

**The Institutional Review Board (IRB)
of the Virginia Department of Health (VDH):**

***Standard Operating Procedures and
Guidelines for Obtaining Review***

December 2010

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I. GUIDELINES FOR OBTAINING REVIEW BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH)

A. Introduction

One of the many ways the Virginia Department of Health (VDH) serves the public and fulfills its mission is through research. Research is defined in federal regulations as a *systematic investigation designed to develop or contribute to generalizable knowledge*. Periodically VDH conducts research that involves human subjects. VDH considers the protection of human subjects as important as the methodology, research findings, or any other component of the research project.

VDH has developed policies and procedures to ensure that the rights and welfare of human subjects involved in research are protected and consistent with both [State \(12 VAC 5-20-10\)](#) and [Federal \(45 CFR Part 46\)](#). The Office for Human Research Protections (OHRP), under the U.S. Department of Health and Human Services Assistant (HHS) Secretary for Health, is responsible for ensuring the safety and welfare of people who participate in HHS-sponsored research. Policies, guidelines and regulations from OHRP, provided the framework for the development of the State regulations, and provide the structure for VDH review and approval of human subjects research.

A major component of the process for ensuring the protection of the rights and welfare of human subjects involved in VDH research is the Institutional Review Board (IRB), also known as the research review committee. Research protocols must be either approved or granted an exemption by the IRB before human subjects can begin participation. The IRB also conducts continuing review of each approved protocol at least annually. 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, stipulations, and requirements.

The purpose of this document is to assist researchers and managers with determining whether a particular project requires review by the IRB, and if so, which of the various types of review is required. Additionally, this document outlines the actual processes and procedures needed for obtaining review by the IRB. Finally, this document also contains the text of the state regulations concerning the conduct of human research for VDH and a reproducible copy of all forms needed for obtaining review by the IRB.

B. Key Decisions about Human Subjects Review Requirements

In general, any human subjects research that is conducted by VDH, by outside investigators in collaboration with VDH, or by outside investigators using VDH data, is subject to review and approval by the VDH Institutional Review Board. However, not all studies require IRB review. In brief, the decision-making process is divided into five key decision steps:

Step 1: Is the project considered research?

Step 2: Does the project involve human subjects?

Step 3: Does the project qualify for exemption review?

Step 4: Does the project qualify for expedited review?

Step 5: May informed consent and/or its documentation be waived or altered?

In making the determination regarding Step 1, The Council of State and Territorial Epidemiologists have developed a document entitled "Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions". The purpose of this report is to provide a practical guide principally for state and local public health officials, their staff, and their

partners on the distinctions between public health practice and research for activities carried out by, or under the authority of, state or local health departments. The report can be found at: <http://www.vdh.state.va.us/healthpolicy/policyanalysis/documents/PublicHealthPracticeversusResearch.pdf> and may also be helpful to federal government public health officials and public and private sector institutional review board (IRB) members and their staff considering similar issues in reviewing or approving research proposals.

In addition, the following are the Office for Human Research Protections (OHRP) decision charts developed to provide guidance for institutional review boards (IRBs), investigators and others on whether an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at [OHRP Policy Guidance by Topic](#). OHRP invites inquiries for additional information.

