CHAPTER 180

REGULATIONS TO ASSURE THE PROTECTION OF PARTICIPANTS IN HUMAN RESEARCH

12VAC35-180-10. 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 the institution or a member of a household containing an employee of the institution.

"Board" means the State Mental Health, Mental Retardation and Substance Abuse Services Board.

"Commissioner" means the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

"Department" means the Department of Mental Health, Mental Retardation and Substance Abuse Services.

<u>“Health information” means any information, whether oral or recorded in any form or medium, that:</u>

1. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

"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).

"Human ~~participant~~ subject" or "subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information.

"Individually identifiable health information" means information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

a. That identifies the individual; or

b. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"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 for such consent shall include:

1. A statement that the study involves research, and a reasonable and comprehensible explanation to the individual of the procedures or protocols to be followed, their purposes, including identification of any procedures which are experimental; the expected duration of the individual's participation; and the extent, if any, to which confidentiality of records identifying the subject will be maintained; how the results of the study will be disseminated; and if any data from the study are published, the individual will not be identified without written permission;

2. A statement of any attendant discomforts and risks reasonably to be expected and a statement that there may be other risks not identified;

3. A description of any benefits to the individual or to others reasonably to be expected;

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

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

6. 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 that the individual may withdraw his consent and discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

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

8. 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 they consist of, or where further information may be obtained; and

9. An explanation of any costs or compensation which may accrue to the person or medical care that is available and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols.

"Institution" or "Agency" means any community services board or any facility or program operated, funded, or licensed by the department.

"Interaction" includes communication or interpersonal contact between investigator and participant.

"Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the ~~participant~~ subject or ~~participant's~~ subject's environment that are performed for research purposes.

~~"Interaction" includes communication or interpersonal contact between investigator and participant.~~

"~~Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.~~

~~"Human research" means any systematic investigation which utilizes 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 participant's needs.~~

~~"Institution" means any community services board or any facility or program operated, funded, or licensed by the department.~~

"Legally authorized representative" means, in the following specified order of priority, (i) the parent or parents having custody of a prospective ~~participant~~ 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 advanced directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (iii) the legal guardian of a prospective ~~participant~~ subject, (iv) the spouse of a 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 ~~participant~~ subject to such ~~person's~~ subject's participation in the particular human research. For the purposes of this definition, any person authorized by law or regulation to consent on behalf of a prospective ~~participant~~ subject 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. ~~and shall not be authorized to consent to nontherapeutic medical 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, or treatments.

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

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for the obtaining of the information to constitute research involving human subjects.

“Protected health information (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 U.S.C. 1232g;

2. Records described at 20 U.S.C. 1232g(a)(4)(B)(iv) (educational records not otherwise covered under the Family Educational Rights Privacy Act in paragraph 1 above);

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

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this chapter, whether or not they are supported or

funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

~~"Voluntary informed consent" means the knowing consent of an individual so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. With regard to the conduct of human research, the basic elements of information necessary to such consent shall include:~~

~~1. A statement that the study involves research, and a reasonable and comprehensible explanation to the individual of the procedures to be followed and their purposes, including identification of any procedures which 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;~~

~~2. A description of any attendant discomforts and risks reasonably to be expected and a statement that there may be other risks not yet identified;~~

~~3. A description of any benefits to the individual or to others reasonably to be expected;~~

~~4. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;~~

~~5. An offer to answer and answers to any inquiries by any individual concerning the procedure;~~

~~6. 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;~~

~~7. 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;~~

~~8. 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 they consist of or where further information may be obtained; and~~

~~9. 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.~~

12VAC35-180-20. Authority.

This chapter is promulgated under the authority of §§37.1-24.01 and ~~37.1-10.6~~ 37.1-10 of the Code of Virginia, to effectuate the provisions of Chapter 5.1 (§32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

12VAC35-180-30. Applicability.

This chapter shall apply to the Department of Mental Health, Mental Retardation and Substance Abuse Services; ~~and to~~ any community services board; 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~~ subjects.

