VIRGINIA DEPARTMENT OF HEALTH

INSTITUTIONAL REVIEW BOARD

Guidelines and Procedures

August 2023

The Virginia Department of Health IRB Guidelines and Procedures Manual is available on the VDH web site:

irbguidelines.pdf (virginia.gov)

Acknowledgements

Special thanks to Gail Jennings, Ph.D. Co-Chair and the Virginia Department of Social Services (VDSS) IRB Administrative Coordinator for graciously sharing information from their IRB Guidelines and Procedures Manual. We also continue to be grateful to Kathy Wibberly, Ph.D. for all the work that she contributed in establishing the VDH IRB.

Thanks also to the VDH IRB members for their review and comments on this manual.

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The VDH Institutional Review Board
Guidelines and Procedures Manual

I. Introduction

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

A. Purpose of the VDH Institutional Review Board

The purpose of the Virginia Department of Health (VDH) Institutional Review Board (IRB) is to ensure that human research involving VDH clients maintains an individual's rights to privacy and protection from harm or risk. The IRB reviews research proposals and request 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, VDH authorized contractors or outside researchers to ensure the privacy and protection of VDH clients.

Human research means any systematic investigation, including research development, testing, and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. *Human subject* means a living person about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the person or identifiable private information. *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. *Intervention* includes manipulations of the subject or the subject's environment that are performed for research purposes.

Human Subject Research regulations apply to:

- All program divisions and units within the Virginia Department of Health including all district health departments.
- Any facilities licensed by VDH.
- All contractors or outside researchers who are authorized to conduct or propose to conduct any human research involving VDH clients or VDH data.

B. Legal Authority for the VDH Institutional Review Board

The VDH IRB is authorized to review and approve proposed research as directed by the Code of Federal Regulation CFR Title 45, Part 46 (Protection of Human Subjects). Section 32.1-12.1 of the *Code of Virginia* charges the State Board of Health with promulgating regulations pursuant to the *Administrative Process Act* (§2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16) of this title for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by

the Department. The *Virginia Administrative Code*, 12VAC5-20-10-120 (The Conduct of Human Research Regulations) and the state law are included in Appendix A.

C. Board Membership

State regulations require that the VDH IRB consists of at least five (5) members who are appointed by the State Health Commissioner. At least (one) 1 member of the board must be an individual whose primary concerns are in non-scientific or ethical areas. 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, alternate/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 additional 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.

II. Institutional Review Board Policies

This section describes the policies guiding IRB review of human research activities and 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 VDH unless the VDH 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 *45 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* following the IRB review. Research proposals must be either approved or granted an exemption by the VDH IRB before any research activities begin.

During the review process, no personal identifiers of present or potential participants shall be presented or discussed.

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. The IRB may modify, suspend or terminate approval of research that has been associated with serious harm to subjects or is not being conducted in accord with the IRB's decisions and requirements.

The IRB also conducts continuing review of each approved protocol at least annually. The required frequency of the review shall be consistent with the nature and degree of risk of the research projects. Investigators must also submit a final report from the research project following the conclusion of the project.

B. Key Determinations for Human Subjects Research Review

Any research that is conducted by VDH, outside investigators in collaboration with VDH, any facilities licensed by VDH, or by outside investigators using VDH data, is potentially subject to review and approval by the VDH IRB. Accordingly, research conducted or supported by a federal department or agency involving VDH clients must be reviewed and approved by the VDH IRB.

However, not all studies require VDH 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:

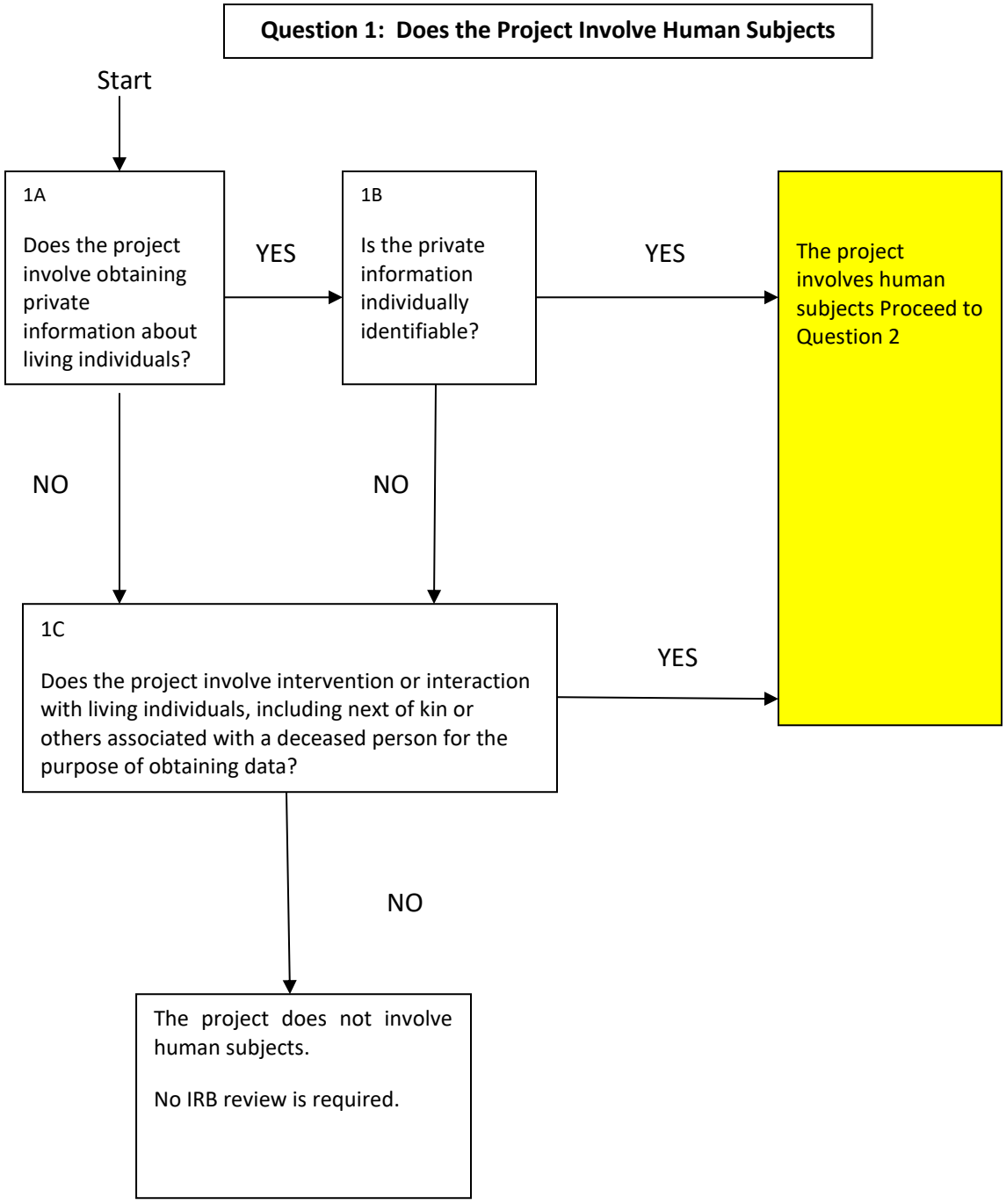
Question 1: Does the project involve human subjects?

Question 2: Is the project considered research?

Question 3: Does the project qualify for exemption review?

Question 4: Does the project quality 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
Start
1A
Does the project involve obtaining private information about living individuals?
YES
1B
Is the private information individually identifiable?
YES
The project involves human subjects Proceed to Question 2
NO
NO
1C
Does the project involve intervention or interaction with living individuals, including next of kin or others associated with a deceased person for the purpose of obtaining data?
YES
NO
The project does not involve human subjects.
No IRB review is required.

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.