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

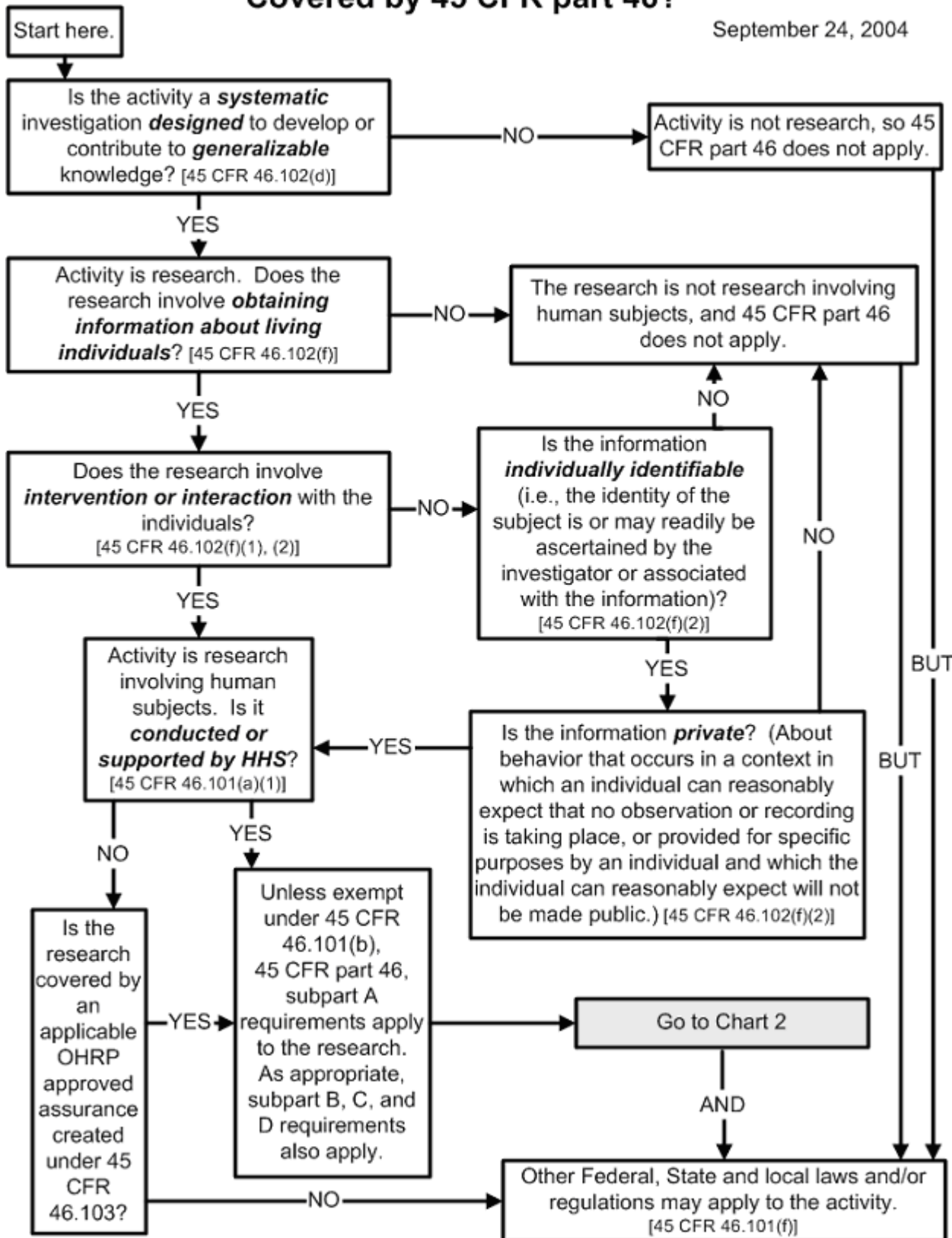


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

