VIRGINIA DEPARTMENT OF SOCIAL SERVICES

Institutional Review Board:

Guidelines and Procedures Manual

Office of Research and Planning
11/30/2012

The VDSS IRB Guidelines and Procedures Manual is available on the VDSS web site: http://www.dss.virginia.gov/about/irb.cgi.

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Acknowledgements

The contents of this manual are based upon the first edition, prepared by Zandra Relaford in June 2005, and the second and third editions, prepared by Todd Areson, in November 2005 and July 2006, respectively. The third edition also incorporated federal revisions published on June 23, 2005, by the U.S. Department of Health and Human Services' Office for Human Research Protection (OHRP). All three editions relied upon the procedures for IRB review used by the Virginia Department of Health (VDH), and contained in the *Virginia Department of Health IRB Guidelines and Procedures Manual* (March 2005). We gratefully acknowledge the assistance provided by VDH, particularly the review offered by Kathy H. Wibberly, Ph.D., former chair of the VDH IRB.

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VDSS Institutional Review Board
Guidelines and Procedures Manual

I. Introduction

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

A. Purpose of the VDSS Institutional Review Board

The purpose of the Virginia Department of Social Services (VDSS) Institutional Review Board (IRB) is to ensure that human research involving VDSS clients maintains an individual's rights to privacy and protection from harm or risk. The IRB reviews research proposals and requests to determine how federal and state human research subject regulations apply to proposed research activities. The IRB conducts competent, complete, and professional review of human research activities conducted or authorized by the department, local departments of social services, VDSS-licensed facilities, or VDSS-authorized contractors to ensure the privacy and protection of VDSS clients.

Human subject means a living individual about whom a research investigator, whether professional or student, obtains: (1) data (through intervention or interaction), or (2) identifiable private information. *Intervention* includes manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information that the individual provides for specific purposes and can reasonably expect will not be made public. (See flow chart for Question 1 on page 5 and subsequent description.)

Human Subject Research regulations apply to:

- All program divisions and units within the Virginia Department of Social Services (VDSS);
- All local Departments of Social Services (LDSS);
- All facilities licensed by VDSS; and
- All contractors who authorize, conduct, or propose to conduct any human research involving VDSS clients.

B. Legal Authority for the VDSS Institutional Review Board

The VDSS IRB is authorized to review and approve proposed research as directed by the Code of Federal Regulations (CFR) Title 45, Part 46 (Protection of Human Subjects); the *Code of Virginia* §63.2-104, §63.2-217, and §63.2-218; and the *Virginia Administrative Code*, specifically, 22VAC40-890-10:100 (Human Subject Research Regulations) and 22VAC40-910-10:110 (General Provisions for Maintaining and Disclosing Information of Public Assistance, Child Support Enforcement, and Social Services Records). The state law and regulations are included in Appendix A.

C. Board Membership

State regulations require that the VDSS IRB consist of seven (7) members who are appointed by the Commissioner of VDSS. At least two (2) members of the board must be individuals whose primary concerns are in non-scientific or ethical areas (e.g., members of the clergy, lawyers).

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 his 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. 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, substitute 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 with members of the IRB. Appendix B lists the current members of the IRB, who serve an appointed term of three years (July 1, 2012 – June 30, 2015).

II. Institutional Review Board Policies

This section describes the policies guiding IRB review of human research activities, especially the key determinations that must be made. 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 research shall be conducted or authorized by the department unless the VDSS IRB has reviewed and approved the proposed human research project, except for research that is exempt from IRB review. 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. Whether the research presents more than a minimal risk to the subject;
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 the people 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 properly submitted research proposals *within 30 days* after submission to the IRB.

The IRB will notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval *within seven (7) 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 he is participating or has participated. All complaints shall be referred to the IRB to determine if there has been a violation of the established protocol.

All investigators must submit an annual report to the IRB to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each

research project. Investigators must also submit to the IRB a final report from the research project after the conclusion of the project.

B. Key Determinations for Human Subjects Research Review

Any research that is conducted by VDSS, local departments of social services (LDSS), outside investigators in collaboration with VDSS or LDSS, facilities licensed by VDSS, or by outside investigators using VDSS data, is potentially subject to review and approval by the VDSS Institutional Review Board. Accordingly, research conducted or supported by a federal department or agency involving VDSS clients must be reviewed and approved by the VDSS IRB.

Not all studies require 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?

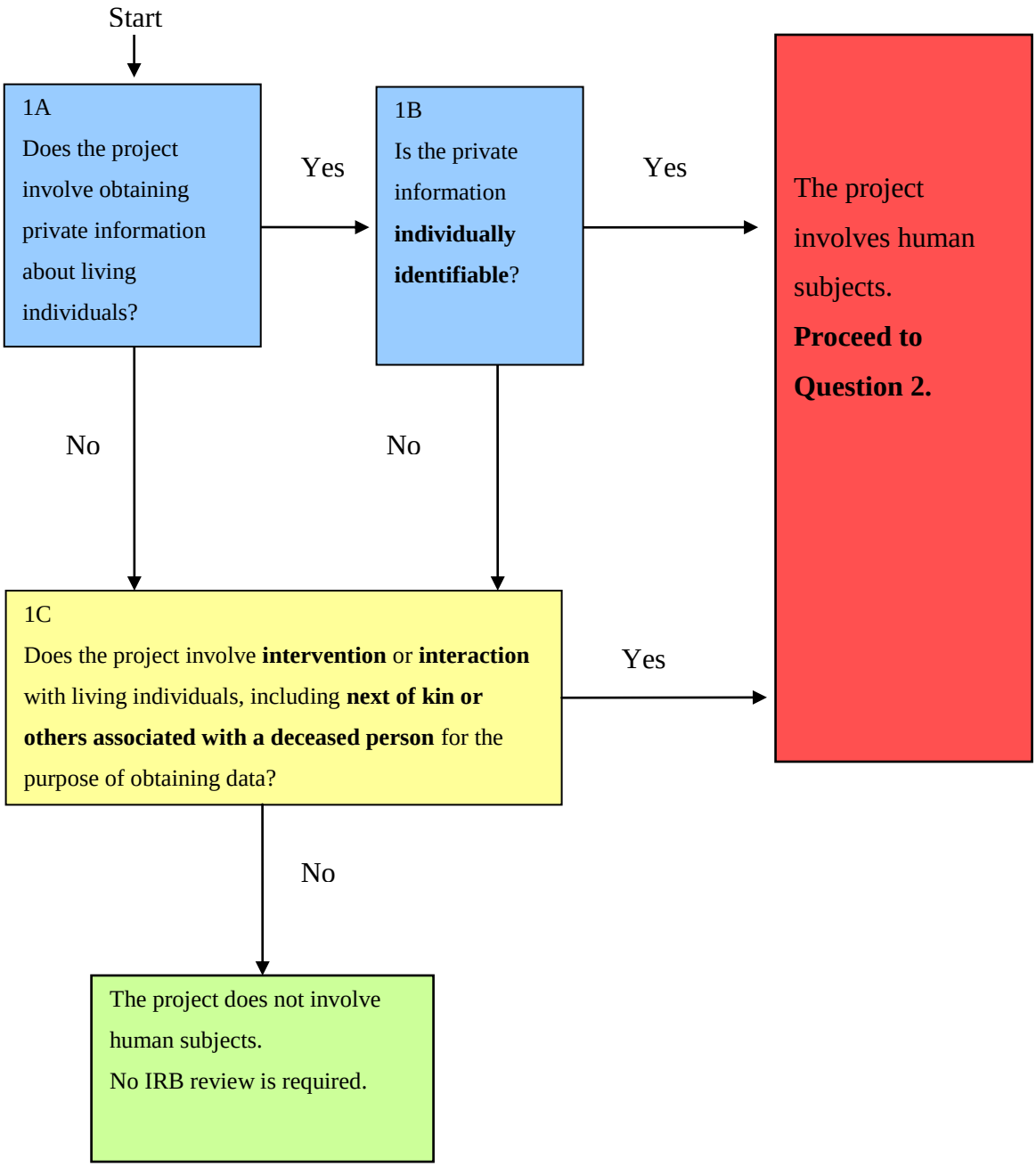
Question 2: Is the project considered research?

Question 3: Does the project qualify for exemption review?

Question 4: Does the project qualify for expedited review?

Each question is outlined in a flow chart and is followed by a brief description.

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 (s)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.