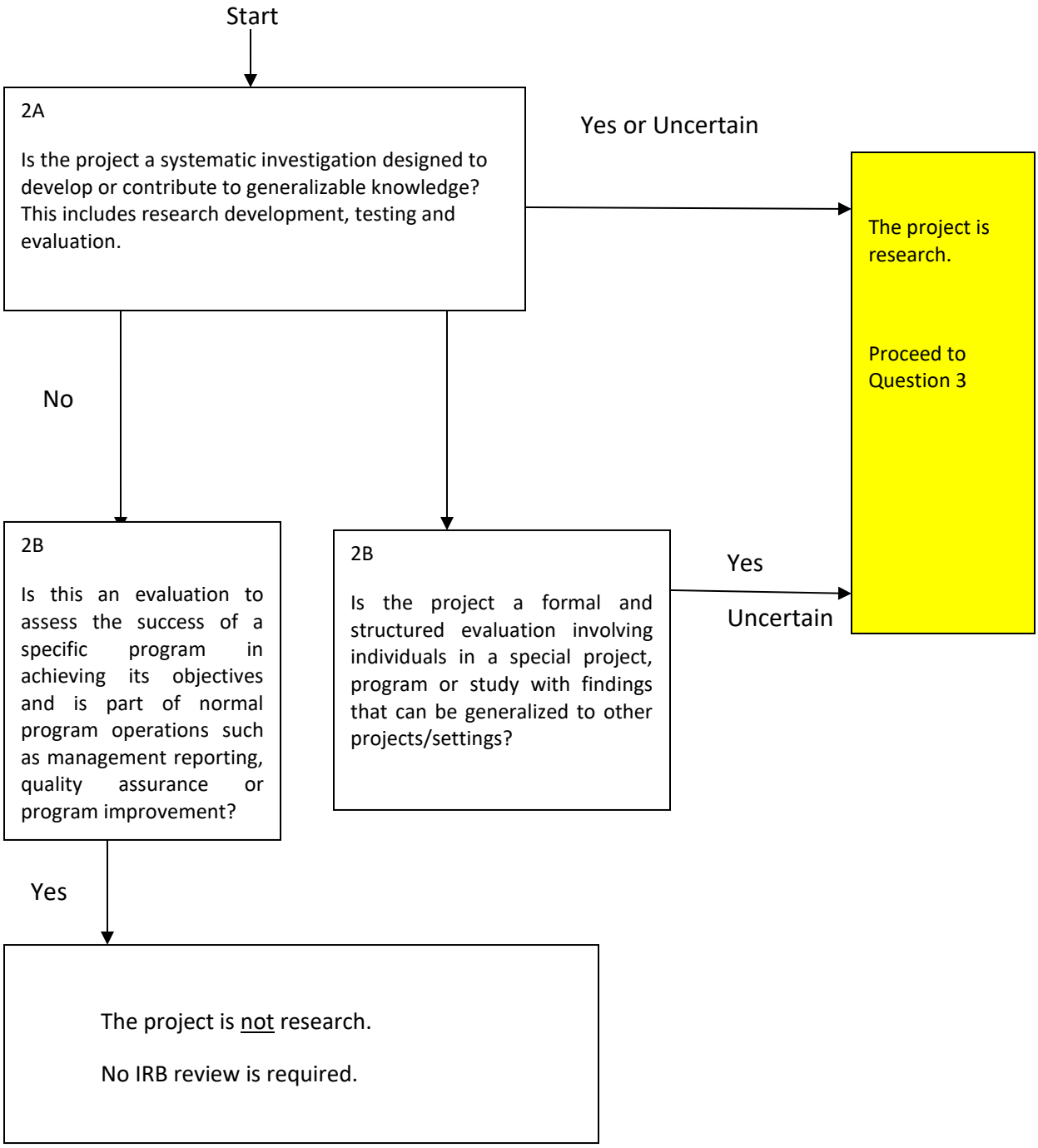
1C. Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?

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 <u>not</u> need to be reviewed by the VDH 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 VDH IRB to determine the need for review.

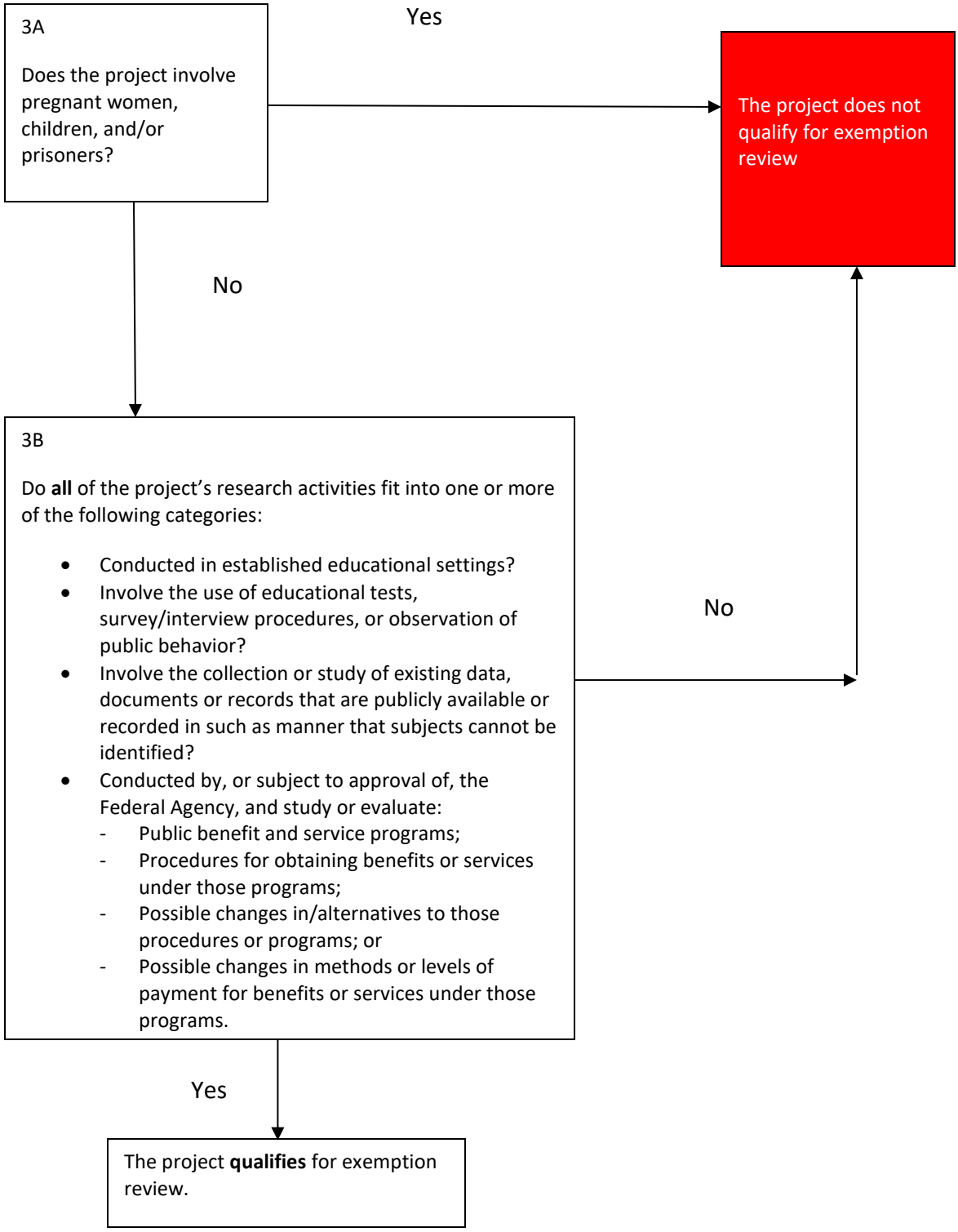
2B. Is the Project a Formal and Structured Evaluation Involving Individuals in a Special Project, Program or Study?

The *Virginia Administrative Code* 12VAC5-20-10 defines "human research" as "any systematic investigation including research development, testing, and evaluation, utilizing human subjects that is designed to develop or contribute to generalized knowledge." Evaluations of ongoing health department 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 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 there is an unresolved question as to whether the project should be reviewed by the IRB, it is better to err on the side of having the project reviewed by the IRB.

If the project is considered human research or if it is not clear, you will need to submit your research proposal to the IRB for review. You should proceed to Question 3 to determine if your proposal should be submitted for exemption review, expedited review, or full IRB 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 project being proposed falls into one of the exemption categories, those protocols should be submitted to the IRB for exemption review.

The decision to approve or disapprove a project submitted for exemption review will be determined by the Chair of the IRB (or his/her designee) and one other member of the review board within 45 days after submission. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the Investigator in writing within seven (7) days after the review. The reviewer may contact the investigator to clarify or request additional information that would be helpful in the review process.

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 involves human subjects must be exempt in order for the project to be submitted for exemption.

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.

