COMMONWEALTH OF VIRGINIA
DEPARTMENT OF SOCIAL SERVICES

October 1, 2005

TO: The Honorable Mark R. Warner

and

General Assembly of Virginia

Section 63.2-218 of the *Code of Virginia* requires the State Board of Social Services to adopt regulations regarding human research. The statute further requires that the regulations provide for an annual report to the Governor and General Assembly on the human research projects reviewed and approved.

In May 2005, the Department established the Institutional Review Board (IRB) to serve as its human research committee. The IRB is charged with reviewing, approving and monitoring research conducted by the Department, local departments of social services, contractors and licensed facilities. The enclosed report addresses the Department's human research activities for calendar year 2005, and the two research proposals that were reviewed and approved by the IRB. The projects focus on child maltreatment and foster care youth transitioning to adulthood. The report also includes IRB's policy and procedures manual and membership information.

Respectfully submitted,

Anthony Conyers, Jr.
Commissioner

7 North 8th Street • Richmond, VA, 23219
http://www.dss.state.va.us • (804) 726-7000 • TDD 1-800-828-1120

REPORT ON THE VIRGINIA DEPARTMENT OF SOCIAL SERVICES HUMAN RESEARCH COMMITTEE FOR CALENDAR YEAR 2005

Virginia Department of Social Services
October 1, 2005

REPORT ON THE VIRGINIA DEPARTMENT OF SOCIAL SERVICES HUMAN RESEARCH COMMITTEE FOR CALENDAR YEAR 2005

TABLE OF CONTENTS

REPORT ON THE VIRGINIA DEPARTMENT OF SOCIAL SERVICES HUMAN RESEARCH COMMITTEE FOR CALENDAR YEAR 2005

EXECUTIVE SUMMARY

The purpose of this report is to provide the General Assembly with a summary of the activities of the Virginia Department of Social Services' (VDSS) human research committee for calendar year 2005. Section 63.2-218 of the Code of Virginia directs the State Board of Social Services to establish regulations regarding human subjects research. The statute further provides that the human research committee will report to the Governor, General Assembly and Commissioner at least annually on research projects reviewed and approved. The Institutional Review Board (IRB) serves as the Department's human research committee, and is charged with reviewing, approving and monitoring research conducted or authorized by the Department, local departments of social services, contractors, and licensed facilities.

A key foundation for establishing human subjects research regulations is the National Research Act of 1974 (Public Law 93-348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In April 1979 the Commission produced a landmark document, known as the Belmont report, to provide guidance for protecting human subjects involved in research.

Research involving VDSS clients generally involves no risk of physical harm, because it is not clinical research but observational studies of human behavior. The potential risks for VDSS studies most often involve issues of clients' privacy and, to a lesser extent, psychological harm (for example, from surveys that include sensitive questions). The VDSS IRB has been established to protect clients' privacy and more generally to minimize the risks of research activities.

For calendar year 2005 to date, the VDSS IRB has reviewed two proposed research studies. Both studies were approved. In addition, a policy and procedures manual was developed for the IRB to delineate processes for conducting reviews of proposed research.

REPORT ON THE VIRGINIA DEPARTMENT OF SOCIAL SERVICES HUMAN RESEARCH COMMITTEE FOR CALENDAR YEAR 2005

Study Mandate

The purpose of this report is to summarize for the Governor and General Assembly the activities of the Virginia Department of Social Services' (VDSS) Institutional Review Board (IRB) for calendar year 2005. The IRB is charged to review, approve and monitor research conducted or authorized by the Department, local departments of social services, contractors, and licensed facilities. Section 63.2-218 provides the following:

> *"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."*

Background

A key foundation for establishing human subjects research regulations is the National Research Act of 1974 (Public Law 93-348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979 the Commission produced a landmark document, known as the Belmont report, to provide guidance for protecting human subjects involved in research. Public attention on the welfare of individuals participating in research climaxed during the Nuremberg Trials after World War II, resulting in the creation of the Nuremberg Code and other rules that provide limited direction for physicians and scientists conducting research using human subjects.[1] Based on the three principles and three applications outlined in the Belmont Report, current federal and state regulations provide systematic processes for protecting the rights and welfare of individuals who participate in research activities. Current review standards employed by the VDSS IRB are based on the guiding principles of the Belmont Report- respect of persons, beneficence and justice- and incorporate the requirements of informed consent, risk/benefit assessment, and the equitable selection of research subjects.