September 24, 2004

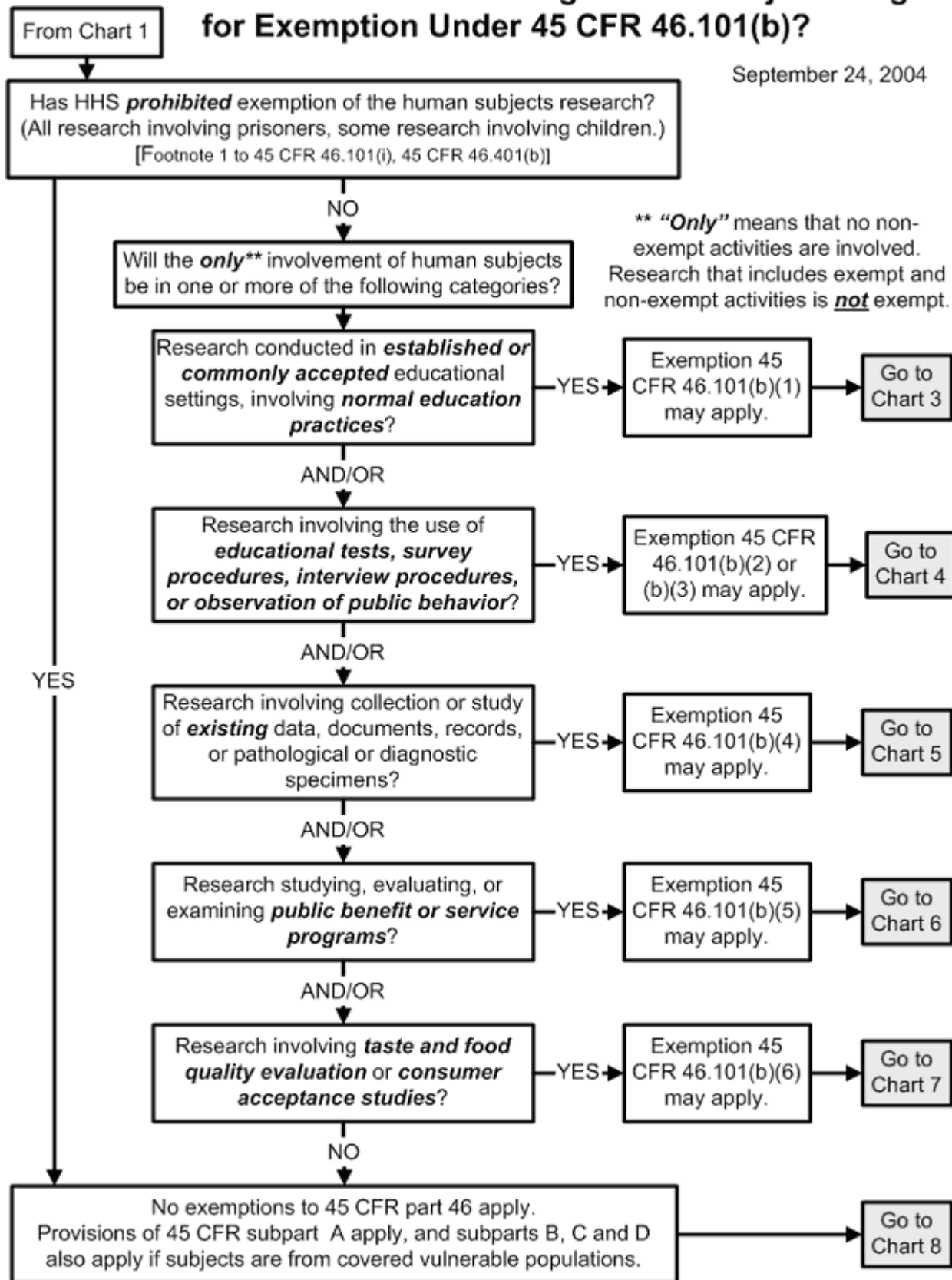
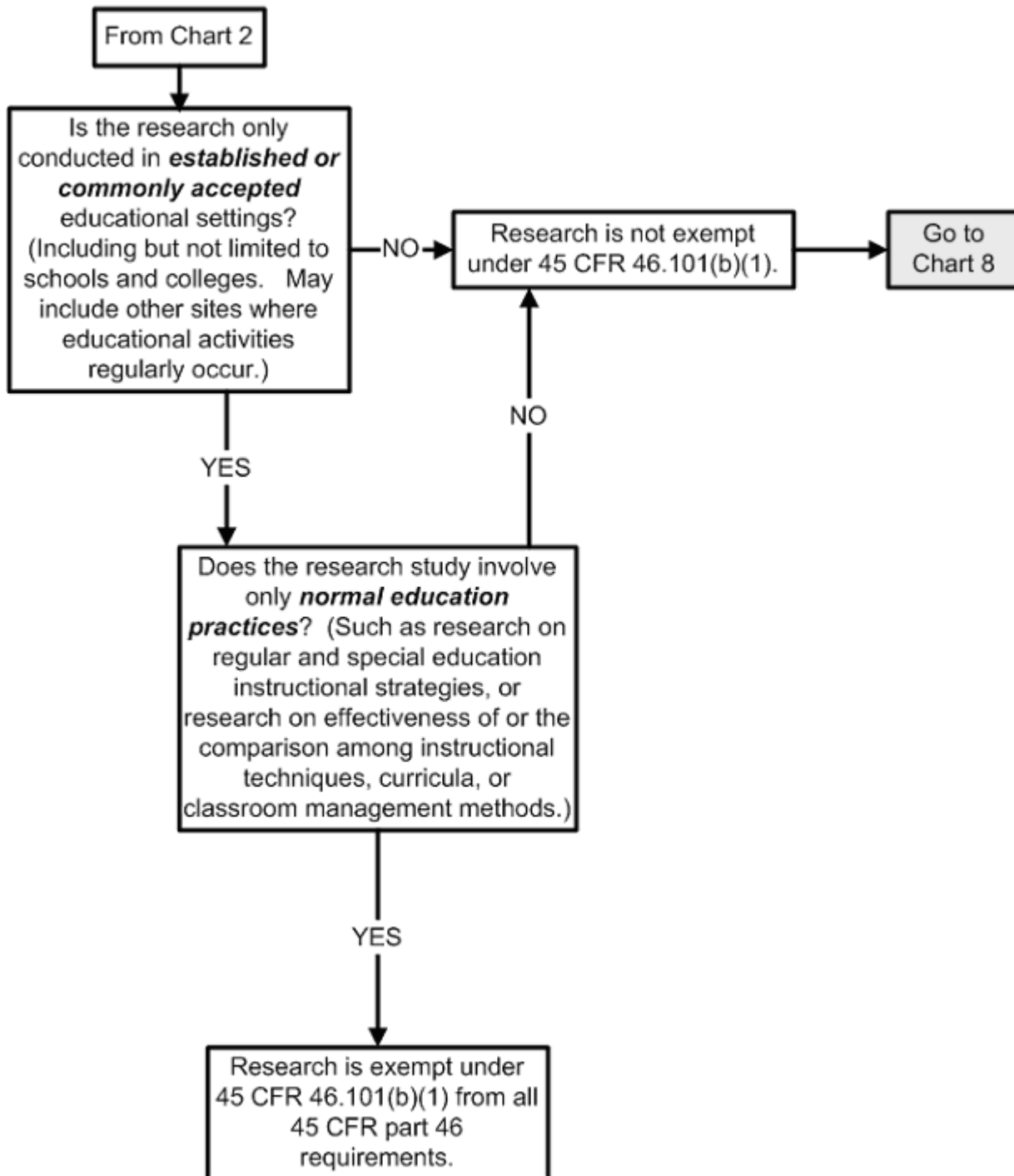
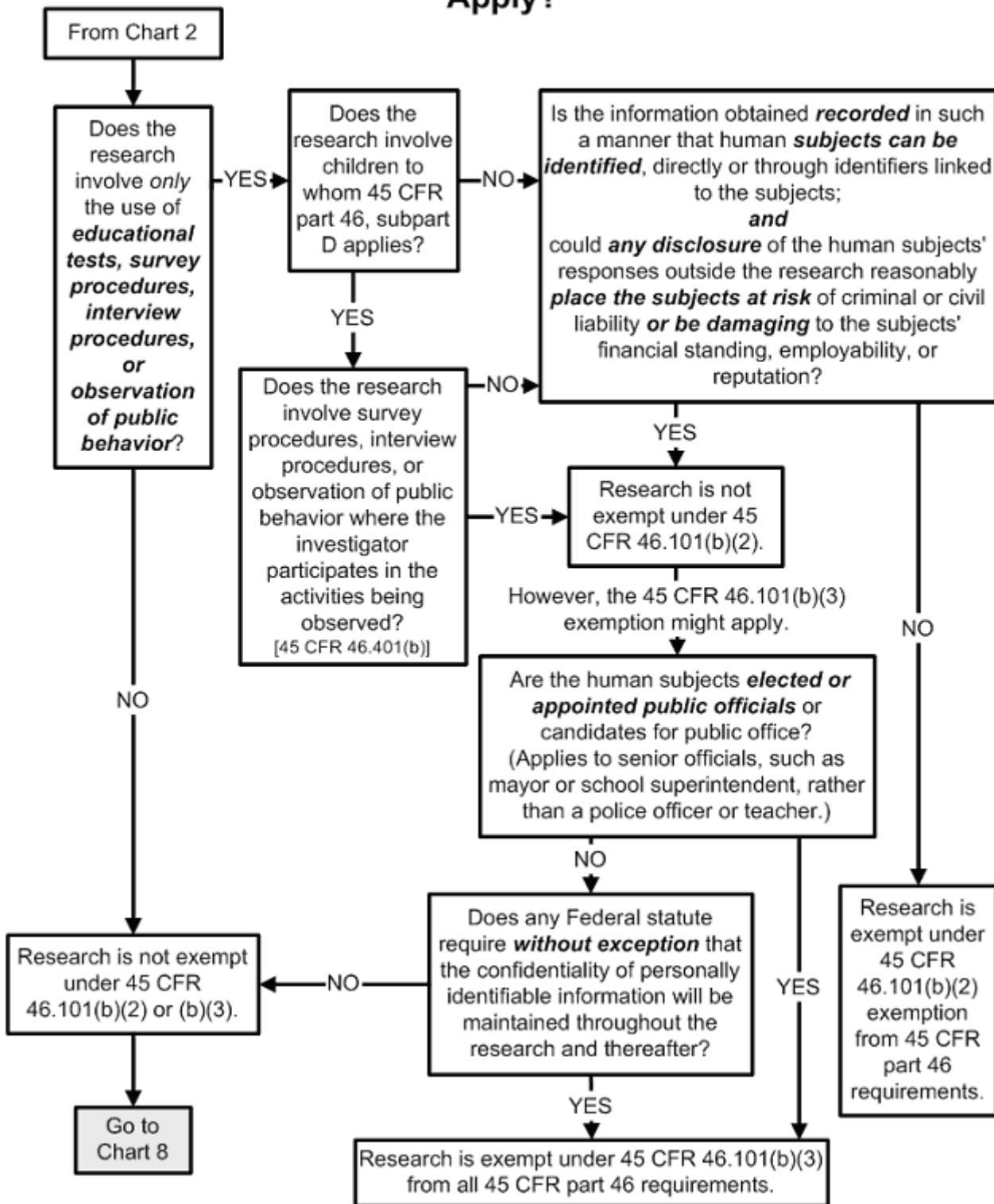