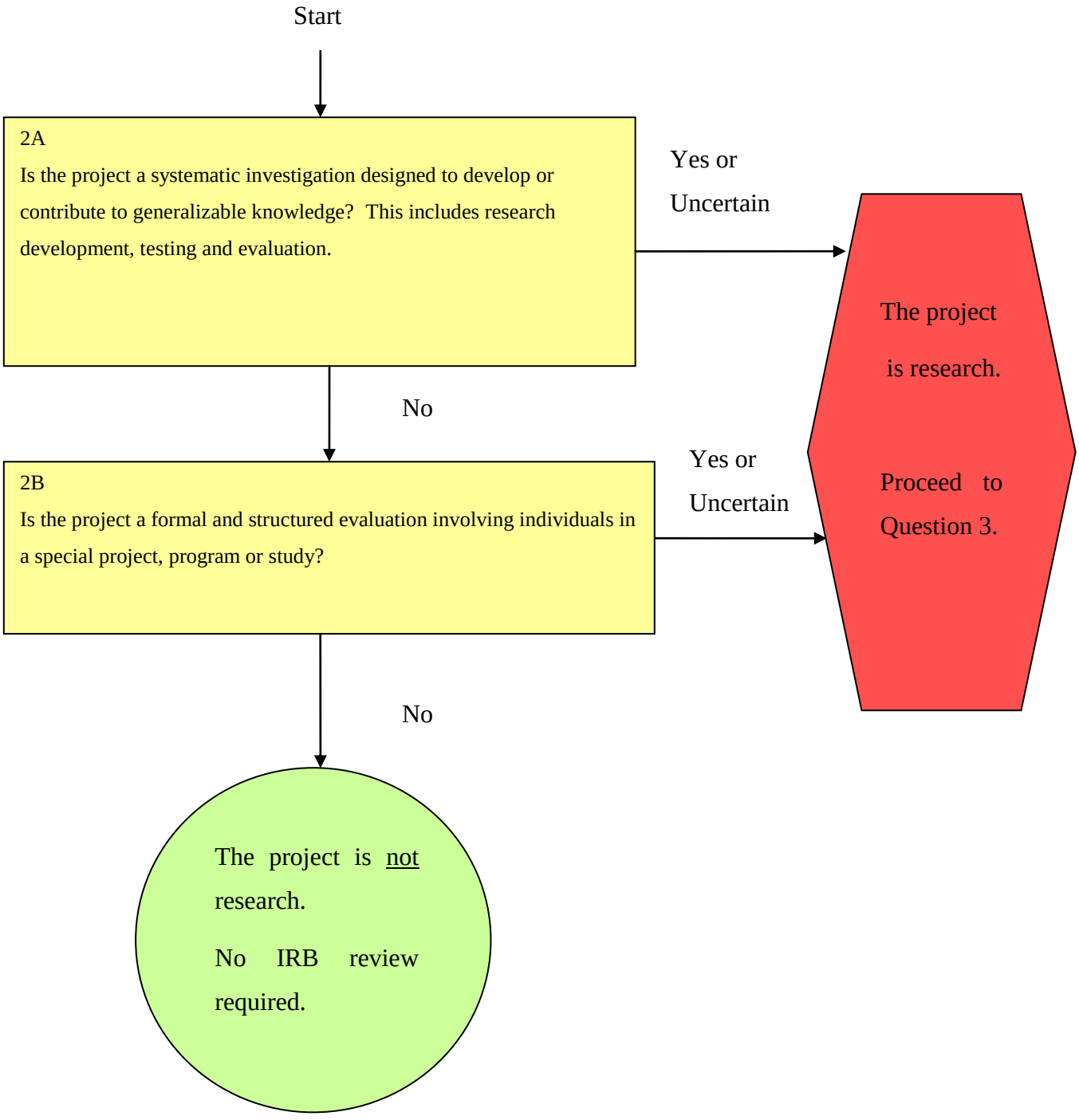
1C. Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?

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 *[45 CFR 46.102(d)]*.

The project is ***not*** research if it is primarily being conducted to gain knowledge and information that can be used immediately to benefit participants. Note that if, at any point, the ***purpose*** of the project changes so that the project becomes a systematic investigation designed to develop or contribute to generalizable knowledge, the investigator must consult the IRB to determine the need for review.

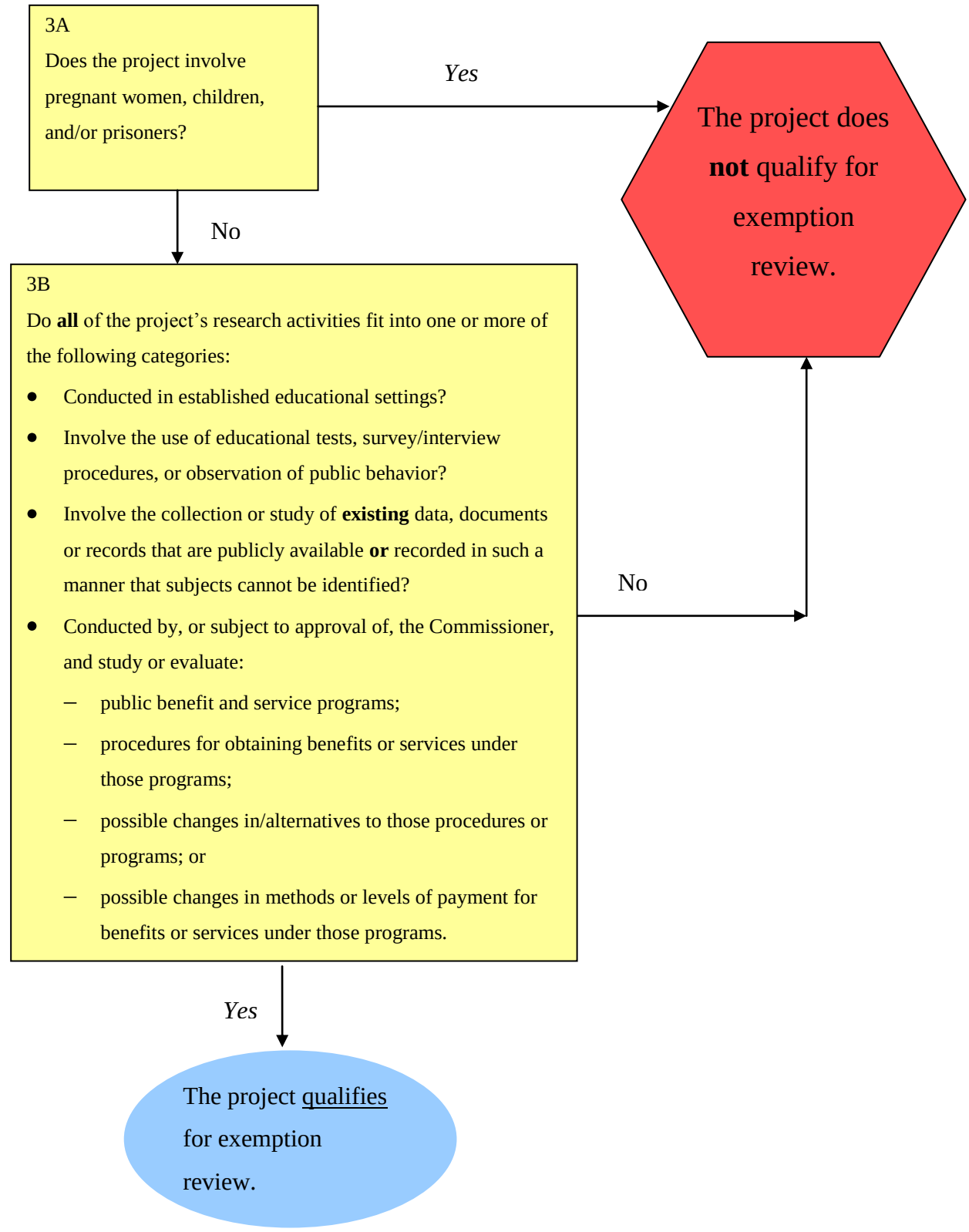
2B. Is the project a formal and structured evaluation involving individuals in a special project, program or study?

The *Virginia Administrative Code [22 VAC40-890-10]* 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 review (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. Even if IRB review is not required, the project may still request IRB review to address ethical questions posed by the Principal Investigator or reviewers, or because of potential controversy or publicity associated with the project.

If the proposed activity is considered human research or if it is not clear, you will need to submit your research protocol to the IRB for review. You should proceed to Question 3 to determine if your protocol should be submitted for exemption review, expedited review, or full board review.

Question 3: Does The Project Qualify for Exemption Review?



Certain research activities involving human subjects have been given exemptions from IRB full board review through either federal and/or state regulations. If an investigator feels that the research activities being proposed fall into one of the exemption categories, those protocols should be submitted to the IRB for exemption review (see previous page for flow diagram).

The decision to approve or disapprove a project submitted for exemption review will be made by the Chair of the IRB (or his/her designee) and one other member of the review board *within 30 days after submission*. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the Principal Investigator in writing *within seven (7) business days* after the exemption review.

The purpose of the exemption review process is to provide assurance that a particular research project does indeed meet the criteria for exemption. **All** of the research activities in a project that involve human subjects must be exempt in order for the project to be submitted for exemption review. If even one activity is not exempt, the entire project is not exempt.

3A. Does the project involve pregnant women, children, or prisoners?

Pregnant women, children (persons who have not attained the legal age for consent to treatments or procedures involved in the research), or prisoners are considered vulnerable populations. Any project involving vulnerable populations does **not** qualify for exemption review and must undergo either expedited or full board review.