The Office for Human Research Protections (OHRP), an office of the U.S. Department of Health and Human Services (HHS), is responsible for ensuring the rights and welfare of individuals who participate in research activities supported by or conducted by HHS. OHRP oversees compliance with federal regulations on human subjects research established in Title 45 CFR Part 46. In 1992 the Virginia General Assembly authorized the State Board of Social

1 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington DC: U.S. Printing Office, 1979 The report can be accessed at http://ohsr.od.nih.gov/guidelines/belmont.html

Services to establish a human subject research committee and promulgate state regulations concerning the review and approval of research conducted by VDSS, local departments of social services, or VDSS licensed facilities and contractors.

Most research involving VDSS clients is not biomedical in nature. Typically, VDSS clients participate in social or behavioral studies and evaluations. Questions of physical risk are rare. Most often potential risks in VDSS related studies involve issues of privacy. Research projects may also include survey questions on subjects that are psychologically or sociologically sensitive. The VDSS IRB reviews such research in advance to ensure that the rights of our clients are protected and that proposed research maintains the privacy and welfare of participants.

HUMAN RESEARCH ACTIVITES FOR CALENDAR YEAR 2005

In May 2005, the VDSS Commissioner appointed seven members to the IRB. Appendix D lists the members of the IRB. Staff in the VDSS Office of Research are responsible for administering the IRB and ensuring VDSS compliance with human subjects research regulations. The VDSS Director of Research serves as the chairperson of the IRB and a policy planning analyst coordinates the administration of the IRB and proposal reviews. Major activities in support of the IRB for CY 2005 included:

- Attending a the federally-sponsored videoconference entitled, "Human Subjects Protections: A Regulatory Overview", held at the Virginia Department of Health;
- Reviewing federal and state regulations on human subjects research, and guidelines from various sources on IRB administration, policies and procedures;
- Developing a policy and procedures manual for the IRB to use in reviewing proposed research, which was approved by the IRB (Appendix B); and
- Developing forms for researchers seeking approval from the IRB for research activities.

Human Research Projects Reviewed

The IRB conducted a full board review of two research proposals to date during calendar year 2005. No expedited or exemption reviews were conducted during this time frame. The following section summarizes each proposal received and the decisions reached by the IRB.

Study #: **20051W**
Principal Investigator: Andrea Sedlak, P.h.D
Westat
Title of Protocol: Fourth National Incidence Study of Child Abuse and Neglect (NIS-4)
Date approved: August 2, 2005
Description of Study: The protocol is a congressionally mandated national incidence study on child maltreatment. The study measures the incidence and prevalence of child maltreatment by a wide array of demographic characteristics, including age, sex, race, family structure, household relationship, school enrollment, educational attainment,

disability, grandparents as caregivers, labor force status, and income. Information is gathered from formal reports made to Child Protective Services (CPS) system and from community level "sentinels" who are professionals who encounter child abuse and neglect situations during the course of their work in law enforcement, health care, child care, education and other sectors.

The IRB approved the study without any special conditions.

Study #:	**20052G**
Principal Investigator:	Glenda Clare, Doctoral Candidate College of William and Mary
Title of Protocol:	"Perception of Barriers and Coping Efficacy as Determinants of Readiness for Transition to Adulthood Among Youth in Care"
Date approved:	August 2, 2005 (Conditional Approval)
Description of Study:	The researcher proposes to investigate whether the perception of barriers and coping-efficacy of foster care youth transitioning to adulthood are related to acquisition of life skills and predict success in adulthood. Three Ansell-Casey Life Skills assessments will be used to measure life skills, perception of barriers and coping abilities for a convenience sample of 250 foster care youth who are 18 years of age or older. The researcher proposes to include former foster care youth from state social service agencies and other youth organizations in several cities and states, including Virginia, Arizona, Maryland, and Tennessee.

The IRB conditionally approved the proposal and requested that the investigator (1) modify the informed consent document to improve its readability and clarity for the intended audience; and (2) confirm an appropriate process for identifying potential participants with the Independent Living program manager.

Significant Changes to Approved Proposals

No research projects were reviewed or approved by the VDSS research committee during the previous year. There are no reports regarding significant changes to previously approved protocols for Calendar Year 2005.