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



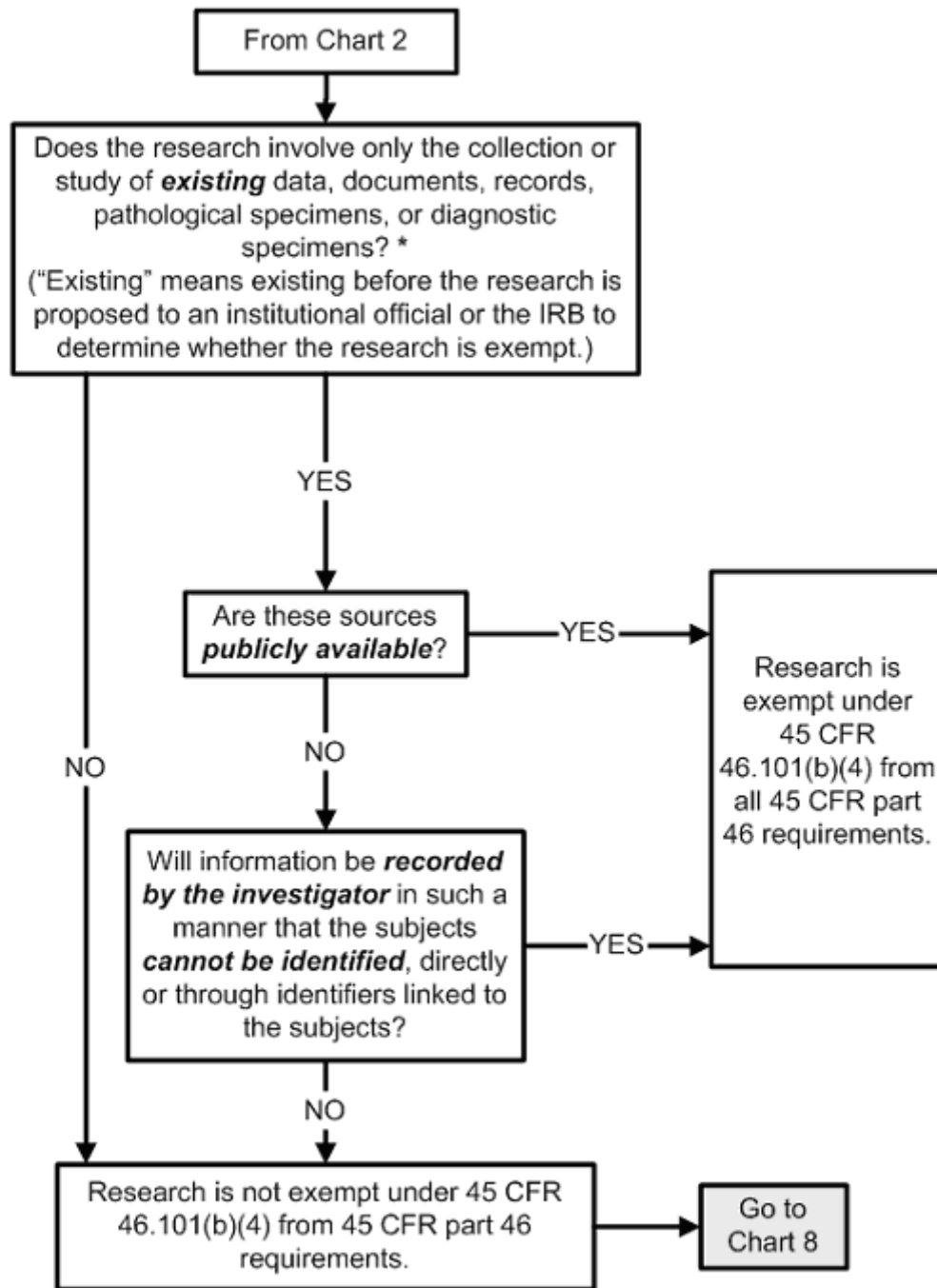
September 24, 2004

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



September 24, 2004

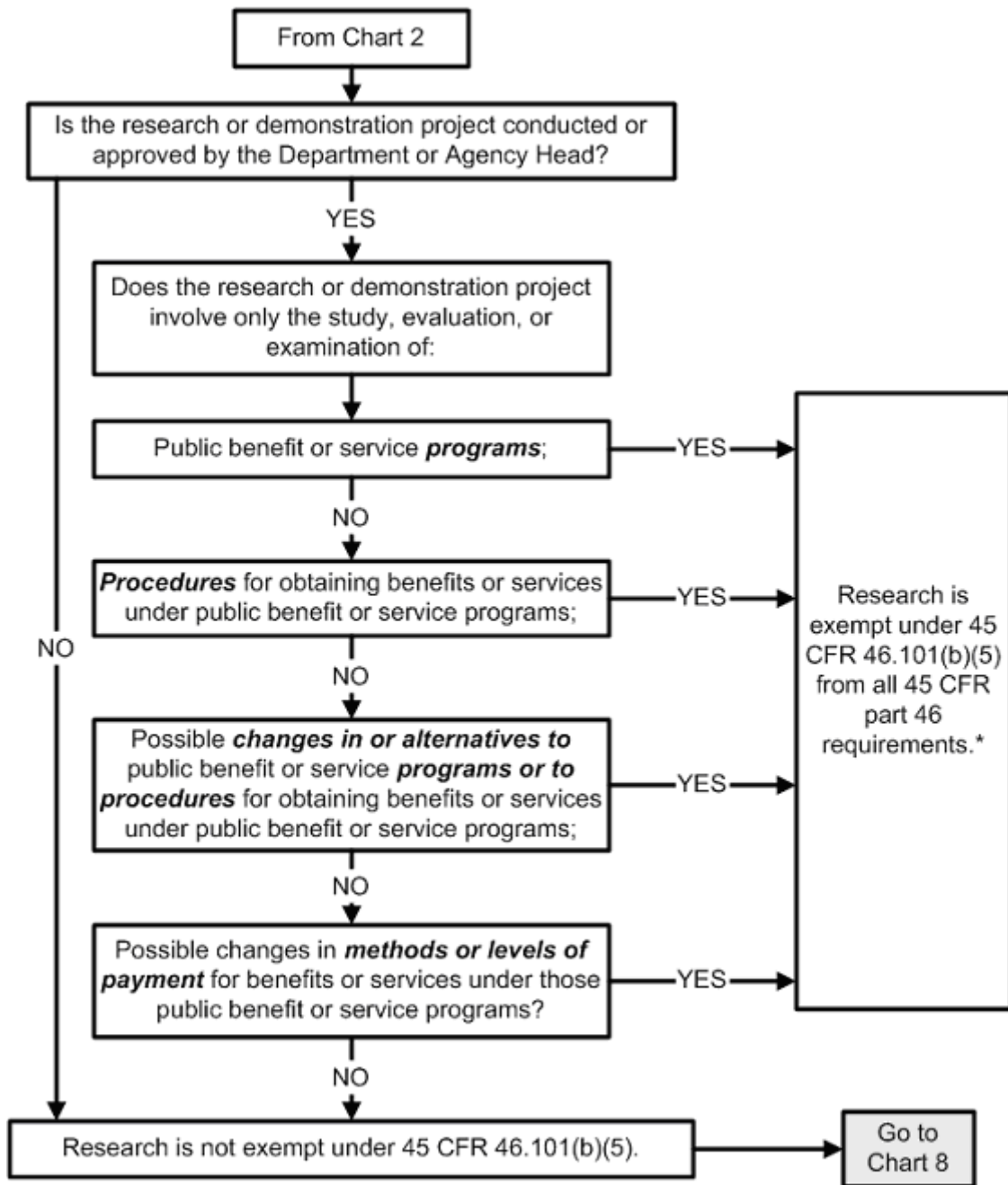
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and #stem, and on coded data or specimens at #coded for further information on those topics.