3B. Do ALL research activities in the project fit one or more of the following categories?

If all research activities in the project fit one or more of the following categories, then that research project may qualify for exemption review.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices. This includes research on regular and special education instructional strategies, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
2) Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior unless:
    a. the information is recorded in such a manner that subjects can be identified, directly or

through identifiers linked to the subjects; and

b. any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

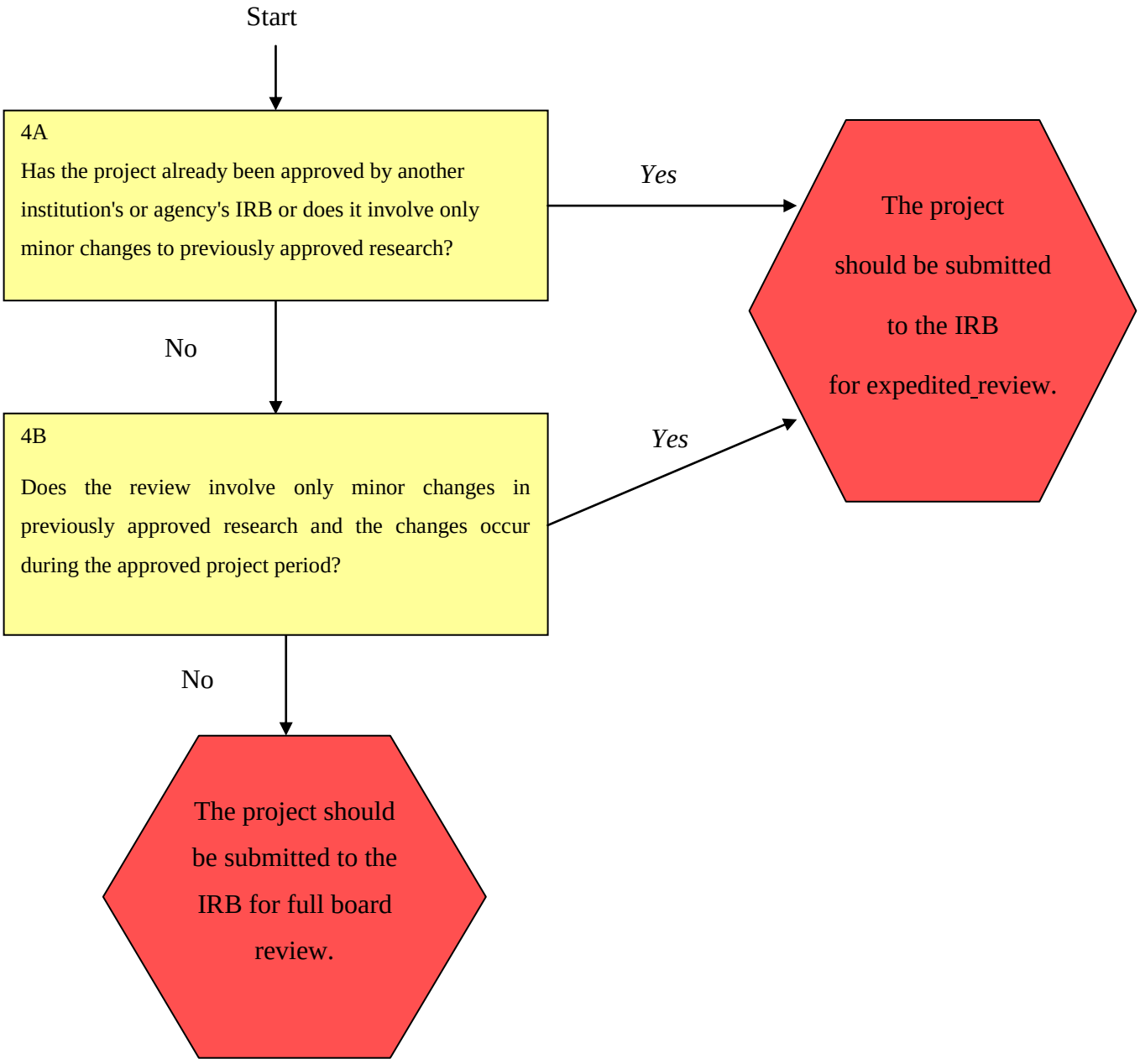
There are special circumstances in which the research included above in item (2) is not exempt. These circumstances occur when the subjects are elected or appointed officials or candidates for public office; or federal statute(s) require(s), without exception, the confidentiality of the personally identifiable information be maintained throughout the research, and thereafter.

3) Research involving the collection or study of existing data, documents and records, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject qualifies for exemption review.
4) Research and demonstration projects conducted by federal agencies or subject to the approval of federal department or agency heads and are designed to study, evaluate or otherwise examine:
    a. public benefit or service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternatives to those programs or procedures; or
    d. possible changes in methods or levels of payment for benefits or services under those programs.

If the project does **not** involve vulnerable populations **and** all activities fit into one or more of the above categories, then the investigator should submit the protocol to the IRB for exemption review. Even if the IRB determines that a study is indeed exempt, the investigator may still request a full board review. This might be done to address ethical questions posed by the investigator or reviewers, or it might be done because of potential controversy or publicity associated with the project.

If the project **does** involve vulnerable populations and/or all activities **do not** fit into one or more of the above categories, then you should proceed to Question 4, to determine if your protocol would qualify for expedited review or need to be submitted for full board review.

Question 4: Does the Project Qualify for Expedited Review?



Certain research activities involving human subjects qualify for an expedited review process as a result of either federal and/or state regulations. The decision to approve projects submitted for expedited review will be made by the Chair of the IRB or his/her designee, and one additional member of the review board *within 30 days after submission*. All IRB decisions regarding approval or required modifications will be communicated to the Principal Investigator in writing *within seven (7) business days after review*. Projects submitted for expedited review that are not approved through the expedited process will be submitted to the IRB for a full 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 (22VAC 40-890-80). 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.

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

State regulations allow research project that involve only minor changes in previously approved research, where the changes occur during the approved project period, to undergo expedited review (22VAC40-890-80). 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 subjects, conducted or sponsored by the U.S. Department of Health and Human Services.

Children are persons who have not yet attained the legal age for consent to treatments or procedures involved in the proposed research. *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. 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.
2. 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 signed by the participant or by the participant's legally authorized representative is required for all human research projects (in Appendix C: "General Requirements for Informed Consent"). The VDSS IRB may waive or alter the basic elements of informed consent 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 it 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 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 will be released for research purposes if the following conditions are met:

1. For public assistance and social services, the Commissioner of the Virginia Department of Social Services or his/her designee(s), or division director or his/her 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 his/her designee(s), or the Director of Child Support Enforcement, authorizes the plan and the release of the client records; and
3. The requestor either submitted a signed *Assurance of Confidentiality and Use of Data Agreement* form (in Appendix D) or has entered into a contract with the Department or agency that stipulates the Department's or agency's requirements for use of confidential client records.

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 describes the operation of the IRB, meetings, documentation required for IRB reviews, and procedures for approval of research.

A. Board Meetings

The VDSS IRB will convene at least once annually and will convene more often as needed. The IRB Administrative Coordinator 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. Quorum

For review purposes, a quorum will consist of a simple majority of the IRB members, including at least one member whose primary expertise is considered to be nonscientific in nature. In order for research to be approved by the IRB, it must receive the approval of a majority of those members present at a meeting in which a quorum exists.

Except for research projects that qualify for expedited review under 22VAC40-890-80, the IRB is required by state regulations to consider all requests *within 30 days* after submission. The IRB shall communicate decisions regarding approval, disapproval, or of required modifications to the Principal Investigator in writing *within seven (7) 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. Request for Exemption from IRB Review;
2. Request for Expedited Review; or
3. Request for Full Board Review.

All requests for review are to be submitted to the IRB Administrative Coordinator at the Virginia Department of Social Services, Office of Research and Planning.

1) Exemption from IRB Review

If the Principal Investigator believes that the research project qualifies for exemption (see Question 3, pp. 9-11), the following is a checklist of documents that must be submitted in order to obtain IRB

exemption status:

☐ *Request for Exemption Review* Form (in Appendix E)

☐ Cover letter with a detailed written explanation why the project should be determined as exempt

☐ 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)

☐ Curriculum Vitae (CV) or resume of Principal Investigator

Exemption review requires the submission of electronic copies of the "Request for Exemption Review" application form and supporting documents. The decision to approve or not approve a project submitted for exemption review will be made by the IRB Chair (or his/her designee) and one additional member of the review board *within 30 days after submission*. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the Principal Investigator in writing *within seven (7) business days* following the exemption review or determination.

2) Expedited Review

The following is a checklist of documents that must be submitted by the Principal Investigator in order to obtain *expedited* IRB review and clearance:

☐ *Request for Review and Clearance of Human Subjects Research* Form (in Appendix E)

☐ 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); if seeking a waiver for the informed consent requirement [see section II-D (Informed Consent) on page 14], submit an electronic copy of the "Request for Waivers of Informed Consent".