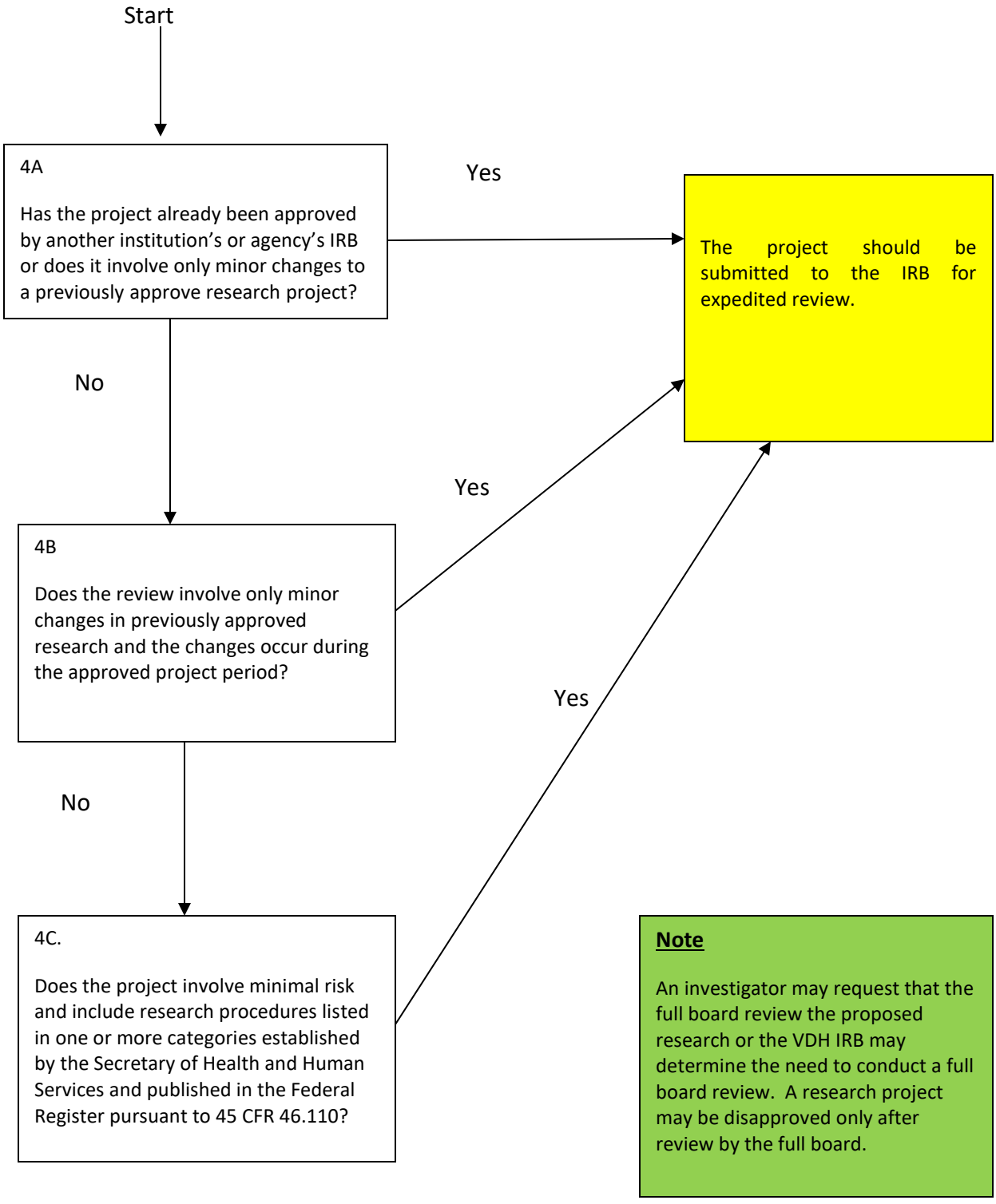
There are special circumstances in which the research included above in item (2) is not exempt. These circumstances occur when the subjects are elected or appointed officials or candidates for public office; or federal statute(s) require(s), without exception, the confidentiality of the personally identifiable 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 quality for expedited review or need to be submitted for full board review.

Question 4: Does the Project Quality 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 *45 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 the 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 an expedited review (12VAC 20-90). 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. Documentation of approval by another institution's or agency's IRB must be submitted at the time that the Expedited Review Request is forwarded to the VDH IRB.

4B. Does the Review Involve Only Minor Changes to Previously Approved Research Occurring During the Approved Project Period?

State regulations allow a research project that involves only minor changes in previously approved research, where the changes occur during the approved project period, to undergo an expedited review (12VAC 20-90). If the project has been previously reviewed and approved by another institution's or agency's IRB, then the approval of the minor changes by the other institution's or agency's must be forwarded to the VDH IRB along with a completed Request for Modification form.

4C. Has the Project <u>Not</u> been Reviewed by Another Institution's or Agency's IRB?

State regulations allow research that involves no more than minimal risk to the human subjects and involves only research procedures listed in one or more categories established by the Secretary of Health and Human Services and published in the Federal Register pursuant to 45 CFR 46.110 to undergo expedited review.

C. Additional Protections for Children Involved as Subjects in Research

Children are persons who have not yet attained the legal age for consent to treatments or procedures involved in the proposed research. The written consent from a parent or legally authorized representative is required for a child's participation in research. If the child is capable of rendering informed consent, the consent must be obtained from both the child and the parent or legally authorized representative.

All research 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. The two most common categories impacting VDH related studies include:

1. Research not involving greater than minimal risk to the child subjects. The IRB must determine that the research presents no greater than minimal risk to the child and that adequate provisions are made for obtaining informed consent from child (as appropriate) and parent/ legally authorized individual.

2. Research involving greater than minimal risk but presenting direct benefit to the child subjects. The IRB must determine that the risk is justified by the anticipated benefits to the child and that adequate provisions are made for obtaining informed consent from child (as appropriate) and parent/ legally authorized individual.

D. Informed Consent

Voluntary informed consent signed by the research subject or their legally authorized representative is required for all human subject research projects (in Appendix C "*General Requirements for Informed Consent*"). The VDH 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 VDH IRB may waive the requirement for some or all subjects if it finds that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether they want documentation linking them with the human research. In cases where the documentation requirement is waived, the committee may require the investigator to provide subjects with a written statement explaining the human research.

E. Release of VDH Data or Conducting Research Involving VDH clients

Prior to the submission of a request for VDH IRB review, the principal investigator is required to contact the VDH program staff who has responsibility for the data of interest. The principal investigator should discuss research plans with the program staff. The program staff will determine the appropriateness of using the data for the research project. Once this is determined, the principal investigator will submit a letter or email from the program staff indicating support for the research project along with the request for the VDH IRB review. In addition, a copy of any required data sharing agreement and/or confidentiality agreement must also be submitted with the request for the VDH IRB review along with a list of requested data variables.

For proposed research that will include health district data or health district clients as research subjects, the principal investigator must contact the district health director to discuss the project and must submit a letter or email from the health director indicating support for the research project along with the request for the VDH IRB review. In addition, a copy of any required data sharing agreement and/or confidentiality agreement must also be submitted to the IRB and will be maintained in the project file.

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. IRB Meetings

The VDH IRB convenes quarterly and will convene more often as needed. Any documents to be reviewed at the meeting will be distributed to the members prior to all meetings. The minutes from the previous meeting and a meeting agenda will be provided to the members prior to the meeting.

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 each member has all the pertinent material prior to the meeting and each participant can actively and equally participate in any discussions.

All VDH IRB meetings will follow generally accepted practices for parliamentary procedures as outlined in Robert's Rules of Order. A quorum of the Board consists of a majority of the members including at least one member whose primary concerns are in nonscientific areas.

B. Board Membership

The VDH IRB is made up of at least 5 members, appointed by the Commissioner, with varying backgrounds to provide complete and adequate review of proposed research. The membership includes at least one member who is not otherwise affiliated with the Virginia Department of Health. The Board 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. A list of current members is presented in Appendix B.

C. Elements of the Board Review Process

The following are elements that the VDH IRB considers in the review process:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the human research;
2. The degree of the risk and, if the human research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the human subjects involved are adequately protected;
4. Whether the risks to the human subjects are outweighed by the potential benefits to them'
5. Whether the risks to subjects are minimized (i) by using procedures that are consistent with sound human research design and that do not unnecessarily expose subjects to risk and (ii) whenever appropriate, by using currently accepted procedures for diagnostic or treatment purposes;
6. Whether additional safeguards have been included in the study to protect the rights and welfare of the subjects when some or all of the subjects are likely to be incapable of providing informed consent or are otherwise vulnerable to coercion or undue inducement, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
7. Whether the informed consent is to be obtained by methods that are adequate and appropriate and whether the written consent form is adequate and appropriate in both content and language for the particular human research and for the particular subjects of the research.
8. Whether the persons proposing to supervise or conduct the research are appropriately competent and qualified;
9. Whether criteria for selection of subjects are equitable; and
10. Whether the human research conforms with other requirements of the department.