IRB Membership

The State Board of Social Services' human research regulations require that IRB members "ensure the competent, complete, and professional review of human research." Five of the seven appointed members represent various divisions and expertise of VDSS, and bring a wealth of knowledge and experience related to VDSS programs and constituents. Additionally, regulations require that two members hold no affiliation with VDSS. Two members are members of the community at large, including one member of the clergy. The current IRB members fully meet the membership requirements of both state and federal human research regulations. Appendix D identifies the name, area of expertise and education, and affiliation with VDSS for each current IRB member.

IRB Meetings

The VDSS IRB planned to hold a full board meeting on July 26, 2005. However, only three members were able to attend and the committee did not reach a quorum for a full board review. On August 2, 2005 the IRB met and voted on two research proposals. Members in attendance conducted the reviews as summarized in the previous section. Minutes of the August 2, 2005 meeting are included in Appendix C.

Results of Approved Research

VDSS' IRB has requested that each of the investigators responsible for the research projects approved in 2005 submit copies of their final research reports at the conclusion of their research activities. There are no previously approved studies for which results were generated in CY 2005.

Appendix A

Study Mandate

STUDY MANDATE

Code of Virginia

§ 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.

APPENDIX B

VIRGINIA DEPARTMENT OF SOCIAL SERVICES INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES

Acknowledgements

The contents of this manual, particularly the procedures for IRB review, borrow heavily from the Virginia Department of Health IRB Guidelines and Procedures Manual. We gratefully acknowledge their assistance.

For questions or comments about this manual, please contact:

Zandra Relaford
Virginia Department of Social Services
Division of Quality Management/Office of Research
7 North Eighth Street
Richmond, VA 23219
zandra.relaford@dss.virginia.gov
804-726-7619

Table of Contents

1. 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 authorized contractors to ensure the privacy and protection of VDSS clients.

Human Subject Research regulations apply to:

- All program divisions and units within the Virginia Department of Social Services;
- Local Departments of Social Services;
- Facilities licensed by the department ; and
- Contractors that 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: Title 45, Part 46 Protection of Human Subjects; the Code of Virginia, §63.2-217 and §63.2-218; and Virginia Administrative Code 22 VAC 40-890-10:110 and 22VAC 40-910-10:110. The state law and regulations are included as Appendix A.

C. Board Membership

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

2. 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 is 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 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 at 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, outside investigators in collaboration with VDSS or local departments of social services, facilities licensed by VDSS, or by outside investigators using VDSS data, is potentially subject to review and approval by the VDSS Institutional Review Board.

However, not all studies require IRB review. This section covers the process for determining the need for IRB review. The decision-making process is divided into four key questions:

Question 1: Does the project involve human subjects?

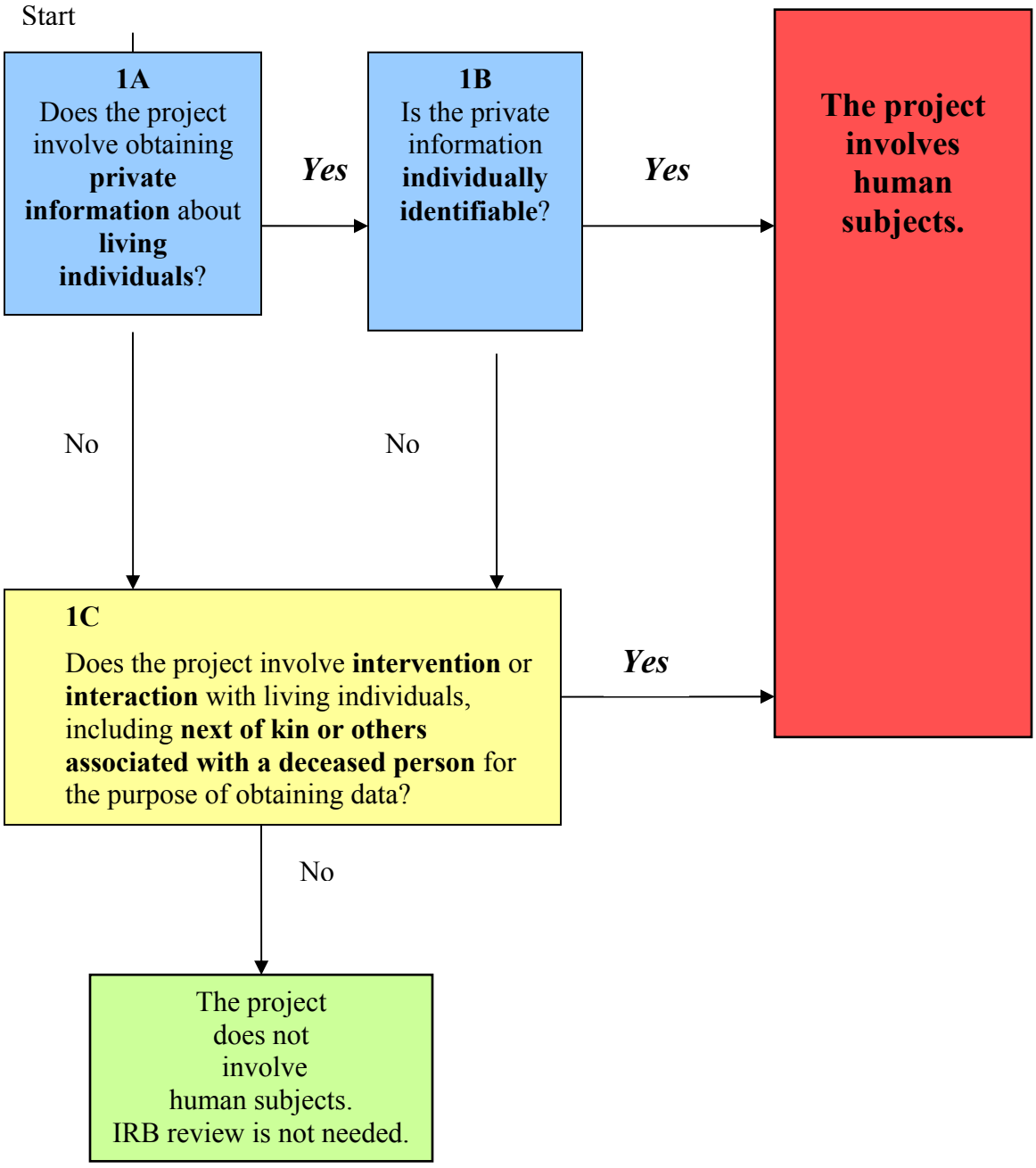
Question 2: Is the project considered research?