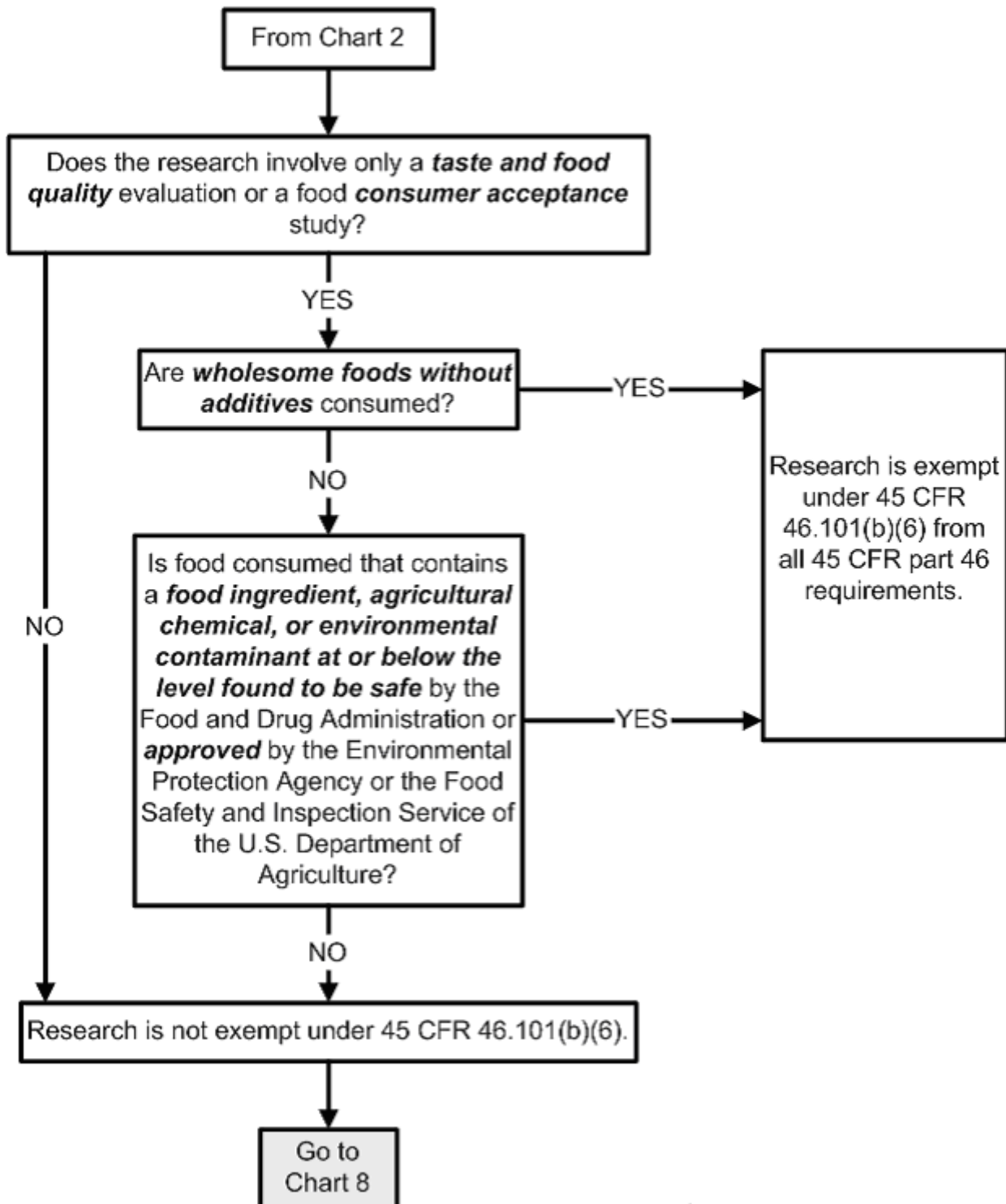
September 24, 2004

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

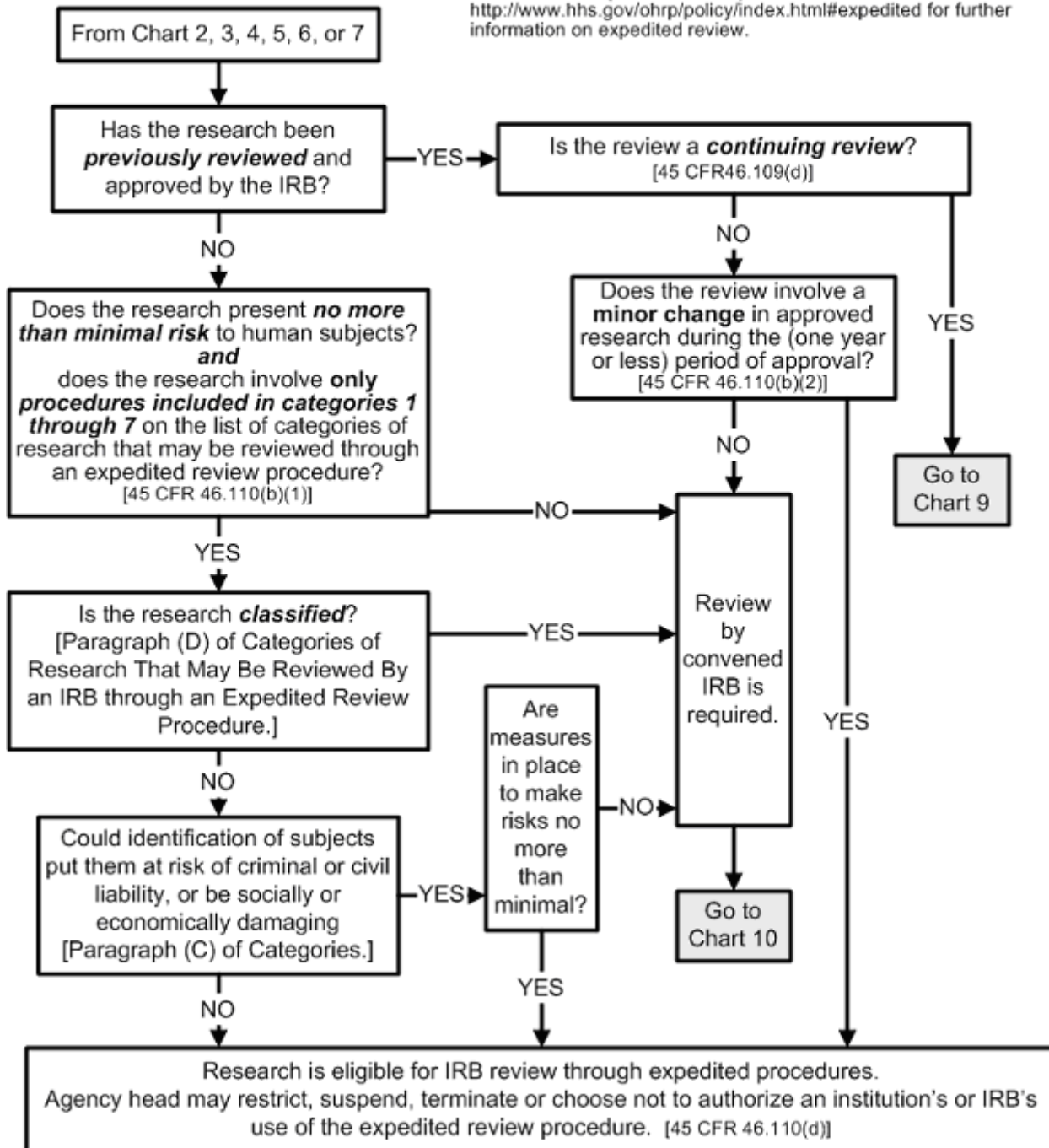
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



September 24 2004

Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

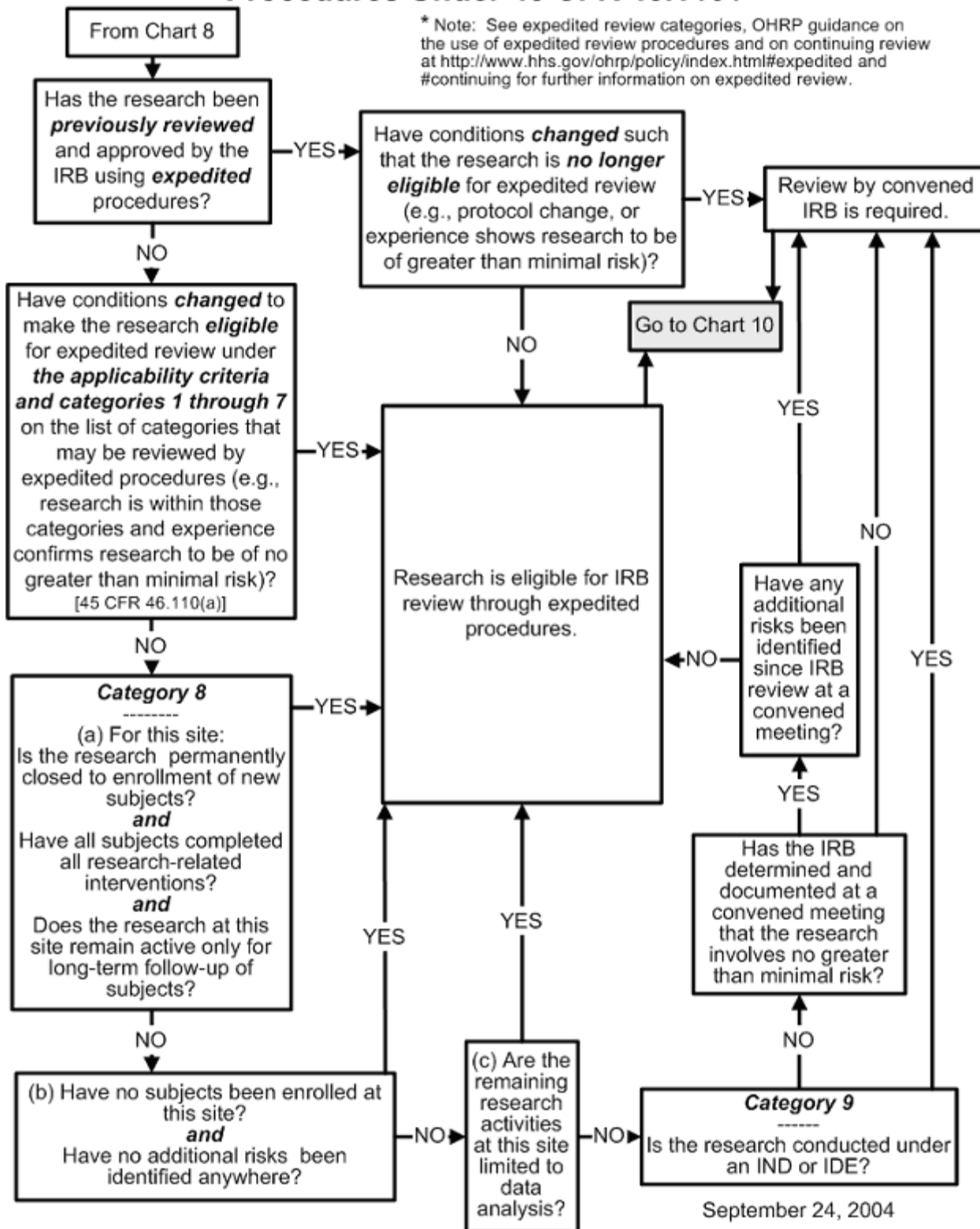
* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