D. Requests for IRB Review

Researchers who have reviewed the guidelines and determined that a project does indeed involve human subjects and is considered research will need to request a review by the VDH IRB. The request for IRB review may be in one of three categories:

1. Request for Exemption from VDH IRB Review;
2. Request for Expedited Review; or
3. Request for Full Board Review

The completed request using the appropriate form may be submitted to the VDH IRB via email to VDHIRB@vdh.virginia.gov

Exemption from IRB Review

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

- Request for *Request for Exemption from IRB Review Form* (in Appendix D)
- Complete Study Protocol including:
  - Hypothesis

  - Methods and procedures
  - Subject selection/recruitment
  - Risks and benefits
  - Subject compensation/incentive – if applicable
  - Study Management/Personnel
  - Confidentiality and data storage
  - Data analysis and dissemination plans
- Principal Investigator's CV.
- Copies of survey/interview instruments.
- List of all data fields/elements to be collected (if requesting VDH data)
- Copies of informed consent/assent forms, scripts, and recruitment material.
- Evidence (letter or email) that the district health director and/or VDH Central office supervisor is aware/approves of the involvement of Virginia Health Department clients or the use of VDH data for the purposes of this study.
- Application and Approval letter from any other IRB reviewing this proposal

The decision to approve or not approve the project as exempt will be made by the IRB Chair (or his/her designee) within 45 days after submission. The investigator will be notified of the outcome within 7 business days following the review. During the review process, the investigator may be asked to provide additional information or clarification.

1) Expedited and Full IRB 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 Expedited/Full Review for Research Involving Human Participants Form* (in Appendix D)
- Complete Study Protocol including:
  - Hypothesis
  - Methods and procedures
  - Subject selection/recruitment
  - Risks and benefits
  - Subject compensation/incentive – if applicable
  - Study Management/Personnel
  - Confidentiality and data storage
  - Data analysis and dissemination plans
- Principal Investigator's CV.
- Copies of survey/interview instruments.
- List of all data fields/elements to be collected (if requesting VDH data)
- Copies of informed consent/assent forms, scripts, and recruitment material.
- Evidence (letter or email) that the district health director and/or VDH Central office supervisor is aware/approves of the involvement of Virginia Health Department clients or the use of VDH data for the purposes of this study.

- Application and Approval letter from any other IRB reviewing this proposal

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 45 days after submission. The full board will review any proposals if the investigator requests that a full review be completed or the VDH IRB Chair determines the need to conduct a full board review. A research project may be disapproved only after review by the full board. The investigator will be notified of the outcome within 7 business days following the review. During the review process, the investigator may be asked to provide additional information or clarification and may be asked to provide clarifying information during the full board review.

E. Continuing Review

The VDH IRB is required to conduct continuing review of ongoing studies at intervals appropriate to the nature and degree of risk posed by the research project, but not less than once every twelve months from the date of the IRB approval. It is the principal investigator's responsibility to submit the *Continuation Review Form* (in Appendix D) to ensure conformity with the approved proposal. The Continuation Review form must be received by the VDH IRB by the due date. The IRB staff will send a reminder to the principal investigators approximately four weeks prior to the review date.

F. Modifications to the Study

All modifications to currently approved studies must be reported to and approved by the IRB before implementation in the study. The principal investigator is required to submit the *Request for Modification Form* (in Appendix D)

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) would not substantially change the specific aims or design of the study. Examples include: an increase/decrease in the proposed sample size; the addition of other study sites; changes in principal investigator or other major study staff; correcting or adding clarifying language or correcting typographically errors on study material.

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 designs. Examples include: revised consent or other study procedures; addition of questions including those that are potentially sensitive questions on the research instruments; and changes in the subject population.

The principal investigator will be notified of the approval/disapproval of the requested modification following the IRB review.

G. Reporting Adverse or Unexpected Events

Any adverse or unexpected events that occur during the research that involve risks to subjects or others or any serious or non-compliance with the VDH IRB approved research protocol or any requirements must be reported within 5 days of the occurrence to the VDH IRB. In addition, the principal investigator must report the suspension or termination by any other IRB that has approved the research. The principal investigator is required to submit the *Adverse Event Reporting Form* (in Appendix D).

The VDH IRB will review the reported event and determine the adequacy of any remediation plan as appropriate. The VDH IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to the subjects.

H. Completion/Termination of the Study

The principal investigator is required to complete and summit only section 1 of the *Continuation Form* and submit a *Study Summary Report* (in Appendix D) within 90 days after the conclusion of the research project.

Appendices

A. Code of Virginia and the Virginia Administrative Code Citations
B. VDH Institutional Review Board Membership
C. General Requirements for Informed Consent
D. VDH Institutional Review Board Forms
- Request for Exemption Review
- Request for Expedited/Full Review
- Request for Waiver of Informed Consent
- Continuation Form
- Request for Modification
- Adverse Event Reporting Form
- Study Summary Report

E. VDH IRB Principal Investigator Responsibilities

Appendix A

Code of Virginia

§ 32.1-12.1. Board to establish regulations regarding human research.

The Board shall promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of this title for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Commissioner or his designee 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.

§ 32.1-162.16. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Human research" means any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 C.F.R. § 46.101(b) .

"Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;

2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person;

3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;

4. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and

5. An offer to answer and answers to any inquiries by the person concerning the procedures and protocols.

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"Legally authorized representative" means, in the following specified order of priority, (i) the parent or parents having custody of a prospective subject who is a minor, (ii) the agent appointed under an advance directive, as defined in § 54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (iii) the legal guardian of a prospective subject, (iv) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (v) an adult child of the prospective subject, (vi) a parent of the prospective subject when the subject is an adult, (vii) an adult brother or sister of the prospective subject or (viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney in fact shall not be employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm 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.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

1979, c. 38, § 37.1-234; 1986, c. 274; 1992, c. 603; 2002, c. 754.

Virginia Administrative Code

12VAC 20-10-130 The Conduct of Human Research Regulations

12VAC5-20-10. 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 institution" means employed by or contracting with the institution or directly or indirectly involved in the management thereof.

"Commissioner" means the Commissioner of the Department of Health.

"Committee" means human research committee assembled pursuant to 12VAC5-20-70 of this chapter by any institution defined herein.

"Department" means the Department of Health.

"Human research" means any systematic investigation, including research development, testing, and evaluation, utilizing human subjects that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 CFR 46.101(b).

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

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"Legally authorized representative" means, in the following specified order of priority, (i) the parent or parents having custody of a prospective subject of human research who is a minor; (ii) the agent appointed under an advance directive as defined in § 54.1-2982 of the Code of Virginia, executed by the person who is the prospective subject of human research, provided the advance directive authorizes the agent to make decisions regarding the person's participation in human research; (iii) the legal guardian of a prospective subject of human research; (iv) the spouse of a prospective subject of human research, except where a suit for divorce has been filed and the divorce decree is not yet final; (v) an adult child of a prospective subject of human research; (vi) a parent of a prospective subject of human research when the individual is an adult; (vii) an adult brother or sister of a prospective subject of human research; or (viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject of human research to such person's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm or discomfort 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, tests, or treatments.

"Minor increase over minimal risk" means there is only slightly more than minimal risk; any potential harms are transient and reversible with respect to any harm; and there is an extremely small probability that the subject will experience severe pain, discomfort, stress or harm.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the subject.

"Protected health information" or "PHI" means individually identifiable health information that is created or received by or on behalf of the institution or agency that is maintained or transmitted in any medium, including electronic media. PHI excludes individually identifiable health information in:

1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 USC § 1232g;

2. Records described at 20 USC § 1232g(a)(4)(B)(iv) (educational records not otherwise covered under the Family Educational Rights and Privacy Act in subdivision 1 of this definition); or

3. Employment records held by a covered entity in its role as an employer.

"Subject" or "human subject" means a living person about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the person or (ii) identifiable private information.

12VAC5-20-30. Applicability.

This chapter shall apply to the department, including any local health department and to any facility operated, funded or licensed by the department that conducts or proposes to conduct or authorize research using human subjects.

12VAC5-20-40. Policy.

A. No human research shall be conducted without informing the subject or his legally authorized representative of the procedures, risks, and discomforts of the research. The consent of the subject or his legally authorized representative to participate in the research shall be subscribed to in writing by the subject or his legally authorized representative and supported by the signature of a witness not involved in the conduct of the research, except as provided for in 12VAC5-20-100. Special arrangements shall be made for those who need assistance in understanding the consequences of participating in the research.

B. Each human research activity shall be reviewed and approved by a committee as set forth in 12VAC5-20-70 composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities.

C. Every person engaged in the conduct of human research or proposing to conduct human research shall associate himself with an institution or 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.

D. Nontherapeutic research using patients or residents within an institution as defined herein is forbidden unless it is determined by the research review committee that such nontherapeutic research shall not present greater than minimal risk.