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?



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. by name, SSN), or (2) the identity of the subject may readily be inferred from the information obtained.

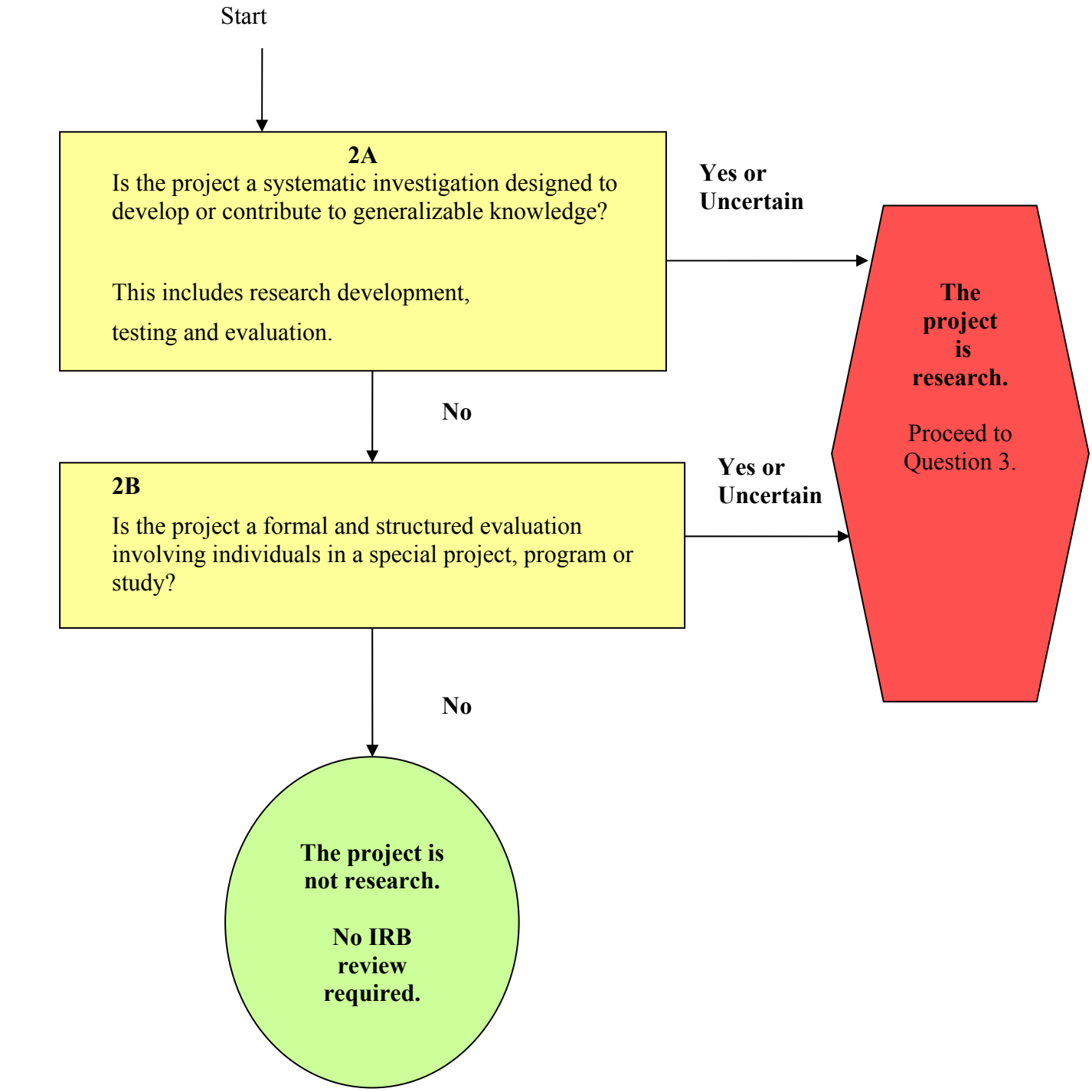
1C. Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?