☐ Letter(s) and other materials that will be supplied to study subjects

☐ Questionnaire(s) (when applicable)

☐ CV or resume of Principle Investigator

☐ IRB approval document(s) (if requesting expedited review because the study has been approved as a Full Board Review by the IRB of another agency)

Investigators must submit an electronic copy of the "Request for Review and Clearance of Human Subjects Research" application 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 his/her designee) and one additional member of the review board *within 30 days after submission*. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the Principal Investigator in writing *within seven (7) 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 IRB Review and Clearance of Research* Form (in Appendix E)

☐ Study protocol, 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); if seeking a waiver for the informed consent requirement [see section

II-D (Informed Consent) on page 14], submit a "Request for Waivers of Informed Consent" form.

☐ Letter(s) and other materials that will be supplied to study subjects

☐ Questionnaire(s) (when applicable)

☐ CV or resume of Principal Investigator

According to state regulations, "the committee shall consider research proposals within 30 days after submission to the committee". In order for the research proposal to be approved, it must receive approval by a majority of those IRB members present at a meeting in which a quorum exists. All IRB decisions regarding approval, disapproval, or required modifications will be communicated to the Principal Investigator in writing *within seven (7) business days* following the full board review.

The VDSS Institutional Review process is outlined in Appendix F.

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 Principal Investigator's responsibility to submit the *Continuation Review* Form (in Appendix E) to ensure conformity with the approved proposal. The Continuation Review form must be received by the IRB by the due date. As a courtesy, the IRB Coordinator will send a reminder to investigators approximately four weeks prior to the review due date.

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. For minor modifications, the Principal Investigator should send a communication in writing (e.g., email message, FAX transmittal, postal letter) to the IRB Chair/Coordinator about these changes. The

Investigator should reference the title of the study and, where applicable, attach the revised study materials and/or protocol with changes or additions highlighted.

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. The Principal Investigator is required to submit a Request for Review form as if it was a new study.

F. Completion/Termination of the Study

The Principal Investigator is required to complete and submit only section I of the *Continuation Form* (in Appendix E) and attach a written, brief (1-2 paragraph) study summary report *within 90 days* after the conclusion of the research project.

Appendices

A. Code of Virginia and Virginia Administrative Code Citations

B. VDSS Institutional Review Board: Membership

C. General Requirements for Informed Consent

D. Assurance of Confidentiality and Use of Data Agreement

E. Requests for Review Forms:

- Request for Exemption Review
- Request for Review and Clearance of Human Subjects Research
- Request for Waivers of Informed Consent
- Continuation Review

F. VDSS Institutional Review of Human Subjects Research: The Process

Appendix A

CODE OF VIRGINIA AND *VIRGINIA ADMINISTRATIVE CODE* CITATIONS

Code of Virginia

§ 63.2-104. Confidential records and information concerning social services; penalty.

A. The records, information and statistical registries of the Department, local departments and of all child-welfare agencies concerning social services to or on behalf of individuals shall be confidential information, provided that the Commissioner, the Board and their agents shall have access to such records, information and statistical registries, and that such records, information and statistical registries may be disclosed to any person having a legitimate interest in accordance with state and federal law and regulation.

It shall be unlawful for any officer, agent or employee of any child-welfare agency; for the Commissioner, the State Board or their agents or employees; for any person who has held any such position; and for any other person to whom any such record or information is disclosed to disclose, directly or indirectly, any such confidential record or information, except as herein provided or pursuant to § 63.2-105. Every violation of this section shall constitute a Class 1 misdemeanor.

B. If a request for a record or information concerning applicants for and recipients of social services is made to the Department or a local department by a person who does not have a legitimate interest, the Commissioner or local director shall not provide the record or information unless permitted by state or federal law or regulation.

C. This section shall not apply to the disposition of adoption records, reports and information that is governed by the provisions of § 63.2-1246.

(Code 1950, §§ 63-41, 63-140, 63-140.15, 63-161, 63-204, 63-220, 63-246; 1958, c. 433; 1962, c. 621; 1968, cc. 43, 578, §§ 63.1-34, 63.1-126, 63.1-209; 1972, c. 540; 1976, c. 365; 1977, c. 547, § 63.1-55.4; 1979, cc. 218, 666; 1981, c. 456; 1983, c. 604; 1986, c. 213; 1988, cc. 151, 898; 1994, c. 643; 2000, cc. 500, 830; 2001, cc. 503, 518; 2002, c. 747.)

§ 63.2-217. Board to adopt regulations.

The Board shall adopt such regulations, not in conflict with this title, as may be necessary or desirable to carry out the purpose of this title. Before the Board acts on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the Board shall examine the potential fiscal impact of such regulation on local boards. For regulations with potential fiscal impact, the Board shall share copies of the fiscal analysis with local boards prior to submission of the regulation to the Department of Planning and Budget for purposes of the economic impact analysis under § 2.2-4007.04. The fiscal impact analysis shall include the projected costs and savings to the local boards to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

The Board also may adopt such regulations to authorize local boards to destroy or otherwise dispose of such records as the local boards in their discretion deem are no longer necessary in such offices and that serve no further administrative, historical or financial purpose.

(Code 1950, § 63-25; 1956, c. 125; 1968, c. 578, § 63.1-25; 1974, c. 507, § 63.1-238.5; 1976, c. 216; 1998, c. 558; 2002, cc. 391, 747; 2007, cc. 873, 916.)

§ 63.2-218. Board to adopt regulations regarding human research.

The Board shall adopt regulations to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department, any agency or facility licensed by the Department, or any local department. The regulations shall require the human research committee to submit 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 shall require the committee to report any significant deviations from the proposals as approved.

(1992, c. 603, § 63.1-25.01; 2002, c. 747.)

Virginia Administrative Code

22VA40-890 Human Subject Research Regulations

22VAC40-890-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Affiliated with the department" means any individual employed, either on a paid or volunteer basis, by the Virginia Department of Social Services, by a local department of social services, or by an agency licensed by the Virginia Department of Social Services.

"Authorized" means to permit the implementation or conducting of research.

"Board" means the Virginia State Board of Social Services.

"Commissioner" means the Commissioner of the Virginia Department of Social Services or his designee.

"Committee" means the human research review committee which reviews and approves human research activities related to this chapter.

"Contractor" means agencies, organizations, or individuals providing goods or services, receiving funds, or under contract with the department or a local agency including, but not limited to, foster homes and day-care homes.

"Department" means the Virginia Department of Social Services.

"Discomforts, risks, and benefits" means the expected advantages and disadvantages to the participant for participating in the research.

"Facility" means any agency licensed by the department including, but not limited to, adult and child day and residential facilities.

"Human participant" or "participant" means any individual, customer, volunteer, or employee who is the subject of research conducted or authorized by the department, facility, local agency, or contractor.

"Human research" or "research" means any formal and structured evaluation involving individuals in a special project, program, or study.

"Informed consent" means the knowing and voluntary agreement of the participant exercising free choice, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

"Legally authorized representative" means a person with authority to consent on behalf of a prospective participant to include (i) the parent or parents having custody, (ii) the legal guardian, or (iii) any person or judicial or other person or body authorized by law or regulation, including an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make a decision related to human research. The attorney in fact shall not be employed by the person or department conducting the human research. No official or employee of the department, facility or local agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Local department" means the local department of social services of any county or city in this Commonwealth.

"Minimal risk" means that the risks of harm to the prospective participant anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 1, eff. August 11, 1993; amended, Virginia Register Volume 28, Issue 1, eff. November 1, 2011.

22VAC40-890-20. Applicability.

This chapter shall apply to the Virginia Department of Social Services, to local departments of social services or departments of welfare, to facilities licensed by the department, and to contractors that authorize, conduct, or propose to conduct or authorize any human research.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 2, eff. August 11, 1993.

22VAC40-890-30. Research exempt from chapter.

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this chapter unless the research is covered by other sections of this chapter:

1. Human research which is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government, except for the provisions in 22VAC40-890-40 C and 22VAC40-890-90 B.

2. Research conducted in established or commonly accepted educational settings involving commonly used educational practices, provided that participants cannot be identified, directly or through identifiers, for:

a. Regular and special education instructional strategies;

b. The effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods; or

c. Educational tests.

3. Research involving solely the observation of public behavior or survey or interview procedures, except when observations or responses are recorded in such a manner that participants can be identified directly or through identifiers linked to the participants, and when either (i) the participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; or (ii) the research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use or illegal conduct.

4. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.

5. Research involving solely the collection or study of existing data, documents, or records, if these sources are publicly available or if the information taken from these sources is recorded in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

6. Research and demonstration projects covered under 45 CFR 46.101(b)(5) which are conducted by or subject to the approval of the commissioner, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 3, eff. August 11, 1993.