E. The person, institution, or agency conducting the human research shall notify all subjects of human research of the risks caused by the research that are discovered after the research has concluded. If consent has been obtained by the signature of the legally authorized representative, the legally authorized representative shall also be notified.

F. No official or employee of the institution or agency conducting or authorizing the human research shall be qualified to act as a legally authorized representative for a subject of the particular human research.

12VAC5-20-50. Review process for department.

A. Prior to the initiation of a human research project by any component of the department, a description of the proposed human research project shall be submitted to a research review committee established by the department for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion as a subject in the research project, a description of what will be done to the subjects, and a copy of the informed consent statement.

B. The committee shall report by March 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

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

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

C. The chair of the committee shall report as soon as possible to the commissioner any violation of the research protocol that led the committee to either suspend or terminate the research.

D. The commissioner may inspect the records of the committee.

E. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by any component of the department as annually reported to the commissioner by the committee.

12VAC5-20-60. Review process for institutions or agencies funded or licensed by the department.

A. Prior to the initiation of a human research project by any institution or agency funded or licensed by the department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The description shall include

a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a subject in the research project, a description of what will be done to the subjects, and a copy of the informed consent statement.

B. When more than one such institution or agency is involved in a research project, the cooperating entities may enter into joint review.

C. Such institutions or agencies having a committee shall report by March 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

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

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

D. The chair of the committee shall report as soon as possible to the head of such institution or agency and to the commissioner any violation of the research protocol which led the committee to suspend or terminate the research.

E. The commissioner may inspect the records of the committee.

F. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by such institutions or agencies as annually reported to the commissioner by the relevant research review committees.

12VAC5-20-70. Composition of research review committee.

A. Each committee shall have at least five members, appointed by the head of the institution, with varying backgrounds to provide complete and adequate review of activities commonly conducted by the institution. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its advice and counsel in safeguarding the rights and welfare of subjects in human research. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews research that has an impact on patients or residents within an institution as defined herein or other vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects].

B. No committee shall consist entirely of members of one profession, and at least one member shall be an individual whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy).

C. Each committee shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

D. No member of a 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 conflicting interest. The committee size shall be maintained at no fewer than five persons by appointment of a substitute representative for each member with a conflicting interest.

E. 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 shall not vote with the committee.

F. A quorum of the committee shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas.

G. The committee and the institution shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

12VAC5-20-80. Elements of committee review process.

A. No human research shall be conducted or authorized by a person, institution, or agency unless a research review committee has reviewed and approved the proposed human research project giving consideration to:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the human research;

2. The degree of the risk and, if the human research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the human subjects involved are adequately protected;

4. Whether the risks to the human subjects are outweighed by the potential benefits to them;

5. Whether the risks to subjects are minimized (i) by using procedures that are consistent with sound human research design and that do not unnecessarily expose subjects to risk and (ii) whenever appropriate, by using currently accepted procedures for diagnostic or treatment purposes;

6. Whether additional safeguards have been included in the study to protect the rights and welfare of the subjects when some or all of the subjects are likely to be incapable of providing informed consent or are otherwise vulnerable to coercion or undue inducement,] such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;

7. Whether the informed consent is to be obtained by methods that are adequate and appropriate and whether the written consent form is adequate and appropriate in both

content and language for the particular human research and for the particular subjects of the human research;

8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified;

9. Whether criteria for selection of subjects are equitable; and

10. Whether the human research conforms with other requirements of the department, where applicable.

B. The committee shall consider a research proposal within 45 days after its submission to the committee. In order for the research proposal to be approved, it shall receive the approval of a majority of the committee members present at a meeting for which a quorum exists. A committee shall notify investigators and the institution in writing of its decision to approve or disapprove the research proposal or of modifications required to secure committee approval.

C. During the committee review of research proposals, no personal identifiers of present or potential subjects shall be stated.

D. The committee shall develop a written description of the procedure to be followed when a subject has a complaint about a research project in which he is participating or has participated.

E. Any subject who has a complaint about a research project in which he is participating or has participated shall be referred to the committee to determine if there has been a violation of the protocol.

F. The committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the committee requirements or that has been associated with unexpected serious harm to the subjects. Any suspension or termination of approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, the department or agency head, and the commissioner.

G. The chair of the committee shall provide a written report to the head of the institution of any violation of the human research protocol that led the committee to suspend or terminate the human research.

H. 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 at the conclusion of the research project.

I. The committee shall ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (42 USC § 1320d et seq.), if applicable, and federal and state regulations regarding the use and disclosure of PHI created for human research. In particular, authorization shall be obtained for the use and disclosure of PHI created for the purpose of human research, except as otherwise permitted by 45 CFR 164.512(i).

J. When cooperating institutions conduct some or all of the human research involving some or all of the subjects of the human research, each cooperating institution shall be responsible for safeguarding the rights and welfare of the subjects and for complying with this chapter, provided however, in complying with this chapter, institutions may enter into joint review, rely upon the

review of another qualified committee, or come to similar agreements aimed at avoiding duplication of effort. Any such agreement shall be in writing and designate a lead institution, which shall be the institution responsible for reporting and handling any possible misconduct in the human research. Such agreements shall be entered into by the committee chair with the approval of a majority of the committee members. If an institution or agency does not have a research review committee, such agreements shall be approved and entered into by the chief executive officer of the institution or his designee.

12VAC5-20-90. Expedited review of human research projects.

A. The committee is authorized to conduct an expedited review of a human research project that involves no more than minimal risk to the subjects and involves only research procedures listed in one or more categories established by the Secretary of Health and Human Services and published in the Federal Register pursuant to 45 CFR 46.110.

B. The committee also is authorized to conduct an expedited review of a human research project that involves no more than minimal risk to the subjects if:

1. Another institution's or agency's human research review committee 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.

C. An expedited review may be carried out by the chair of the committee or by one or more experienced reviewers designated by the chair from among the committee members. In reviewing the research project, the reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research project. A research project may be disapproved only after review by the full committee in accordance to the procedures set forth in 12VAC5-20-80.

D. Each committee that uses an expedited review procedure shall adopt a method for keeping all members advised of research projects that have been approved under the procedure.

12VAC5-20-100. Informed consent.

A. "Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to determine the existence of such consent shall include the following:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected, how the results of the human research are disseminated, and how the identity of the person is protected;

2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person, together with their side effects, risks, and benefits;

3. A description of any adverse consequences and risks to be expected and an indication of whether there may be other significant risks not yet identified;

4. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him or fear of reprisal;

5. An explanation of any costs or compensation that may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols or any medical care that may be available if an injury occurs;

6. An offer to answer any inquiries by the person or, if applicable, his legally authorized representative concerning the procedures and protocols and a description of the ways in which concerns may be raised or questions asked;

7. A statement that the study involves research, and an explanation that includes identification of any procedures that are experimental; the expected duration of the person's participation; a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the person will not be identified without his written permission;

8. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person;

9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the person is otherwise entitled, and the person may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

10. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and

11. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained.

Information shall be provided in a manner that is understandable to the person with regard to his educational level and language of greatest fluency.

B. No human research shall be conducted in the absence of informed consent subscribed to in writing by the person or by the person's authorized representative except as provided for in subsection E of this section. If the person is capable of providing informed consent, written consent shall be provided by the person and witnessed. If the person is incapable of making an informed decision as defined in § 54.1-2982 of the Code of Virginia, at the time consent is required, written consent shall be provided by the person's legally authorized representative and witnessed. If the person is a minor otherwise capable of rendering informed consent, the consent shall be provided by both the minor and his legally authorized representative. An investigator shall seek such consent only under circumstances that provide the person who is the prospective subject or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the person or, if applicable, the person's legally authorized representative shall be in language understandable to the person or representative.

C. No person shall participate in human research unless the informed consent requirement in this section is met. No informed consent shall include any language through which the person waives or appears to waive any of his legal rights, including any release of any person, institution, or agency or any agents thereof from liability for negligence. No person shall be forced to participate in any human research if the investigator conducting the human research knows that participation in the human research is protested by the person.

D. No legally authorized representative shall consent to nontherapeutic human research unless it is determined by the research review committee that such nontherapeutic research will present no more than a minor increase over minimal risk to the subject [, and (a) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; and (b) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. A legally authorized representative may not consent to participation in human research on behalf of a subject if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research protocol is contrary to the religious beliefs or basic values of the subject, whether expressed orally or in writing.