Intervention includes physical procedures by which data are collected, such as venipuncture, and manipulations of the subject or the subject's environment. ***Interaction*** includes communication or interpersonal contact with the subject, the subject's next of kin, or the subject's physician or hospital.

If "yes" is the answer to any of the above three questions, then proceed to Question 2: Is the Research Exempt from Human Subject Regulations?

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 Research?



Question 2: Is The Project 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 immediately used to benefit the 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?

Virginia Administrative Code defines research as any formal and structured evaluation involving individuals in a special project, program, or study. *[22 VAC 40-890-10]*

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.

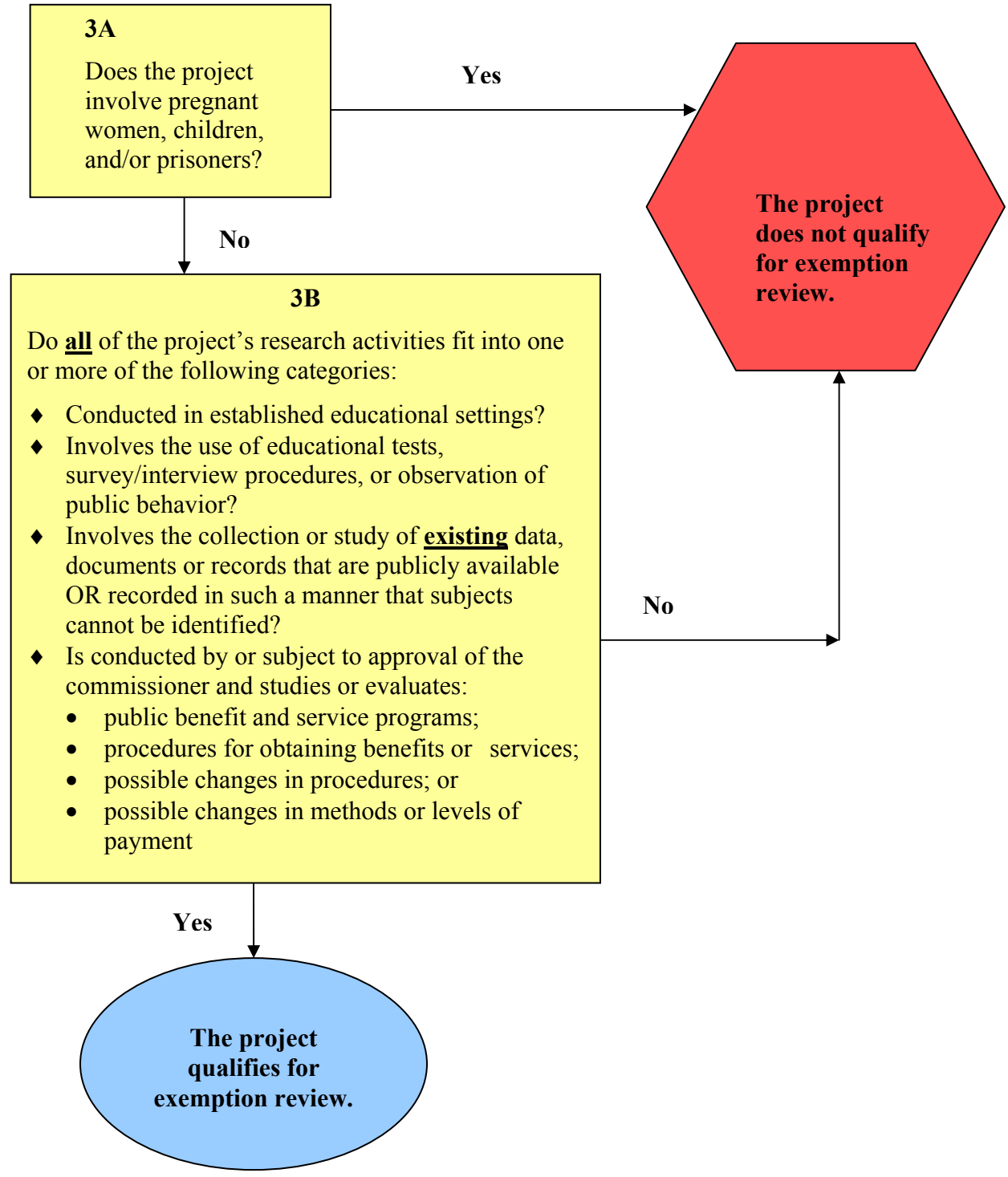
However, if the purpose of a program evaluation is to develop or contribute to generalized knowledge, the project is considered research. In some instances, evaluation research may qualify for exemption review (see Question 3).