September 24, 2004

Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

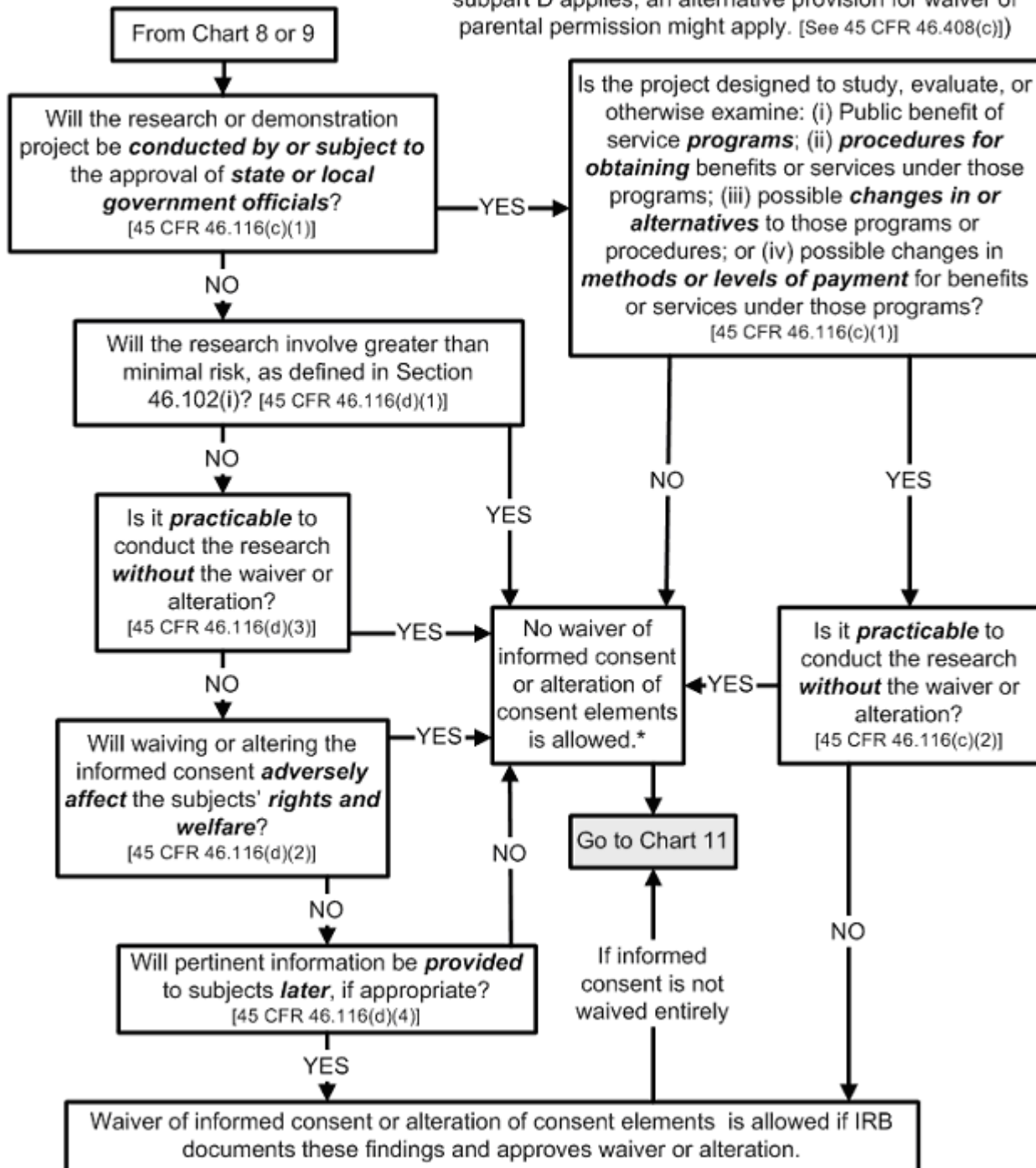
* Note: See expedited review categories, OHRP guidance on the use of expedited review procedures and on continuing review at <http://www.hhs.gov/ohrp/policy/index.html#expedited> and #continuing for further information on expedited review.



September 24, 2004

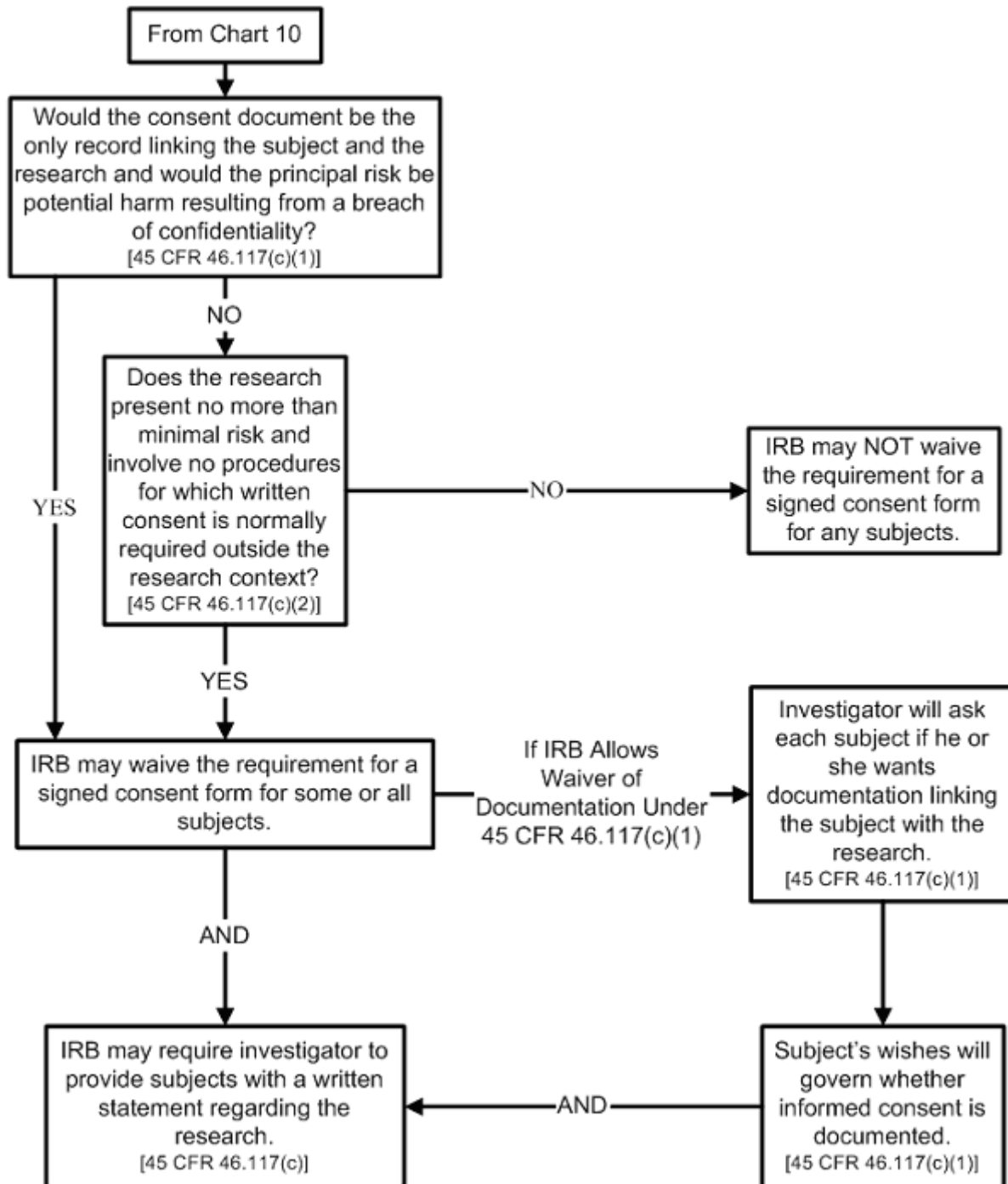
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver.

Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



September 24, 2004

II. PROCEDURES FOR OBTAINING REVIEW BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH)

A. Introduction

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

- (1) Request for Full Board Review;
- (2) Request for Expedited Review; or
- (3) Request for Exemption from IRB Review.