E. The research review committee may approve a consent procedure that does not include or that alters some or all of the elements of informed consent set forth in this section, or that waives the requirements to obtain informed consent provided the committee finds and documents that:

1. The human research involves no more than minimal risk to the subjects;

2. The omission, waiver, or alteration will not adversely affect the rights and welfare of the subjects;

3. The human research could not practicably be performed without the omission, waiver, or alterations; and

4. After participation, the subjects shall be provided with additional pertinent information, whenever appropriate.

F. Consent may take the form of either of the following:

1. A written consent document that embodies the elements of informed consent required by this section. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed and witnessed; or

2. A short form written consent document stating that the elements of informed consent required by this section have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the subject or the representative. Only the short form written consent is signed by the subject or the representative. However, the witness shall sign both the short form written consent and a copy of the summary, and the person actually obtaining consent shall sign

a copy of the summary. A copy of the summary and a copy of the short form written consent shall be given to the subject or the representative.

G. The research review committee may waive the requirement in subsection B of this section for the investigator to obtain a written informed consent form for some or all subjects if it finds that the only record linking the subject and the human research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject shall be asked whether the subject wants documentation linking the subject with the human research, and the subject's wishes shall govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide subjects with a written statement explaining the human research.

12VAC5-20-110. Categories of human research exempt from regulation.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from this chapter:

1. The surveillance and investigation by the department into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted pursuant to § 32.1-39 of the Code of Virginia.

2. Research designed to study on a large scale anonymous vital records and registry data collected pursuant to the Code of Virginia, Chapter 7 (§ 32.1-249 et seq.) of Title 32.1 (Vital Records), § 32.1-64.1 (Virginia Hearing Impairment Identification and Monitoring System), § 32.1-69.1 (Virginia Congenital Anomalies Reporting and Education System), § 32.1-70 (Statewide Cancer Registry), § 32.1-46.01 (Virginia Immunization Information System), and § 32.116.1 (Emergency Medical Services Patient Care Information System).

3. Research or student learning outcomes assessment conducted in educational settings such as research involving:

a. Regular or special education instructional strategies; or

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

c. The use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.

4. Research involving survey or interview procedures unless responses are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects, and either:

a. The subject'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 his financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of the subject's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct.

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

6. Research involving solely the observation of public behavior, including observation by participants, unless observations are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects, and either:

a. The observations recorded about the subject, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of the subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.

7. Research involving the collection or study of existing data, documents, records, or pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.

12VAC5-20-120. Committee records.

A. Documentation of committee activities shall be prepared and maintained by each such committee and shall include the following:

1. Copies of all research proposals reviewed, scientific evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;

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

3. Records of continuing review activities;

4. Copies of all correspondence between the committee and the investigators;

5. A list of committee members;

6. Written procedures for the committee; and

7. Statements of significant new findings provided to subjects.

B. The records required by this chapter shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

C. Each research review committee of a state institution or agency shall ensure that an overview of approved human research projects and the results of such projects are made public on such institution's or agency's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

12VAC5-20-130. Applicability of federal policies.

Human research that is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government shall be exempt from this chapter. Institutions where research is performed that is subject to federal policies and regulation shall notify the commissioner annually, by March 31, of their compliance with the policies and regulations of federal agencies. The commissioner shall identify institutions exempt from this chapter as reported in accordance with this section in the annual report to the Governor and the General Assembly provided in accordance with 12VAC5-20-60 F.

Appendix B

Virginia Department of Health Institutional Review Board

Name	Qualifications/Job Title	Institutional Affiliation

Bethany Geldmaker, Chair	PhD, Nursing Child Care Consultant	Virginia Department of Health, Division of Child and Family Health
Pastor Maceo Freeman	Doctor of Divinity	St. Paul's Baptist Church, Richmond, VA
Nicole Bissell	MD, MPH	Director, New River Health District, Virginia Department of Health
Kavita Imrit-Thomas	MD	Director, Portsmouth Health District, Virginia Department of Health
Ana Colon	MPH, Epidemiology Epidemiologist	Eastern Region Field Office Virginia Department of Health
Antonio Villa Payares	MD, MPH	Department of Kinesiology, Virginia Commonwealth University
Janice Hicks, IRB Coordinator Alternate Member	PhD, Social Policy/Social Work	Virginia Department of Health, Office of Governmental and Regulatory Affairs

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

§ 46.116 General requirements for informed consent.

(a) ***General.*** General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to

participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

(b) ***Basic elements of informed consent.*** Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(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 that 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 that 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;

(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; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) ***Additional elements of informed consent.*** Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(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) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject;

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

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) ***Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.*** Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is

asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) ***Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials***—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) ***Alteration.*** An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may

not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) ***Requirements for waiver and alteration.*** In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) 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:

(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; and

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

(f) ***General waiver or alteration of consent***—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) ***Alteration.*** An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) ***Requirements for waiver and alteration.*** In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

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

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

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

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

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) ***Screening, recruiting, or determining eligibility.*** An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) ***Posting of clinical trial consent form.***

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) ***Preemption.*** The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) ***Emergency medical care.*** 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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

Appendix D

VDH IRB Forms

- Request for Exemption Review
- Request for Expedited/Full Review
- Request for Waiver of Informed Consent
- Continuation Form
- Request for Modification
- Adverse Event Reporting Form
- Study Summary Report

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448
VDHIRB@vdh.virginia.gov

REQUEST FOR EXEMPTION FROM IRB REVIEW

Part 1 – Administrative Information

1. Title of Study or Project: Click here to enter text.	ID No. (to be assigned by IRB staff)
2. Name of Principal Investigator: Click here to enter text. Institution: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number: Click here to enter text.
3. Name of Department of Health Collaborator, if included in study and different from Principal Investigator: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number: Click here to enter text.
4. Name of Faculty Supervisor, if this is a student project and different from the Principal Investigator: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number: Click here to enter text.
5. Funding Source: Click here to enter text.	

Part 2 – Exemption Review Checklist

While the VDH IRB has the ultimate responsibility for deciding if research qualifies for exemption, investigator(s) are asked to make an initial determination of the appropriate exemption category. Please select all the categories that apply from the list below.

Note: Research projects involving prisoners or the collection of biological samples cannot be granted an exemption.

The Federal Code [45 CFR 46.101] permits research activities in the following six categories to be exempted. Please check the relevant exemption category/categories that apply to your research.

The Federal Office of Human Research Protections has made Decision Charts available here to help in determining whether a particular study falls within a particular Exemption Category.

Categories of Research Activities Exempt from Continuing Review

❑	**d(1).** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **NOTE:** Research with minors is exemptible if the activities fall within this category.
❑	**d(2).** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7) **NOTE:** Paragraphs (d)(2)(i) and (ii) only may apply to research subject to subpart D (minors) involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section many not be applied to research subject to subpart D (minors).
❑	**d(3)(i)** Research involving benign behavioral intervention in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects: (B) Any disclosure of the human subjects' response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise

	conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
❑	**d(4).** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.
❑	**d(5).** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedure for obtaining benefits or services under those programs, possible changes in or alternative to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
❑	**d(6).** Taste and food quality evaluation and consumer acceptance studies, (i) If wholesome foods without additives are consumed, or (ii)If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental

	Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
❑	**d(7).** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
❑	**d(8).** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through(4), (a)(6), and (d). (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117. (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section, and (iv). The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Part 3 – Study Design, Methods and Procedures

1. Type of Project/study: Please select ALL of the categories of work that apply to this proposed project.

   ❑ Active collection of data (not human biological materials or physiological data)

   ❑ Use of existing data (not human biological materials)

   ❑ Use of existing human biological materials

2. Will the research subjects include Virginia Department of Health clients? _____Yes _____No

If yes, please indicate which of the following clients will be included in the study:

Family Planning Clients _____
Prenatal Clients _____
WIC Clients _____
STD/HIV Clients _____
Immunization Clients _____
Dental Clients _____
Well Child Clients _____
Home Visiting Clients _____
Other VDH Clients (Specify) _____

3. Will the research require existing VDH data? If so, please describe:

4. Please provide a lay summary of the study, including the purpose and the research questions and hypothesis to be tested. (attach a copy of the **complete** study protocol)

5. Please describe briefly how this study will contribute to existing knowledge in the field.

Part 4 – Privacy and Confidentiality

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

- ❑ Subject's name
- ❑ Date of birth
- ❑ Mailing or email address
- ❑ Phone or fax numbers
- ❑ Social Security number
- ❑ Medical records
- ❑ License, certificate or Vehicle ID
- ❑ Biometric identifiers
- ❑ Photos/images/audio recording
- ❑ Signatures, handwriting samples
- ❑ Any unique identifier not mentioned above
- ❑ No member of the research team will have access to any personal identifiers

2. How will the confidentiality of data be ensured? Check all the following precautions that will be used to maintain the confidentiality of identifiable information.