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 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, then 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?



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 who is also a member of the review board.

All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

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 only one activity is not exempt, the 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 must undergo either expedited or full board review and does **not** qualify for exemption 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 ore more of the following four 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 subjects' 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 will be retained 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

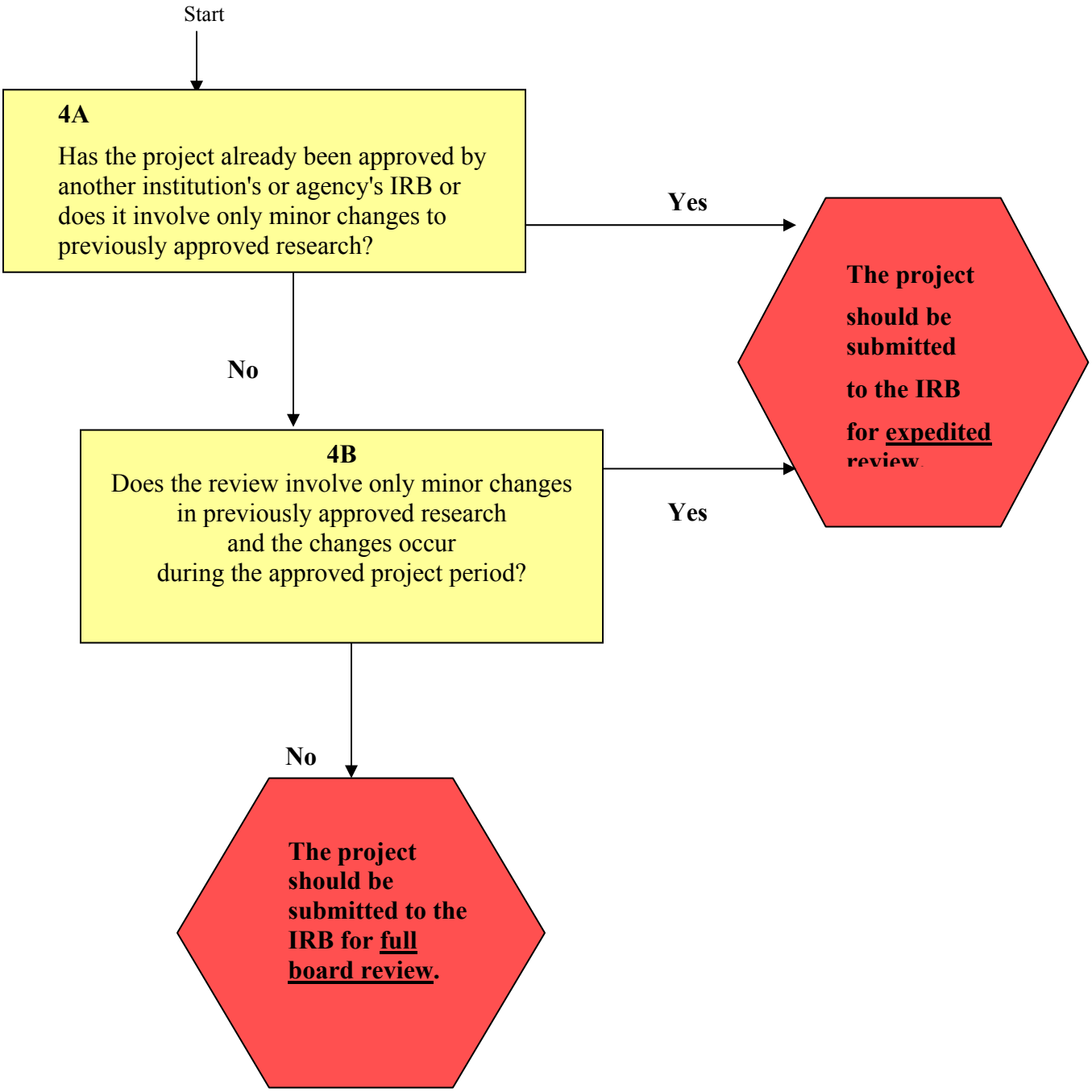
(d) possible changes in methods or levels of payment for benefits or services under those programs

