS IRB on an individual basis. Anticipated problems can be reported and summarized at the time of the continuation review (or at the end of the study) on the Continuation Review Form. If, in the course of conducting the study, the principal investigator finds that the expected events are occurring with greater frequency or at a higher level of severity than expected, it becomes an "unanticipated problem" and should be reported to the VDSS IRB *within ten business days* of when the finding is noted.