All requests for review are to be submitted to the Office of Minority Health and Health Equity/ Institutional Review Board, VDH. Criteria and procedures for obtaining clearance for each of the specific categories are described in Sections B, C, and D.

1. General Criteria for IRB Approval of Research: In order to approve non-exempt research, the IRB will consider the following elements of the proposal:

- a. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research. *Risks to subjects are to be minimized and benefits to subjects maximized by using procedures which are consistent with sound research design*
- b. The degree of risk, and, if the research is nontherapeutic*, whether it presents greater than minimal risk**. *Risks to subjects are to be minimized by using procedures which do not unnecessarily expose the subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.*
- c. The necessity and utility of the research and whether the risks to the subjects are outweighed by the potential benefits of the research and the importance of the knowledge that may reasonably be expected to result. *In evaluating risks and benefits, the IRB will consider only risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks or potential benefits that fall within the purview of its responsibilities.*
- d. The equity in criteria for selection of subjects, especially in research regarding the future development of mental or physical illness. *In making this assessment, the IRB will take into*

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

** Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, consider *in daily life or during the performance of* *Please consult complete descriptions on the following pages

account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically/educationally disadvantaged persons.

- e. The adequacy of protection of rights and welfare of the participants. These include the following:
- ◆ *Voluntary informed consent is sought from each prospective subject or the subjects' legally authorized representative and appropriately documented.*
 - ◆ *Voluntary informed consent is obtained by methods that are adequate and appropriate to the subject's educational level and language of greatest fluency.*
 - ◆ *The written consent form is adequate and appropriate in both content and wording for the particular research and for the particular subjects of the research relative to their educational level and language of greatest fluency and reasonably reflects full explanation and adequate understanding.*
 - ◆ *The person(s) proposed to supervise or conduct the particular research protocol are appropriately competent and qualified.*
 - ◆ *When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*
 - ◆ *When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.*
 - ◆ *When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically/educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these subjects*

2. General Requirements for Informed Consent: 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 individual;
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 that may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols;
5. An offer to answer any inquiries by any individual concerning the procedures and protocols;
6. A statement that the study involves research, and an explanation that includes identification of any procedures that are experimental; the expected duration of the individual'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 individual will not be identified without his written permission;

7. A statement that there may be other risks not yet identified;
8. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;
9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual 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 individual with regard to his educational level and language of greatest fluency.

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

- a. the research involves no more than minimal risk* to the subjects;
- b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- c. the research could not practicably be carried out without the waiver or alteration; and
- d. whenever appropriate, the subjects will be provided with additional pertinent information after participation

3. General Requirements for Documentation of Informed Consent: Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative with the exception of the following situations:

- a. 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 the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Consent may take the form of either of the following:

- a. 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
- b. 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 itself is to be signed by the subject or the representative. However, the witness shall sign both the short form 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 shall be given to the subject or the representative.

All forms and documents should be submitted to:

Office of Minority Health and Health Equity/
Institutional Review Board
Virginia Department of Health
109 Governor Street, 10th Floor East
P.O. Box 2448
Richmond, VA 23218-2448

For questions or additional information, please contact:

Kathy H. Wibberly, Ph.D., Chair of the VDH IRB
Phone: 804-864-7426
Fax: 804-864-7440
E-mail: Kathy.Wibberly@vdh.virginia.gov

B. Requests for Full Board Review

The following is a checklist of documents that must be submitted by the principal investigator in order to obtain full board review and clearance:

- Request for Review and Clearance of a Project Involving Human Subjects (Appendix B)
- Study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).
- Letter(s) and other materials that will be supplied to study subjects
- Questionnaire(s) (when applicable)
- CV or resume of Principle Investigator

Full Board review requires the submission of 1 electronic OR 7 hard copies of the "Request for Review" application and supporting documents, and requires attendance of the principal investigator at a meeting of the IRB. The IRB is required by state regulations to review all requests within 45 days after submission. The IRB is scheduled to meet quarterly (January, April, July, October) and will convene more often as needed. In order for research to be approved, it must receive the approval of a majority of those members present at a meeting in which a quorum exists. A quorum consists of a majority of the members, including at least one member whose primary concerns are in a nonscientific area. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the investigator in writing within 7 business days of the IRB meeting where the submission is reviewed.

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

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

C. Requests for Expedited Review

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

- Request for Review and Clearance of a Project Involving Human Subjects ([Appendix B](#))
- Study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress)..
- Letter(s) and other materials that will be supplied to study subjects
- Questionnaire(s) (when applicable)
- CV or resume of Principle Investigator
- IRB approval document(s) (if requesting expedited review because the study has been approved via Full Board Review by the IRB at another institution or agency)

Expedited review requires the submission of 1 electronic OR 2 hard copies of the "Request for Review" application and supporting documents. The decision to approve or disapprove a project submitted for expedited review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

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

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

D. Requests for Exemption from IRB Review

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

- Request for Exemption from IRB Review Form (Appendix D)
- Cover letter with a detailed written explanation of why the project should be regarded as exempt
- Study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).
- Letter(s) and other materials that will be supplied to study subjects
- Questionnaire(s) (when applicable)
- CV or resume of Principal Investigator

Exemption review requires the submission of 1 electronic OR 2 hard copies of the "Request for Exemption" application and supporting documents. The decision to approve or disapprove a project submitted for exemption review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

All forms and documents should be submitted to:

Office of Minority Health and Health Equity/
Institutional Review Board
Virginia Department of Health
109 Governor Street, 10th Floor East
P.O. Box 2448
Richmond, VA 23218-2448

For electronic submissions, questions or additional information, please contact:

Kathy H. Wibberly, Ph.D., Chair of the VDH IRB
Phone: 804-864-7426
Fax: 804-864-7440
E-mail: Kathy.Wibberly@vdh.virginia.gov

APPENDIX A:
**REGULATIONS FOR THE CONDUCT
OF HUMAN RESEARCH**

**COMMONWEALTH OF VIRGINIA
BOARD OF HEALTH
12 VAC 5-20-10 –
12 VAC 5-20-120**

Effective: July 1, 1993

CHAPTER 20 REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

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 utilizing human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participants' needs.

"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 individual;
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 any inquiries by any individual concerning the procedures and protocols.

In addition to the required elements, the information provided to the individual should also include the following:

1. A statement that the study involves research, and an explanation that includes identification of any procedures which are experimental; the expected duration of the individual's participation; and 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 individual will not be identified without his written permission;
2. A statement that there may be other risks not yet identified;

3. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;
5. 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
6. 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 should be provided in a manner that is understandable to the individual with regard to his educational level and language of greatest fluency.

"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 the parent or parents having custody of a prospective participant, the legal guardian of a prospective participant or any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant 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 participant to his 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 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 participant.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 1, eff. July 1, 1993.

12VAC5-20-20. [Reserved]

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 which conducts or which proposes to conduct or authorize research which uses human participants.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 3, eff. July 1, 1993.

12VAC5-20-40. Policy.

A. No human research may be conducted without informing the participant or his legally authorized representative of the procedures, risks, and discomforts of the research. The consent of the participant or his legally authorized representative to participate in the research shall be subscribed to in writing by the participant 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 F and H of this chapter. 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 of this chapter 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 these regulations.

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 will not present greater than minimal risk.

E. The individual conducting the research shall be required to notify all participants of research of the risks caused by the research which 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.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 4, eff. July 1, 1993.

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 of a participant in the research project, a description of what will be done to the participants, and a copy of the informed consent statement.

B. The committee shall report by January 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 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 chairman of the committee shall report as soon as possible to the commissioner any violation of the research protocol which 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.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 5, eff. July 1, 1993.