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?



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. All IRB decisions regarding approval or required modifications will be communicated to the principal investigator in writing within 30 business days after submission. 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 or does it involve only minor changes to previously approved research occurring during the approved project period?** 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)

4B. The review involves only minor changes in previously approved research and the changes occur during the approved project period. (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 with human subjects in one or more of the qualifying categories, then the investigator should submit the protocol for expedited review.

However, if the project has **NOT** been reviewed by another IRB, **and/or** all activities do **NOT** involve more than minimal risk with human subjects in one or more of the qualifying categories, then the project must be submitted to the IRB for full board review.

C. Informed Consent

Voluntary informed consent signed by the participant or by the participant's legally authorized representative is required for all human research projects.

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 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.

D. 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 designee(s), or division 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.

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.

3. Institutional Review Board Procedures

This section describes the operation of the IRB, in terms of 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 in the U.S. Department of Health and Human Services recognizes IRB meetings that are conducted via telephone calls and video conferences provided that:

a. Each participating IRB member has received all pertinent material prior to the meeting, and

b. Each participant can actively and equally participate in the discussion of all protocols.

In addition to the usual regulatory requirements, 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.

The IRB is required by state regulations to review 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 7 business days of the IRB meeting where 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 Management.

(1) Requests for Exemption from IRB Review

If an investigator believes that their research project qualifies for exemption (see Question 3), the following is a checklist of documents that must be submitted in order to obtain IRB exemption status:

☐ Request for Exemption from IRB Review Form (Appendix D)

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

☐ Study protocol, including sections on:

- Hypotheses
- Goals 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)

☐ CV or resume of Principal Investigator

Exemption review requires the submission of electronic copies of the "Request for Exemption" application and supporting documents. 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 additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

(2) Requests for 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 a Project Involving Human Subjects (Appendix C)

☐ Study protocols, including sections on
- Hypotheses
- Goals 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).

☐ 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 via Full Board Review by the IRB of another agency)

Investigators must submit one electronic copy of the "Request for Review" application and supporting documents.

The decision to approve or disapprove a project submitted for expedited review will be made by the Chair of the IRB, his/her designee and one additional member of the review board.

All IRB decisions regarding approval, disapproval, or of required modifications will be submitted in writing to the principal investigator within 15 business days following completion of the expedited review.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project. The Office of Research Management will automatically mail out the continuing review report form to principal investigators just prior to the review due date. The form must be completed and returned for ongoing projects.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments) in the protocol or the subject population, another request for IRB review must be filed.

(3) Requests for Full Board Review

The following is a checklist of documents that must be submitted in order to obtain IRB exemption status:

☐ Request for IRB Review and Clearance of Research Form (Appendix C)

☐ Study protocol, including sections on

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

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

☐ Questionnaire(s) (when applicable)

☐ CV or resume of Principal Investigator

All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the investigator in writing within 7 business days of the IRB meeting where the submission is reviewed.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, another request for IRB review must be filed.