22VAC40-890-40. Policy.

A. Each human research activity, as well as significant changes to approved research proposals, shall be submitted to and approved by a committee composed of representatives of varied backgrounds prior to implementation of the research. The committee shall ensure the competent, complete, and professional review of human research activities conducted, authorized, or proposed to be conducted or authorized by the department, local agencies, facilities, or contractor. The committee shall ensure the participants' rights to privacy are maintained.

B. Every person engaged in the conduct of human research or proposing to conduct human research shall report to an agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in this chapter.

C. Every person or organization engaged in a human research project that requires an allowable variance or other approval related to department regulations must obtain approval for such from the department prior to requesting the committee's review and approval of the proposed research.

D. Prior to the initiation of any human research, each participant or legally authorized representative must be informed in writing of the following:

1. Procedure or procedures to be utilized, their purposes, and any expected discomforts, risks, and benefits;

2. Instruction that the participant may withdraw his consent and discontinue participation in the human research at any time without loss of services or benefits to which the participant is otherwise entitled;

3. Explanation of any costs or benefits which may accrue to the participant or the participant's family;

4. An offer to answer any inquiries by the participant concerning the procedures and use of the results;

5. Statement assuring confidentiality of records and describing the extent to which confidentiality of records identifying the participant will be maintained; and

6. Expected duration of participation.

E. Where the human research activity exposes to risk others not participating, all must give their signed voluntary informed consent.

F. The committee may suspend or terminate research that is in violation of the research protocol.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 4, eff. August 11, 1993.

22VAC40-890-50. Informed consent.

A. No human research may be conducted without voluntary informed consent signed by the participant or by the participant's legally authorized representative, except as provided for in subsection C of this section. If the participant is a minor otherwise capable of rendering voluntary informed consent, the consent shall be signed by both the minor and his legally authorized representative. A researcher shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.

B. The committee may approve a consent procedure which omits or alters basic elements of informed consent or may waive the requirements to obtain informed consent, provided the committee finds and documents that:

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.

C. The committee may waive the requirement for the researcher to obtain a signed consent form for some or all participants if it 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 committee may require the investigator to provide participants with a written statement explaining the research. Each participant shall be asked whether he wants documentation linking him to the research and the subject's wishes shall govern.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 5, eff. August 11, 1993.

22VAC40-890-60. Human research review committee.

A. The department shall establish a department committee, consisting of seven members, appointed by the commissioner. The department committee is authorized (i) to determine if a proposed project is human subject research; and (ii) to review and approve any human research proposed, authorized, or conducted by the department, by any local agency, by any facility, or by any contractor.

B. All human research conducted or authorized by the department, local agency, facility, or contractor must be reviewed and approved by the department committee, except local agencies, facilities, or contractors collaborating with another organization on a research project may instead elect to utilize that organization's research review committee.

C. Members of the committee will be appointed to ensure the competent, complete, and professional review of human research. No member of the committee shall be directly involved in the proposed human research project or have administrative approval authority over the proposed research, except in connection with his responsibilities as a member of the committee. At least two members of the committee must be individuals whose primary concerns are in nonscientific or ethical areas (e.g., the clergy, lawyers).

D. The committee shall include at least two members who are not affiliated with and are not immediate family members of persons who are affiliated with the department.

E. No member of the committee shall participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflict of interest. If necessary, the committee size shall be maintained by the appointment of a substitute representative to review a project where a member has a conflicting interest.

F. A committee may, at its discretion, 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 committee. These individuals may not vote with the committee.

G. A quorum of the committee shall consist of a majority of its members.

H. The committee shall establish procedures and rules of operations necessary to fulfill the requirements of this chapter.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 6, eff. August 11, 1993.

22VAC40-890-70. Review and approval process.

A. Prior to the initiation of a human research project, a description of the proposed human research project shall be submitted to the department committee for review and approval, except for projects which are exempt or those reviewed by another organization's committee. The description shall include a statement of the purpose of the proposed project and justification of it, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and the proposed informed consent statement.

B. No human research shall be conducted or authorized by the department unless the department committee has reviewed and approved the proposed human research project giving 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. Whether the research presents more than a minimal risk to the subject;

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 the people proposing to supervise or conduct the research are competent and qualified; and

8. Whether the criteria for selection of participants is equitable.

C. Except for the research referenced in 22VAC40-890-80, the committee shall consider research proposals within 30 days after submission to the committee. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. The committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure committee approval.

D. During the committee review of research projects, no personal identifiers of present or potential participants shall be presented or discussed.

E. The committee shall require a written description of the procedure to be followed when a participant has a complaint about a research project in which he is participating or has

participated. All complaints shall be referred to the committee to determine if there has been a violation of the established protocol.

F. The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. The committee shall also require a report from the research project at the conclusion of the project.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 7, eff. August 11, 1993.

22VAC40-890-80. Expedited review of human research participants.

A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the participants if:

1. The research review committee affiliated with another state department, local agency, licensed facility or institution has reviewed and approved the project; or

2. The review involves only minor changes in previously approved research and the changes occur during the approved project period.

B. The committee shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 8, eff. August 11, 1993.

22VAC40-890-90. Reporting.

A. The department's research review committee shall report by December 15 of each year to the commissioner on activities of the committee during the year. The report shall include:

1. A description of each human research project reviewed and whether approved or disapproved;

2. Any significant changes from research proposals as approved by the committee;

3. A list of committee members, their qualifications for service on the committee, and their affiliation with the department, local agency, or facility;

4. A copy of the minutes of each committee meeting; and

5. Results of the research after its conclusion.

B. A local agency, facility or contractor participating in a human subject research project reviewed by another agency's research review committee shall report to the department research review committee by December 1 of each year on such participation. The report shall include:

1. A description of each human research project in which the agency participated; and

2. Results of the research after its conclusion.

C. The chairperson of the department's committee shall report as soon as possible to the commissioner any violation of the research protocol that may lead the committee to either suspend or terminate the research.

D. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects authorized or conducted by the department, local agency, facility, or contractor.

E. Other reports may be required by the committee, as indicated in 22VAC40-890-70 F.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 9, eff. August 11, 1993.

22VAC40-890-100. Committee records.

A. Documentation of all committee activities shall be prepared and maintained and shall include the following:

1. Copies of all research documents, including proposals reviewed, evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by researchers, reports of injuries to participants, and correspondence related to the research project;

2. Minutes of committee meetings which shall be in sufficient detail to show attendance; actions taken by the committee; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research and a summary of the discussion of controversial issues and their resolution;

3. Records of continuing review activities;

4. A list of committee members; and

5. Written procedures for the committee.

Statutory Authority: §§ 63.2-217 and 63.2-218 of the Code of Virginia.

Historical Notes: Derived from VR615-80-01 § 10, eff. August 11, 1993.

22VAC40-910 General Provisions for Maintaining and Disclosing Information of Public Assistance, Child Support Enforcement, and Social Services Records

22VAC40-910-10. Definitions.

The following words and terms when used in this chapter will have the following meanings unless the context clearly indicates otherwise:

"Agency" means a local department of social services.

"Agent" means any individual authorized to act on behalf of or under the direction of the Commissioner of the Virginia Department of Social Services or State Board of Social Services for the sole purpose of accessing confidential client records in the administration of public assistance, child support enforcement, or social services programs.

"Client" means any applicant for or recipient of public assistance or social services or any individual about whom the child support enforcement division maintains information.

"Client record" or "client information" means any identifying or nonidentifying information, including information stored in computer data banks or computer files relating to a client.

"Department" means the Virginia Department of Social Services.

"Human research" means any formal and structured evaluation involving individuals in a special project, program, or study.

"Legally responsible person" means (i) the biological or adoptive parent or other relative with whom the child primarily resides and who has legal custody of the child; (ii) the biological or adoptive parent with whom the child does not primarily reside and who has legal custody of the child; or (iii) a committee or guardian appointed by a court to represent the interest of a client.

"Near fatality" means an act that, as certified by a physician, places the child in serious or critical condition. Serious or critical condition is a life-threatening condition or injury.

"Provider" means any person, agency or organization providing public assistance, child support enforcement services, or social services through a contract or an agreement with the department or agency.

"Public assistance" means Temporary Assistance for Needy Families (TANF); auxiliary grants to the aged, blind and disabled; medical assistance; energy assistance; food stamps; employment services; child care; and general relief.

"Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge, including research for the development of new knowledge or techniques that would be useful in the administration of public assistance, child support enforcement, or social services programs.

"Social services program" means foster care, adoption, adoption assistance, adult services, adult protective services, child protective services, domestic violence services, family preservation, or any other services program implemented in accordance with regulations promulgated by the State Board of Social Services.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-20. General provisions.

A. Except as otherwise provided in these regulations or consistent with other federal and state laws or regulations, no person shall disclose or use, or authorize, permit or acquiesce to the use of any client information that is directly or indirectly derived from the client records of the department, agency, provider, or the State Board of Social Services. Exceptions to this provision are provided in 22VAC40-910-80, 22VAC40-910-90 and 22VAC40-910-100.