- ❑ Paper-based records will be kept in secure location and only accessed by authorized study personnel.
- ❑ Electronic records will be made available only to those personnel in the study through the use of access controls and encryption.
- ❑ Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location).
- ❑ For research involving web-based surveys, data is secured via passwords and encryption.

❑ Audio or video recordings of subjects will be transcribed and then destroyed to prevent audio or visual identification.

❑ Other precautions: _____

Part 5 – Informed Consent Process

Please indicate the informed consent process(es) and document(s) to be used in the study. Check all that apply. **Provide copies of documents, as applicable**.

❑ Not applicable (existing data or specimens)

❑ Informed consent - form

❑ Informed consent – oral script

❑ Assent (participants under 18) – form

❑ Assent – oral script

❑ Parental Permission – form

❑ Parental Permission – oral script

❑ Translated Consent/Assent – form(s), script(s)

Part 6 – Signature

Principal Investigator

You may submit an electronic copy of this application and required materials by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

I certify that the information I provided in this application is correct and complete. **I also certify that all research staff and I have completed the protection of human research subjects training (www.citiprogram.org).** I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

____ Attestation of Principal Investigator ____Attestation of Faculty Supervisor (if applicable)

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

SUBMISSION CHECKLIST

1. Completed and signed Request for Exemption from IRB Review Form
2. Complete Study Protocol including:
   - Hypothesis
   - Methods and procedures
   - Subject selection/recruitment
   - Risks and benefits
   - Subject compensation – if applicable
   - Study Management/Personnel
   - Confidentiality and data storage
   - Data analysis and dissemination plans
3. Principal Investigator's CV.
4. Copies of survey/interview instruments.
5. Copies of informed consent/assent forms, scripts, and recruitment material.
6. Evidence (letter or email) that the district health director and/or VDH Central office supervisor is aware/approves of the involvement of Virginia Health Department clients or the use of VDH data for the purposes of this study.
7. List of all data fields if requesting VDH data.
8. Application and Approval letter from any other IRB reviewing this proposal.

This form along with supporting documentation may be submitted electronically to vdhirb@vdh.virginia.gov or by mail to:

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448
VDHIRB@vdh.virginia.gov

REQUEST FOR EXPEDITED/FULL REVIEW FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

Part 1 – Administrative Information

1. Title of Study or Project: Click here to enter text.	ID No. (To be Assigned by IRB Staff)
2. Name of Principal Investigator: Click here to enter text. Name of Institution: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number: Click here to enter text.
3. Name of Department of Health Collaborator, if included in study and different from Principal Investigator: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number: Click here to enter text.
4. Name of Faculty Supervisor, if this is a student project and different from the Principal Investigator: Click here to enter text.	E-mail Address: Click here to enter text.
Address: Click here to enter text.	Telephone Number:
5. Funding Source: Click here to enter text.	

Part 2 – Type of Review

While the VDH IRB has the ultimate responsibility for deciding if research qualifies for a full or expedited review, investigators are asked to make an initial determination of the type of review.

❑ Full board Review – **the research involves greater than minimal risk to the subjects.**

❑ Expedited Review – **the research must involve no more than minimal risk to the subjects**. (For expedited review, please indicate the category or categories in which your research falls in the list below.)

The Federal Office of Human Research Protections has made Decision Charts available here to help in determining whether a particular study may be reviewed using Expedited Review Procedures.

Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

❑	1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met: a. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.) b. Research on medical devices for which 1) an investigational device exemption application is not required or 2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
❑	2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a. From healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml. in an eight week period and collection may not occur more than two time per week; or b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the lesser of 50 ml. or 3 ml. per kg. in an eight-week period, and collection may not occur more than two times per week.
❑	3. Prospective collection of biological specimens for research purposes by non-invasive means. <u>Examples:</u> a. hair and nail clippings in a non-disfiguring manner; b. deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction. c. permanent teeth if routine patient care indicates need for extraction; d. excreta and external secretions (including sweat); e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; f. placenta removed at delivery; g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; j. sputum collected after saline mist nebulization.

❑	4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; b. weighing or testing sensory acuity; c. magnetic resonance imaging; d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography; e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing when appropriate given the age, weight, and health of the individual.
❑	5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnoses).
❑	6. Collection of data from voice, video, digital, or image recordings made for research purposes.
❑	7. Research on individual or group characteristics, behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Part 3 – Study Design, Methods and Procedures

1. **Study Sample:** (Groups specifically targeted for study)

   Age range of participants: _____ Projected number of participants _____

   ❑ Employees ❑ Students ❑ Children ❑ Pregnant women

   ❑ Fetuses/neonates ❑ Educationally/economically disadvantaged ❑ Incarcerated

   ❑ Children who are wards of the state ❑ Military personnel ❑ Incompetent persons

   ❑ Other – specify _____

2. Will the research subjects include **Virginia Department of Health clients**? _____Yes _____No
If yes, please indicate which of the following clients will be included in the study:

   Family Planning Clients _____

   Prenatal Clients _____

WIC Clients _____
STD/HIV Clients _____
Immunization Clients _____
Dental Clients _____
Well Child Clients _____
Home Visiting Clients _____
Other VDH Clients (Specify) _____

3. **Recruitment Method:**

Describe how research participants will be recruited in the study. How will you identify potential participants? How will you contact them? **Attach a copy of any material you will use to recruit participants (e.g. advertisements, flyers, telephone scripts, cover letters, etc.)**

4. **Participant Incentives:**

a. Will you pay participants? ❑ Yes ❑ No
Amount $_____ When will money be paid? _____

b. Will you give participants an incentive? ? ❑ Yes ❑ No If yes, please describe:

5. Will the research require existing VDH data? If so, please describe:

6. Please provide a brief lay summary of the study, including the purpose and the research questions and hypothesis to be tested. **(attach a copy of the complete study protocol)**

7. Please describe briefly how this study will contribute to existing knowledge in the field.

Part 4 – Privacy and Confidentiality

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? **Select all that apply.**

❑ Subject's name

❑ Date of birth

❑ Mailing or email address

❑ Phone or fax numbers

- ❑ Social Security number
- ❑ Medical records
- ❑ License, certificate or Vehicle ID
- ❑ Biometric identifiers
- ❑ Photos/images/audio recording
- ❑ Signatures, handwriting samples
- ❑ Any unique identifier not mentioned above (specify _____)
- ❑ No member of the research team will have access to any personal identifiers

2. How will the confidentiality of data be ensured? Check **all** the following precautions that will be used to maintain the confidentiality of identifiable information.

- ❑ Paper-based records will be kept in secure location and only accessed by authorized study personnel.
- ❑ Electronic records will be made available only to those personnel in the study through the use of access controls and encryption.
- ❑ Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location).
- ❑ For research involving web-based surveys, data is secured via passwords and encryption.
- ❑ Audio or video recordings of subjects will be transcribed and then destroyed to prevent audio or visual identification.
- ❑ 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.
- ❑ The identifying information will be used only for statistical purposes in medical and health research.
- ❑ The identifying information will be used only for the study or project proposed and the purposes described in the study protocol. Use of the information for a research project other than the one described will not be undertaken unless a separate request is made to and approved by the Virginia Department of Health IRB.
- ❑ 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.
- ❑ Other precautions: _____

Part 5 – Informed Consent Process

Please indicate the informed consent process(es) and document(s) to be used in the study. Check **all** that apply. **Provide copies of documents, as applicable.**

- ❑ Not applicable (existing data or specimens)
- ❑ Informed consent - form
- ❑ Informed consent – oral script
- ❑ Assent (participants under 18) – form
- ❑ Assent – oral script
- ❑ Parental Permission – form
- ❑ Parental Permission – oral script
- ❑ Translated Consent/Assent – form(s), script(s)

Part 6 – Signature

Principal Investigator

You may submit an electronic copy of this application and required materials by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

I certify that the information I provided in this application is correct and complete. **I also certify that all research staff and I have completed the protection of human research subjects training (**www.citiprogram.org**)**. I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

____ Attestation of Principal Investigator ____Attestation of Faculty Supervisor (if applicable)

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

SUBMISSION CHECKLIST

1. Completed and signed Expedited/Full Review Request Form
2. Complete Study Protocol including:
   - Hypothesis
   - Methods and procedures
   - Subject selection/recruitment
   - Risks and benefits
   - Subject compensation – if applicable
   - Study Management/Personnel
   - Confidentiality and data storage
   - Data analysis and dissemination plans
3. Principal Investigator's CV.
4. Copies of survey/interview instruments.
5. Copies of informed consent/assent forms, scripts, and recruitment material.
6. Evidence (email/letter) that the district health director and/or VDH Central office supervisor is aware/approves of the study if it includes Virginia Health Department clients or data.
7. List of all data fields if requesting VDH data.
8. IRB application and approval letter from any other IRB reviewing this proposal.