FORMS

Virginia Department of Social Services
Institutional Review Board

REQUEST FOR VDSS IRB REVIEW OF HUMAN SUBJECT 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

1. The undersigned hereby agrees to the following terms and conditions related to a request for approval for research:
2. No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable without the written permission of the subject(s) involved.
3. The identifying information will be used only for statistical purposes in human services and social science research.
4. The identifying information will not be used as a basis for legal, administrative, or other actions which may directly affect those particular individuals as a result of their specific identification in this project.
5. The identifying information will be used only for the study or project proposed and the purposes described in the attached document. Use of the information for a research project other than the one described will not be undertaken until a separate request is made to and approved by the Virginia Department of Social Services.
6. 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.
7. All statements made to the Virginia Department of Social Services are correct.

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

REQUEST FOR VDSS IRB REVIEW OF HUMAN SUBJECT RESEARCH

(Continued)

1. Has this project been reviewed by any other IRB? If so, please list the institution's name and date of review. Attached 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 (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 VDSS IRB REVIEW OF HUMAN SUBJECT RESEARCH
(Continued)

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 IRB.

Submit electronic copies of this completed form, copies of the project protocol and other supporting documents to zandra.relaford@dss.virginia.gov .
If you are submitting paper copies of this completed form and other supporting documents, please mail them to
Zandra Relaford, Virginia Department of Social Services,
Office of Research Management/Institutional Review Board
7 North Eighth Street, Richmond, VA 23219-3301.

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 and from Principal Investigator:	E-mail Address
Address	Telephone No.

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

- ☐ Is conducted in established educational settings?
- ☐ Involves the use of educational tests, survey/interview procedures, or observation of public behavior?
- ☐ 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?
- ☐ 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 selected exemption(s) apply to the proposed research project:

Signature of Principal Investigator: _____Date: _____

Appendix C

IRB Meeting Minutes

IRB MEETING MINUTES
July 26, 2005

Meeting Date: July 26, 2005
Location: Virginia Department of Social Services

Members Present	Members Absent
Erik Beecroft, Chairperson	Kathy Hoke
Mary Disse	Cynthia Holden
James Nesmith	Lynette Isbell
	Robert Pyndell

Studies Submitted for Review:
200501W -
200502G -

With three members in attendance, the IRB did not have a quorum. Several members experienced family emergencies and were unable to attend the meeting. Staff presented a brief overview of IRB responsibilities and procedures for conducting research reviews. The group briefly discussed studies submitted for review, but no votes for approval were entered. Members agreed to reschedule a meeting when more members were available.

IRB MEETING MINUTES
August 2, 2005

Meeting Date: August 2, 2005
Location: Virginia Department of Social Services

Members Present	Members Absent
Erik Beecroft, Chairperson	Kathy Hoke
Mary Disse	Cynthia Holden
James Nesmith	Lynette Isbell
Robert Pyndell	

Studies Submitted for Review:
200501W
200502G

Erik Beecroft called the meeting to order. After a brief overview of materials that had been prepared for the meeting, staff presented summaries of each of the studies. The risks and benefits of each study were discussed.

Attending members voted on each of the studies presented. Study #200501W was unanimously approved (4-Yes; 0-No). Study #200502G was conditionally approved (3-Yes/Conditional Approval; 1-Approved as Submitted; 0-No). IRB members requested that the researcher modify the informed consent to increase its readability and clarity for the intended audience. Also, the research will be asked to contact the appropriate VDSS program staff to develop an appropriate process for identification of study participants.

After discussion on these two studies concluded, the meeting was adjourned.

Appendix D

IRB Membership

APPENDIX D
VDSS IRB MEMBERSHIP

VDSS Institutional Review Board		
Name	**Qualification for Service**	**Institutional Affiliation**
Erik Beecroft, Chairperson	Ph.D. in Economics Director of Research	Virginia Department of Social Services
Mary Disse	B.A. in Psychology Post-Baccalaureate Certificate in Information Systems,	Virginia Department of Social Services
Kathy Hoke	Ph.D. in Mathematics Associate Dean for Research Support, Director of the Graduate School of Arts and Sciences	University of Richmond
Cynthia Holdren	M.P.A., Manager of Management Services Unit, Division of Child Support Enforcement	Virginia Department of Social Services
Lynette Isbell	Assistant Director, Division of Family Services	Virginia Department of Social Services
Robert Pyndell	Financial Analyst, Division of Child Care and Development	Virginia Department of Social Services
James Nesmith	M. of Div., Minister	West Broad Church of Christ Urban Ministry in Richmond, Virginia