B. Protecting confidential information. All client records, which could disclose the client's identity, are confidential and must be protected in accordance with federal and state laws and regulations. Such client information includes, but is not limited to:

1. Name, address and any types of identification numbers assigned to the client and all individuals for whom the client receives assistance on behalf of, including but not limited to social security number;

2. Public assistance, child support enforcement services, or social services provided to the client;

3. Information received for verifying income and eligibility;

4. Evaluation of the client's confidential information;

5. Social and medical data about the client and all individuals for whom the client receives assistance on behalf of, including diagnoses and past histories of disease or disabilities;

6. Information received from third parties such as an employer; and

7. Information associated with processing and rendering appeals.

C. Ownership of client records.

1. Client records are the property of the department or agency. Employees and agents of the department or agency must protect and preserve such records from dissemination except as provided herein.

2. Only authorized employees and agents may remove client records from the department or agency's premises.

3. The department and agency shall destroy client records pursuant to records retention schedules consistent with federal and state regulations.

D. Disclosure of client information.

1. Consent. As part of the application process for public assistance or social services, the client or legally responsible person must be informed of the need to consent to a third-party release of client information necessary for verifying his eligibility or information provided. Whenever a person or organization that is not performing one or more of the functions delineated in 22VAC40-910-80 C or does not have a legitimate interest pursuant to 22VAC40-910-100 requests client information, the person or organization must obtain written permission from the client or the legally responsible person for the release of the client information unless one of the conditions delineated in this subsection exists. A client's authorization for release of client information obtained by the department, agency or provider also satisfies this requirement.

Client records may be released without the client's written permission under the following conditions:

a. A court of competent jurisdiction has ordered the production of client records and the department, agency or provider does not have sufficient time to notify the client or legally responsible person before responding to the order.

b. For research purposes as provided in 22VAC40-910-50.

2. The Commissioner of the Virginia Department of Social Services, the State Board of Social Services and their agents shall have the discretion to release nonidentifying statistical information. A client's written permission is not required in order to release nonidentifying statistical information.

3. The Commissioner of the Virginia Department of Social Services, the State Board of Social Services and their agents do not have to obtain consent from the client to obtain or review client records.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-30. Notification of release of confidential client information.

If one of the conditions in 22VAC40-910-20 D 1a is met and consent is not obtained before the release of the client records, the department, agency or provider must make reasonable efforts to

provide written notification to the client or legally responsible person within five business days after disclosure.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-40. Consent process.

The consent for release of client information must contain the following:

1. The name of the entity supplying the information and the name of the requesting party;

2. The consent must be signed and dated by the client or legally responsible person. The client or legally responsible person may add other information, which may include, but is not limited to, a statement specifying the date, event or condition upon which the consent expires.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-50. Release of client records for research purposes.

A. Prior to the initiation of research involving client records by any individual or institution that entered into an agreement with or is funded or licensed by the department or agency, a written plan outlining the proposed research must be submitted to the department or agency for review and approval. In the event client records are requested from multiple agencies or the department and an agency or agencies, the plan must be submitted to the department.

B. The plan must include:

1. The purpose of the proposed research;

2. A description of how client records will be used;

3. A provision that when the research is completed, client records will either be destroyed or returned to the department; and

4. A confidentiality agreement signed by the individual or institution's authorized representative, which includes that:

a. Client records will be used only for the purposes for which they are being provided;

b. Client records will not be released to any persons not connected with the research;

c. Security safeguards will be in place to protect against loss and unauthorized access, use, modification or disclosure of client records;

d. Authorized persons involved in the research are required to maintain confidentiality of all client records connected with the research;

e. Identifying information from client records must not be discussed with or released to anyone except authorized persons involved in the research;

f. Final product(s) of the research will not reveal any information that may serve to identify any person about whom information has been obtained through the department, agency or provider without written consent of such person and the department, agency or provider;

g. Authorized person(s) involved in the research who fail to comply with the terms of this confidentiality agreement will be immediately terminated from the research;

h. This confidentiality agreement must survive and continue after completion of the research. The individual or institution continues to be responsible for any breach; and

i. Disclosure of client records in violation of §§ 63.2-102 and 63.2-104 of the Code of Virginia is a Class 1 misdemeanor.

C. Client records will be released for research purposes if the following conditions are met:

1. For public assistance and social services, the Commissioner of the Virginia Department of Social Services or his designee(s), or agency director or 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 his designee(s), or the Director of Child Support Enforcement authorizes the plan and the release of the client records; and

3. The individual or institution complied with the appropriate security forms for the release of the client records or has entered into a contract with the department or agency that stipulates the department's or agency's requirements for the confidentiality of client records.

D. The confidentiality of human research activities involving public assistance, child support enforcement, and social services programs and clients is governed by 22VAC40-890, Human Subject Research Regulations, established pursuant to § 63.2-218 of the Code of Virginia.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-60. Client's right of access to client information.

Any client has the right to obtain their client record upon written or verbal request. The client must be permitted to review or obtain a copy of his client record with the following exceptions:

1. Information that the department, agency or provider is required to keep confidential pursuant to federal and state laws or regulations.

2. Information that the department, agency or provider may withhold from the client pursuant to the Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

3. Information that would breach another individual's right to confidentiality. When the material requested includes confidential client information about individuals other than the client, the parts of the client record relating to other individuals will be redacted.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-70. Publicizing safeguarding requirements.

The department, agency or provider shall inform clients in writing that client information shall be confidential pursuant to federal and state laws.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-80. Confidential client information pertaining to public assistance.

A. Confidentiality of client information of public assistance programs is assured by §§ 63.2-102 and 63.2-805 G of the Code of Virginia.

B. Information may be released only for a purpose directly connected with the administration of a public assistance program, except as herein provided or pursuant to §§ 63.2-102 and 63.2-805 G of the Code of Virginia.

C. Purposes directly related to the administration of a public assistance program include but are not limited to:

1. Establishing eligibility;

2. Determining the amount of public assistance;

3. Providing services for public assistance clients; and

4. Conducting or assisting in an investigation or prosecution of a civil or criminal proceeding related to the administration of the public assistance program.

D. Release of client records to law-enforcement agencies and Commonwealth's and county or city attorneys is governed by 22VAC40-320.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-90. Confidential client information pertaining to child support enforcement.

A. Confidentiality of child support enforcement client information is assured by §§ 63.2-102 and 63.2-103 of the Code of Virginia.

B. Information may be released only for a purpose directly connected with the administration of the child support enforcement program, except as herein provided or pursuant to §§ 63.2-102, 63.2-103, 63.2-1906 and 63.2-1940 of the Code of Virginia.

C. Purposes directly related to the administration of the child support enforcement program include but are not limited to:

1. Determining the amount of child support;

2. Providing child support enforcement services; and

3. Conducting or assisting in an investigation or prosecution of a civil or criminal proceeding related to the administration of the child support enforcement program.

D. The following regulatory provisions provide guidance on the release of child support enforcement client information:

1. Entities to whom the Division of Child Support Enforcement can release client information is governed by 22VAC40-880-520;

2. The release of client information to and from the Internal Revenue Service is governed by 22VAC40-880-530;

3. Request for client information from the general public is governed by 22VAC40-880-540;

4. Requests for client information from parents is governed by 22VAC40-880-550;

5. Release of health insurance information is governed by 22VAC40-880-560; and

6. Release of client records to law-enforcement agencies and Commonwealth's and county or city attorneys is governed by 22VAC40-320.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

22VAC40-910-100. Confidential client information pertaining to social services programs.

A. Confidentiality of client information of social services programs is assured by §§ 63.2-104 and 63.2-105 of the Code of Virginia.

B. Releasing confidential social services information.

1. The Commissioner of the Virginia Department of Social Services, the State Board of Social Services and their agents shall have access to all social services client records pursuant to § 63.2-104 of the Code of Virginia.

2. Social services client records must be confidential and can only be released to persons having a legitimate interest in accordance with federal and state laws and regulations pursuant to § 63.2-104 of the Code of Virginia. Section 63.2-104 of the Code of Virginia does not apply to the disclosure of adoption records, reports and information. The disclosure of adoption records, reports and information is governed by § 63.2-1246 of the Code of Virginia.

3. The following statutory and regulatory provisions provide guidance on the definition of legitimate interest as applied to specific social services programs:

a. Adult Protective Services client records can be released to persons having a legitimate interest pursuant to 22VAC40-740-50 B.

b. Child Protective Services Client Records and Information Disclosure:

(1) Child protective services client records can be released to persons having a legitimate interest pursuant to § 63.2-105 A of the Code of Virginia.