This form along with supporting documentation may be submitted electronically to vdhirb@vdh.virginia.gov or by mail to:

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448

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P.O. Box 2448
Richmond, Virginia 23218-2448
VDHIRB@vdh.virginia.gov

Request for Waiver of Informed Consent

(To be submitted with the Request for Review of Research Involving Human Participants)

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.*

1. The waiver of written documentation is 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 might be applicable include some Internet or telephone surveys or when signing the consent form might have negative consequences for the subject.
2. With the waiver of informed consent the investigator is not required to give, or read, the informed consent to a participant. The waiver may be approved by the VDH IRB if the following criteria are met:

Please check which type of consent waiver is being requested:

❑ Waiver of written documentation ❑ Waiver of informed consent

Please answer each of the following questions. Make sure that each response includes a through explanation. Please provide any supporting documentation as appropriate.

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

2. Why is it impractical 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/use of the protected health information (PHI)?

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 the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

This form along with supporting documentation may be submitted electronically to vdhirb@vdh.virginia.gov or by mail to:

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P.O. Box 2448

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CONTINUATION REVIEW

This form is to be completed and submitted electronically to VDHIRB@vdh.virginia.gov only for studies that have been reviewed previously.

Title of Study or Project:	ID No.
Name of Principal Investigator:	E-mail Address:
Address: Click here to enter text.	Telephone Number:
Name of Department of Health Collaborator, if included in study and different from Principal Investigator:	E-mail Address:
Address:	Telephone Number:
Name of Faculty Supervisor, if this is a student project and different from the Principal Investigator:	E-mail Address:
Address:	Telephone Number:

Complete **EITHER** Section I or Section II.

Section I - This study does NOT require re-review because:

- ☐ It is no longer in progress. (Attach a brief 1-2 paragraph study summary)
- ☐ It was never started.
- ☐ It was recently re-reviewed on (date) ___ ___/ ___ ___/ ___ ___.
- ☐ Other (Specify):

Section II- For studies that require re-review.

1. During the past year, were there any participant withdrawals from the study or complaints about the research activities?
   ____Yes____No

   If yes, please explain: _____

2. During the past year, were there any unexpected problems or adverse events involving risks to participants?
   ____Yes____No

   If yes, please explain: _____

   Was an Unexpected Event Report submitted? ____ Yes ____No

3. During the past year, were there any changes to your study (including recruitment, informed consent, study design and/or research procedures, research personnel, study location, etc.)?
   ____ Yes ____No

   If yes, please explain: _____

   Was a Request for Modification submitted? ____ Yes ____No

4. During the past year, were there any literature, findings, or other relevant information, especially information about risks associated with the research identified, that the participants should be aware of?
   ____ Yes ____No

   If yes, please explain: _____

   Have participants been informed of these findings?

   ____ Yes ____No

5. Provide a brief summary of the progress of the study and plans for the next year.

You may submit an electronic copy of this Continuation Review by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

Principal Investigator

I certify that the information I provided for this Continuation Review is correct and complete. I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

____ Attestation of Principal Investigator ____Attestation of Faculty Supervisor (if applicable)

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

Virginia Department of Health
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Richmond, Virginia 23218-2448

VDH VIRGINIA DEPARTMENT OF HEALTH

Request for Modification of Currently Approved Project

Part 1 – Administrative Information

IRB #: _____

Study Title: _____

Principal Investigator (PI): _____

Email Address: _____

Faculty Supervisor (if PI is a student) _____

Email Address: _____

Part 2 – Modification Information

1. Please select ALL the categories of amendment(s) you are requesting.

_____ Change in Study Title
_____ Change in Principal Investigator
_____ Addition of/change in research personnel
_____ Addition of/change in funding source
_____ Change to research/study design, methods or procedures (e.g., observations, interventions, collection of biological samples or biometric information, participant tasks, etc.)
_____ Addition of/change to study population
_____ Addition of/change to recruitment or compensation procedure(s)
_____ Addition of/change to survey(s), questionnaire(s), or other research instruments, - **Please attach revised instrument(s).**
_____ Addition of/change to the identifiers collected in the study, or any others that would impact the privacy and confidentiality of the study participants
_____ Addition of/change to informed consent/assent document(s) and/or procedures – **Please attach all related documents**
_____ Change in the data use/analysis plan
_____ Other changes (specify) _____

2. For each of the above selected modifications, please describe the modification that you are proposing and the reason you are making the modification.

3. Will the proposed modifications have an impact on the risks or benefits to the research participants? Please explain.

4. Attach revised protocol and/or consent (Highlight all revisions)

Part 3 – Signature

You may submit an electronic copy of this application and required materials by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

Principal Investigator

I certify that the information I provided in this application is correct and complete. I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

____ Attestation of Principal Investigator ____Attestation of Faculty Supervisor (if applicable)

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

.

For IRB Reviewer Only:
( ) Approved: This signifies notification of IRB APPROVAL of the revision described above.

( ) Not Approved ( ) Abstain ( ) Conditionally Approved

Comments:

IRB Reviewer's Signature: _____ Date: _____

Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
Richmond, Virginia 23218-2448

Adverse Event Report

Part 1 – Administrative Information

IRB #: _____

Study Title: _____

Principal Investigator (PI): _____

Email Address: _____Phone_____ _____

Faculty Supervisor (if PI is a student) _____

Email Address: _____Phone_____

Part 2 – Information on Adverse Event

1. Please describe the adverse event(s). Include details such as the number of events, the dates of occurrences, number of participants involved, any known or potential impact on participants, and any other relevant information.

2. Please describe the known or possible cause(s) for the event.

3. Please describe the actions, if any, that you have taken in response to the event. Include the dates of those actions.

4. Have you submitted or do you plan to submit for IRB review, a modification to the study as a result of the adverse event? If yes, briefly describe the modification. (The Request for

Modification Form is located at http://www.vdh.virginia.gov/OFHS/policy/irb.htm#forms. If no, please explain why you believe that an amendment is not required.

5. Do you plan to inform the participants who are already enrolled in your study about the adverse event or any safety or procedure related information as a result of this event? If yes, describe what will be communicated, and when and how it will be communicated. If the communication will be in writing, please provide the text of the communication to the VDH IRB. If no, please explain.

Part 3 – Signature

You may submit an electronic copy of this form by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

Principal Investigator

I certify that the information I provided in this adverse event report is correct and complete.

____ Attestation of Principal Investigator

____Attestation of Faculty Supervisor (if applicable)

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

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VDH VIRGINIA DEPARTMENT OF HEALTH

STUDY SUMMARY REPORT

Study Title:

Study #:

Principal Investigator:

Institutional Affiliation:

Date of Original VDH IRB Approval:

Date of Study Completion:

Summary/Abstract:

Publications (please provide references for all publications related to this research):

NOTE: Please confirm that you agree with the posting of the summary on the VDH IRB website. _____yes _____No

Please email this form to vdhirb@vdh.virginia.gov.

Appendix E

VDH IRB Principal Investigator's Responsibilities

Virginia Department of Health
Institutional Review Board (IRB)
Principal Investigator's Responsibilities

The Principal Investigator (PI) has direct responsibility for the implementation of the research and for ensuring the protection of human participants in research. The PI must be knowledgeable of federal regulations and institutional policies and procedures related to the conduct of research. The following lists the major responsibilities of the PI.

The PI is responsible for ensuring that:

- All members of the research team comply with the findings, determinations, and requirements of the IRB.
- All members of the research team have completed the human subject research training.
- All student members of the research team are provided appropriate supervision.
- Continuing review and approval of the research has been accomplished within the timeframe stipulated by the IRB.
- Any changes in research activity, including changes to the protocol, and/or consent form(s), completion or termination of the study, are promptly reported to the IRB. No change in approved research may be initiated without the IRB's approval except under conditions where it is necessary to eliminate apparent immediate hazards to human participants.
- No research is continued beyond the designated approval period.
- Any unanticipated problems involving risk to subjects and others, and any adverse events are reported immediately to the IRB.
- The IRB protocol number and title of the research are cited in all correspondence to the IRB.
- Any significant new information that may affect the risk/benefit ratio is submitted promptly to the IRB.
- For every expedited/full review IRB protocol, all signed consent forms (if applicable) are maintained for at least three (3) years after completion of the study and are available for review as needed.
- Only consent/assent/parental permission forms that have been reviewed and approved by the IRB may be presented to the research participants.

- All requests for information from the IRB are responded to in a timely manner.