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 participant in the research project, a description of what will be done to the participants, 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 January 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 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 chairman 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 either 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.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 6, eff. July 1, 1993.

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

A. Each committee shall have at least seven 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 participants 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 participants, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these participants and who have appropriate experience to serve in that capacity.

B. No committee shall consist entirely of members of one profession, and at least one member must 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 seven 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 may 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.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 7, eff. July 1, 1993.

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

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

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

C. The committee shall approve or 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.

D. 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.

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

Statutory Authority

§ 32.1-12.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 8, eff. July 1, 1993; amended, Virginia Register Volume 26, Issue 13, eff. March 31, 2010.

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

A. The committee is authorized to conduct an expedited review of a human research project which 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.

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

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 9, eff. July 1, 1993.

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 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 individual;
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 that may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols;
5. An offer to answer any inquiries by any individual concerning the procedures and protocols;
6. A statement that the study involves research, and an explanation that includes identification of any procedures that are experimental; the expected duration of the individual'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 individual will not be identified without his written permission;
7. A statement that there may be other risks not yet identified;
8. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;
9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual 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 individual with regard to his educational level and language of greatest fluency.

B. 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 itself is to be signed by the subject or the representative. However, the witness shall sign both the short form 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 shall be given to the subject or the representative.

Statutory Authority

§ 32.1-12.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 10, eff. July 1, 1993; amended, Virginia Register Volume 26, Issue 13, eff. March 31, 2010.

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

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

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), § 32.1-71.1 (Statewide Alzheimer's Disease and Related Disorders Registry), and §§ 32.116.1 and 32.116.1:2 (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 participants cannot be identified, directly or through identifiers linked to the participants.
4. Research involving survey or interview procedures unless responses are recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants, and either:
- a. The participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or
 - b. The research deals with sensitive aspects of the participant'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 participants can be identified, directly or through identifiers linked to the participants, and either:
- a. The observations recorded about the individual, 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 participant'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 participants cannot be identified, directly or through identifiers linked to the participants.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 11, eff. July 1, 1993.

12VAC5-20-120. Committee records.

A. Documentation of committee activities shall be prepared and maintained 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 participants;
2. Minutes of committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a 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 participants.

B. The records required by this chapter shall be retained for at least three years, and records relating to research which 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. An overview of approved human research projects and the results of such projects will be made public on the department's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

Statutory Authority

§ 32.1-12.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 12, eff. July 1, 1993; amended, Virginia Register Volume 26, Issue 13, eff. March 31, 2010.

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

Human research at institutions which are subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempt from this chapter. Such institutions shall notify the commissioner annually by January 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.

Statutory Authority

§ 32.1-12.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from VR355-01-400 § 13, eff. July 1, 1993.

APPENDIX B:

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS

**Virginia Department of Health
Office of Minority Health and Health Equity//Institutional Review Board
109 Governor Street, 10th Floor East; PO Box 2448
Richmond, VA 23218-2448**

**REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT
INVOLVING HUMAN SUBJECTS**

STATE USE ONLY	
ID #:	
Date Rec'd:	
Expedited	<input type="checkbox"/>
Full	<input type="checkbox"/>

Submit either 1 electronic copy of this completed form along with the protocol, other supporting documents, and CV or resume of the Principal Investigator OR 7 hard copies for Full Board Review/2 hard copies for Expedited Review to the chair of the VDH IRB to the above address.

Title of Protocol _____

Name and Title of Principal Investigator	Email Address
--	---------------

Name of Institution	Telephone Number
---------------------	------------------

Address _____

Name and Title of Department of Health Collaborator, if included in study and different from Principal Investigator	Email Address
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Address	Telephone Number
---------	------------------

Proposed Dates for Project _____

Beginning: _____ Ending: _____

Assurance of Confidentiality

1. The undersigned hereby agrees to the following terms and conditions related to a request for approval for research:
2. No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable without the written permission of the subject(s) involved.
3. The identifying information will be used only for statistical purposes in medical and health research.
4. The identifying information will not be used as a basis for legal, administrative, or other actions which may directly affect those particular individuals as a result of their specific identification in this project.
5. The identifying information will be used only for the study or project proposed and the purposes described in the attached document. Use of the information for a research project other than the one described will not be undertaken until after a separate request is made to the Virginia Department of Health.
6. While identifiers still appear, access to paper, hardware and software will be secured. Paper records will be kept in locked cabinets and computers will be kept locked or have password protection.
7. All statements made to the Virginia Department of Health are correct.

Signature of Principal Investigator	Date
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Name of Requester, if different from Investigator (Print)	Title
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Signature of Requestor	
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**REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT
INVOLVING HUMAN SUBJECTS**
(Continued)

<i>STATE USE ONLY</i> ID #:

1. Name(s) of any other IRBs reviewing this project.

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

3. List the potential risks to study participants.

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

5. Do your subjects include any of the following:

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

Yes No

b. Institutionalized mentally infirm people?

Yes No

c. Inmates/Prisoners?

Yes No

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

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

STATE USE ONLY ID #:

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

- Yes No

If yes, please enclose a copy of the form. ALL SUBJECTS MUST BE TOLD AND UNDERSTAND THAT THEY CAN DECLINE PARTICIPATION IN THE RESEARCH. If you DO NOT intend to use a consent form, please explain your reasons here:

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

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

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

10. Please provide any other information that would be helpful to the IRB.

APPENDIX C:
CONTINUATION REVIEW

**Virginia Department of Health
Office of Minority Health and Health Equity/Institutional Review Board
109 Governor Street; 10th Floor East
PO Box 2448
Richmond, VA 23218-2448**

CONTINUATION REVIEW

This form is to be completed and submitted to the above address only for studies that have been reviewed previously.

Title of Study or Project	ID No.
Name of Principal Investigator	E-mail Address
Address	Telephone No.
Name of Department of Health Collaborator, if included in study and different from Principal Investigator:	E-mail Address
Address	Telephone No.

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

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

- It is no longer in progress.
- It was never started.
- It was recently re-reviewed on (date) ____ ____ / ____ ____ / ____ ____.
- Other (Specify):

Section II - For studies that required re-review.

1. How many subjects have been entered into the study?

2. Have you received or are you aware of any adverse events or unanticipated problems involving risks to subjects or others, including breach of confidentiality, withdrawal of study subjects, or complaints about the study?
 - Yes No

If Yes, please explain:

-
3. Summarize here any recent literature, findings, or other relevant information, especially information about risks associated with the research, that study subjects should be aware of.

Have study subjects been informed of these findings?

Yes No

If No, why not?

4. Have there been any changes in the informed consent forms?

Yes No

If Yes, please submit a copy of the revised forms.

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

Yes No

If Yes, please describe:

Signature of Principal Investigator

Date

APPENDIX D:
REQUEST FOR EXEMPTION FROM IRB REVIEW

**Virginia Department of Health
Office of Minority Health and Health Equity/Institutional Review Board
109 Governor Street, 10th Floor East
PO Box 2448
Richmond, VA 23218-2448**

REQUEST FOR EXEMPTION FROM IRB REVIEW

Instructions: Submit 1 electronic OR 2 hard copies of this completed form along with cover letter, protocol, letters and other materials that will go to study subjects, questionnaires, and CV or resume of the Principal Investigator to the above address.

Title of Study or Project	ID No.
Name of Principal Investigator	E-mail Address
Address	Telephone No.
Name of Department of Health Collaborator, if included in study and different from Principal Investigator:	E-mail Address
Address	Telephone No.

I (or we) request that the project named above be approved as exempt from review by the Institutional Review Board based on the following exemption criteria (see pages 7 – 9):

Signature of Principal Investigator: _____ Date: _____