(2) The public has a legitimate interest to limited information about child abuse or neglect cases that resulted in a child fatality or near fatality. Pursuant to the Child Abuse and Prevention Treatment Act (CAPTA), as amended (P.L. 108-36 (42 USC § 5106a)) states must have provisions that allow for public disclosure of the findings or information about the case of child abuse or neglect that has resulted in a child fatality or near fatality. Accordingly, agencies must release the following information to the public, providing that nothing disclosed would be likely to endanger the life, safety, or physical or emotional well-being of a child or the life or safety of any other person; or that may compromise the integrity of a Child Protective Services investigation, or a civil or criminal investigation, or judicial proceeding:

(a) The fact that a report has been made concerning the alleged victim child or other children living in the same household;

(b) Whether an investigation has been initiated;

(c) The result of the completed investigation;

(d) Whether previous reports have been made concerning the alleged victim child or other children living in the same household and the dates thereof, a summary of those previous reports, and the dates and outcome of any investigations or actions taken by the agency in response to those previous reports of child abuse or neglect;

(e) The agency's activities in handling the case.

(3) Information regarding child protective services reports, complaints, investigation and related services and follow-up may be shared with the appropriate Family Advocacy Program representative of the United States Armed Forces as provided in 22VAC40-720, Child Protective Services Release of Information to Family Advocacy Representatives of the United States Armed Forces.

(4) The agency must release child protective services client records in the instances of mandatory disclosure as provided in 22VAC40-705-160. The local department may release the information without written consent.

4. Foster care client records about children in foster care or their parents can be released upon order of the court. For instance, client records may be released to the guardian ad litem and the court appointed special advocate who are appointed for a child as a result of a court order or to attorneys representing the child or the child's parents.

Statutory Authority: §§ 63.2-102 and 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003; amended, Virginia Register Volume 26, Issue 1, eff. October 14, 2009.

22VAC40-910-110. Other confidentiality regulatory provisions.

This regulation does not supersede existing regulations pertaining to the confidentiality of client records and should be read in conjunction with all public assistance, child support enforcement, and social services confidentiality regulations under Title 22 of the Virginia Administrative Code.

Statutory Authority: § 63.2-217 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 19, Issue 24, eff. September 1, 2003.

Appendix B

VDSS Institutional Review Board Membership

VDSS Institutional Review Board Members (FY 2013-2015)		
Name	**Qualification for Service/Job Title**	**Institutional Affiliation**
Gail Jennings (Co-Chair; IRB Coordinator)	PhD, Psychology Senior Research Analyst	Virginia Department of Social Services, Office of Research and Planning
Erik Beecroft (Co-Chair)	Ph.D., Economics Director of Research	Virginia Department of Social Services, Office of Research and Planning
Jennifer Behrens*	MSW; PhD candidate (Public Policy and Administration)	VDSS Division of Family Services, Quality Assurance and Accountability Unit
Mary Disse†	B.A., Psychology Post-Baccalaureate Certificate in Information Systems	Virginia Department of Social Services, Enterprise Delivery System Program (EDSP) Office
Erika Jones-Haskins*†	MSW Director for Program Initiatives	Homeward
Susan Spain*	MS, Sociology Senior Research Assistant	Virginia Commonwealth University, Division of Family Medicine
Greg Stolcis*	MSW; PhD, Public Policy and Administration	Virginia Commonwealth University (adjunct faculty)
Najmah Thomas*	PhD, Public Policy and Administration (urban policy) Policy Planning Specialist	Virginia Community College System, Workforce Data Quality Initiative
Tamara Temoney*	MSW; PhD, Public Policy and Administration (child welfare) Assistant Agency Director	Hanover Department of Social Services

* New member

† Non-scientist member

Appendix C

GENERAL REQUIREMENTS FOR INFORMED CONSENT

Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46
PROTECTION OF HUMAN SUBJECTS

[PDF 215 KB]

*** * ***

Revised January 15, 2009
Effective July 14, 2009

(excerpted)

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Appendix D

ASSURANCE OF CONFIDENTIALITY AND USE OF DATA AGREEMENT

Virginia Department of Social Services
Institutional Review Board

State Use Only
ID Number
Date Received

ASSURANCE OF CONFIDENTIALITY AND USE OF DATA AGREEMENT

Project Title

Name and Title of Principal Investigator (P.I.)	Telephone Number

Name of Institution/Agency

Address

Name and Title of Local Department of Social Services Collaborator or Contact (if included in study and different from Principal Investigator)

Address	Telephone Number

Proposed Dates for Project

Begin Date: _____ (mm/dd/yyyy) End Date: _____ (mm/dd/yyyy)

Assurance of Confidentiality

The undersigned hereby agrees to the following terms and conditions related to a request for release and use of confidential client information for research purposes:

1. Client records will be used only for the purposes for which they are being provided. Use of the information for a research project other than the one listed above will not be undertaken until a separate request is made to and approved by the Virginia Department of Social Services.
2. Client records will not be released to any persons not connected with the research.
3. Security safeguards will be in place to protect against loss and unauthorized access, use, modification or disclosure of client records. While identifiers still appear, access to paper, hardware and software will be secured. Paper records will be kept in locked cabinets and computers will be kept locked or have password protection.
4. Authorized persons involved in the research are required to maintain confidentiality of all client records connected with the research.
5. Identifying information from client records must not be discussed with, or released to, anyone except authorized persons involved in the research.
6. Final product(s) of the research will not reveal any information that may serve to identify any person about whom information has been obtained through the department, agency or provider, without written consent of such person and the department, agency or provider.
7. Authorized person(s) involved in the research who fail to comply with the terms of this confidentiality agreement will be immediately terminated from the research.
8. This confidentiality agreement must survive and continue after completion of the research. The individual or institution continues to be responsible for any breach.
9. Disclosure of client records in violation of §§63.2-102 and 63.2-104 of the Code of Virginia is a Class 1 misdemeanor.

Signature and Name of Principal Investigator or Requestor (if different from P.I.)	Date
Title	

Please sign and return completed form electronically (irb@dss.virginia.gov) or by mail to:

IRB Administrator
Institutional Review Board / Office of Research & Planning
Virginia Department of Social Services
801 East Main Street, 15th Floor
Richmond, VA 23219-2901.

Appendix E

VDSS IRB Forms To Request Reviews

- Request for Exemption Review
- Request for Review and Clearance of Human Subjects Research
- Request for Waivers of Informed Consent
- Continuation Review

Virginia Department of Social Services
Institutional Review Board
REQUEST FOR EXEMPTION REVIEW

Title of Study or Project	***State Use Only*** ***ID Number:***
Name of Principal Investigator	***Date Received:***
Address	E-Mail Address
	Telephone No.
Name of Department of Social Services Collaborator or Local Department Contact (if included in study and different from Principal Investigator):	E-Mail Address
Address	Telephone No.

The project identified above should be approved as exempt from review by the Institutional Review Board, based on the following exemption criteria (*please check all that apply*):

- ☐ It is conducted in an established educational setting(s).
- ☐ It involves the use of educational tests, survey/interview procedures, or observation of public behavior.
- ☐ It involves the collection or study of existing data, documents, or records that are publicly available or recorded in such a manner that subjects cannot be identified.
- ☐ It is conducted by, or subject to approval of, the Commissioner and studies or evaluates public benefit and service programs; procedures for obtaining benefits or services; possible changes in procedures; or possible changes in methods or levels of payment.

Please explain how the exemption(s) selected applies to the proposed research project:

Signature of Principal Investigator:_____ Date: _____

If submitting an electronic copy of this form and any supporting documents, please send to: irb@dss.virginia.gov.
If mailing paper copies of the completed form and supporting documents, please send to: IRB Administrator, Office of Research & Planning / Institutional Review Board, Virginia Department of Social Services, 801 East Main Street, 15th Floor, Richmond, Virginia 23219-2901.

Virginia Department of Social Services
Institutional Review Board

State Use Only

ID Number:

Date Received:

REQUEST FOR REVIEW AND CLEARANCE OF HUMAN SUBJECTS RESEARCH

Project Title	
Name and Title of Principal Investigator	Telephone Number
Name of Institution/Agency	
Address	
Name and Title of Local Department of Social Services Collaborator or Contact (if included in study and different from Principal Investigator)	
Address	Telephone Number

Proposed Dates for Project

Begin Date: _____ (dd/mm/yyyy) End Date: _____ (dd/mm/yyyy)

Assurance of Confidentiality

The undersigned hereby agrees to the following terms and conditions related to a request for approval for research:

1. Client records will be used only for the purposes for which they are being provided. Use of the information for a research project other than the one listed above will not be undertaken until a separate request is made to and approved by the Virginia Department of Social Services.
2. Client records will not be released to any persons not connected with the research.
3. Security safeguards will be in place to protect against loss and unauthorized access, use, modification or disclosure of client records. While identifiers still appear, access to paper, hardware and software will be secured. Paper records will be kept in locked cabinets and computers will be kept locked or have password protection.
4. Authorized persons involved in the research are required to maintain confidentiality of all client records connected with the research.
5. Identifying information from client records must not be discussed with, or released to, anyone except authorized persons involved in the research.
6. Final product(s) of the research will not reveal any information that may serve to identify any person about whom information has been obtained through the department, agency or provider, without written consent of such person and the department, agency or provider.
7. Authorized person(s) involved in the research who fail to comply with the terms of this confidentiality agreement will be immediately terminated from the research.
8. This confidentiality agreement must survive and continue after completion of the research. The individual or institution continues to be responsible for any breach.
9. Disclosure of client records in violation of §§63.2-102 and 63.2-104 of the Code of Virginia is a Class 1 misdemeanor.

Signature of Principal Investigator	Date
Name of Requester (if different from Investigator) (*Print*)	Title
Signature of Requestor	

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS

STATE USE ONLY
ID #:

1. Has this project been reviewed by any other IRB? If so, please list the institution's name and the date of review. (Please attach copy of approval if requesting an expedited review of this project.)

2. Summarize the study protocol or project activities (attach a copy of the full protocol to this request, for reference). Indicate specifically the way data will be collected and used.

3. List the potential risks to study participants.

4. List any potential benefits to study participants and/or to society.

5. Do your subjects include any of the following:

   a. Pregnant women or children (i.e., persons who have not attained the legal age for consent to treatments or procedures involved in the research)?

      ☐ Yes ☐ No

   b. Institutionalized, mentally infirm people?

      ☐ Yes ☐ No

   c. Inmates/Prisoners?

      ☐ Yes ☐ No

   Since these subjects and others like them, who are either not competent or not free to give their own consent, are particularly vulnerable to coercion and undue influence, investigators must incorporate safeguards in the research plan, and be certain to document fully their informed consent, or the informed consent of their legal representatives.

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS
(Continued)

STATE USE ONLY
ID #:

6. Informed consent must be obtained from the subjects or, in the case of children, the parent or legal guardian. Do you intend to use an informed consent form?

☐ Yes ☐ No

If yes, please enclose a copy of the proposed consent form. ALL SUBJECTS MUST BE TOLD AND UNDERSTAND THAT THEY CAN DECLINE PARTICIPATION IN THE RESEARCH.

If you DO NOT intend to use a consent form, please explain your reasons here:

7. In what form and to whom will the results of your study or activities be released?

8. Describe how your organization will store and maintain the confidentiality of the identifying information.

9. Describe the disposition of identifying information (method and intended time frame).

10. Please provide any other information that would be helpful to the decision-making of the IRB.

If you are submitting electronic copies of this form, along with copies of the project protocol and other supporting documents, please send to: irb@dss.virginia.gov. If you are submitting paper copies of this form with supporting documentation, please mail to:

IRB Administrator
Institutional Review Board / Office of Research & Planning
Virginia Department of Social Services
801 East Main Street, 15th Floor
Richmond, VA 23219-2901.

Virginia Department of Social Services
Institutional Review Board

REQUEST FOR WAIVERS OF INFORMED CONSENT

(To be submitted with "Request for Review and Clearance of Research")

Under special circumstances, Principal Investigators can request one of two kinds of waivers to obtain written informed consent from research subjects. *These waivers will be given only when there are compelling reasons for doing so.*

The first is a waiver of written documentation, where informed consent is obtained orally. With this waiver, the investigator is required to read or provide the informed consent form to a participant but does not need to obtain the participant's signature on the consent form. Examples when this waiver might be applicable include some Internet or telephone surveys or when signing the consent form might have negative consequences for the subject.

The second is a waiver of informed consent itself. With this waiver, the investigator is not required to give, or read, the informed consent form to a participant. This waiver may be approved by the IRB if the criteria given below are met.

Please check which type of consent waiver is being requested:

☐ **Waiver of written documentation** ☐ **Waiver of informed consent**

In order for your request to be considered, please answer fully each of the following questions. Make sure that each response includes thorough explanation and description. Please provide supporting documentation, as appropriate.

1. Will the research in its entirety involve more than minimal risk to participants? Identify the risk.

2. Why is it practical to conduct the research without the waiver/alteration?

3. Will waiving/altering informed consent adversely affect subjects, their rights, or their welfare? Please explain.

4. Will pertinent information be provided to the subjects later, if appropriate? If yes, when?

5. Can the research be conducted practicably without access to and use of the protected health information?

6. Are the privacy risks to individuals whose protected health information is to be used or disclosed reasonable relative to: (a) the anticipated benefits to the individuals, if any, and (b) the importance of the knowledge that may reasonably be expected to result from the research?

7. Is there an adequate plan to protect the identifiers from improper use and disclosure? Briefly, explain the plan.

8. Is there an adequate plan to destroy the identifiers at the earliest opportunity, consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law?

If you are submitting electronic copies of this form, along with copies of the project protocol and other supporting documents, please send to: irb@dss.virginia.gov. If you are submitting paper copies of this form with supporting documentation, please mail to:

IRB Administrator
Institutional Review Board / Office of Research & Planning
Virginia Department of Social Services
801 East Main Street, 15th Floor
Richmond, VA 23219-2901.

Virginia Department of Social Services
Institutional Review Board

CONTINUATION REVIEW

Please complete this form for multi-year studies that were reviewed initially, on an annual basis.

Project Title	ID Number (***State Use Only***)
Name and Title of Principal Investigator	E-Mail Address
Address	Telephone Number
Name and Title of Local Department of Social Services Collaborator or Contact (if included in study and different from Principal Investigator):	E-Mail Address
Address	Telephone Number

Please complete **either** Section I or Section II.

Section I. This study does not require a continuation review because:

- ☐ It is no longer in progress.
- ☐ It was recently reviewed for continuation on (*date*): ____ / ____ / ____ / .
- ☐ It was never started.
- ☐ Other (*please specify*):

_____

Section II. For studies that require a continuation review:

1. How many subjects are included in the study?

2. Are you aware of any adverse events or unanticipated problems involving risks to subjects or others, including breach of confidentiality, withdrawal of subjects, or complaints about the study?

   ☐ Yes ☐ No

   If Yes, please explain:

3. Please summarize any recent literature, findings, or other relevant information, especially information about risks associated with this research, of which subjects should be made aware.

Have subjects been informed of this information?

☐ Yes ☐ No *If No, why not? When will they be informed?*

4. Have there been any changes in the Informed Consent form?

☐ Yes ☐ No *If Yes, please submit a copy of the revised form.*

5. Have there been any significant changes in your research protocol from the original?

☐ Yes ☐ No *If Yes, please describe:*

Signature of Principal Investigator	Date

If submitting an electronic copy of this form and any supporting documents, please send to: irb@dss.virginia.gov. If mailing paper copies of the completed form and supporting documents, please send to: IRB Administrator, Institutional Review Board / Office of Research & Planning, Virginia Department of Social Services, 801 East Main Street, 15th Floor, Richmond, Virginia 23219-2901.

Appendix F

VDSS Institutional Review of Human Subjects Research: The Process

- The Human Subject Research Regulations (22VAC40-890-10:100 of the *Virginia Administrative Code*), effective February 2003, require the review of proposed human research conducted or authorized by the department, local agencies, facilities, or contractor. The review is intended to ensure that the subjects' rights to privacy and welfare are maintained, that risks are minimal, and that participants provide informed consent. The regulations have been reviewed through the regulatory review process in 1995, 1998, and 2002.

- Data are protected by confidentiality regulations, §63.2-104 in the *Code of Virginia*, which allow information and statistics to be "disclosed to any person having a legitimate interest in accordance with state and federal law and regulation" and by 22VAC40-910-50 (Release of client records for research purposes).

- VDSS is responsible for the application of the Human Subject Research Regulations but does not have the authority to authorize a local agency to provide data to an outside agency.

- The process for obtaining authorization to conduct research on staff or clients involves:

  1. Contacting the VDSS IRB Administrative Coordinator
  2. Submitting to the Administrative Coordinator a research proposal that details:
     - ☐ Purpose and scope of research
     - ☐ Subjects, data source, and subject selection criteria
     - ☐ Methodology
     - ☐ Risk assurances:
       - Statement of potential risks, costs, and benefits to subjects
       - Informed consent forms
       - Method for obtaining signed informed consent forms
       - Statement of voluntary agreement and ability of subject to withdraw at any time
       - Assurance of participation without duress or withholding of services
       - Procedures for proxy informed consent
       - Methods for protecting clients' rights
       - Informed consent forms and other documents to subjects written in understandable language
     - ☐ Confidentiality assurances:
       - Access to records

- Protection of identifying information
- Assurance of releasing only non-identifying data
- Statements to subjects regarding confidentiality, expected length of participation, and intended use and purpose of research

☐ IRB or other approval from sponsoring institutions, if possible

☐ Qualifications of research team (e.g., CV, resume, job description).

3. Coordinator reviews the proposal to determine whether it qualifies as:

☐ Exempt research: Research proposal meets regulation criteria

OR

☐ Non-exempt research

- Commissioner appoints research review committee
- Expedited review for research with minor risks, or
- Full review for all other research

4. Coordinator notifies researcher by mail/email of VDSS decision.