12VAC35-180-40. Policy.

A. No human research may be conducted without ~~informing the participant or his legally authorized representative in writing of the risks, procedures, and discomfort of the research~~ obtaining the informed consent of the subject or his legally authorized representative. The informed consent of the ~~participant~~ subject or his legally authorized representative to participate in the research must be documented in writing and supported by the signature of a witness ~~not involved in the conduct of the research, except as provided for in 12VAC35-180-100 F of this chapter~~. Arrangements shall be made for those who need special assistance in understanding the consequences of participating in the research.

B. Each human research activity shall be approved by a committee composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities.

C. Nontherapeutic research using ~~institutionalized participants~~ subjects receiving care in a residential or hospital setting is prohibited unless it is determined by the research review committee that such nontherapeutic research will ~~not~~ present no more than a minor increase over minimal risk to the human subject ~~greater than minimal risk~~.

D. The individual conducting the research shall be required to notify all ~~participants~~ subjects of research of the risks caused by the research which are discovered after the research has concluded.

12VAC35-180-50. Certification process.

A. Institutions seeking to conduct or sponsor human research are required to submit statements to the department assuring that all human research activities will be reviewed and approved by ~~a~~ an internal or external research review committee. Institutions shall report annually to the commissioner giving assurance that a committee exists and is functioning. These reports ~~should~~ shall include a list of committee members, their qualifications for service on the committee, their institutional affiliation and a copy of the minutes of committee meetings.

B. Prior to the initiation of a human research project, institutions shall also send to the commissioner a description of the research project to be undertaken, which shall include a statement of the criteria for inclusion of a ~~participant~~ subject in the research project, a description of what will be done to the ~~participants~~ subjects, and a copy of the informed consent statement.

C. Each person engaged in the conduct of human research or proposing to conduct human research shall ~~associate~~ affiliate himself with ~~any~~ an institution or agency having a committee, and such human research as he conducts or proposes to conduct shall be subject to review and approval by the committee in the manner set forth in ~~this section~~ these regulations.

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

E. The chairman of the committee shall report as soon as possible to the head of the institution and to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

12VAC35-180-60. Composition of research review committees.

A. Each committee shall have at least five members, appointed by the head of the institution or agency, with varying backgrounds to ~~provide~~ ensure the competent, complete and ~~adequate~~ professional review of human research 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 research activities, the committee must 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 an institutionalized or other vulnerable category of ~~participants~~ subjects, including residents of mental health or mental retardation facilities, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these ~~participants~~ subjects and who have appropriate experience to serve in that capacity.

B. No committee shall consist ~~entirely of men or entirely of women, or~~ 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 or agency and who is not part of the immediate family of a person who is affiliated with the institution or agency.

D. No member of a committee shall participate in the committee's initial or continuing review of any project in which the member is directly involved or for which he has administrative approval authority, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflicting interest. The committee member shall be replaced in the case of conflicting interests resulting in a decrease of the committee below five persons.

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 or agency shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

12VAC35-180-70. Elements of each committee's review process.

A. No human research shall be conducted or authorized by such institution or agency unless such 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 research;

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

3. Whether the rights and welfare of the ~~participants~~ subjects are adequately protected;

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

5. Whether the risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

6. When some or all of the subjects are likely to be incapable of making an informed decision regarding consent or are otherwise vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, whether additional safeguards have been included in the study to protect the rights and welfare of these subjects;

~~5~~ 7. Whether the ~~voluntary~~ 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 research and for the particular ~~participants~~ subjects of the research;

~~6~~ 8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified;

~~7~~ 9. Whether criteria for selection of ~~participants~~ subjects are equitable~~, especially in research regarding the future development of mental or physical illness~~; and

~~8.~~10 Whether the research conforms with such other requirements as the board may establish~~; and~~.

~~9. Whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants.~~

B. Each committee shall review approved projects to ensure conformity with the approved proposal at least annually.

C. Research must be approved by the committee which has jurisdiction over the ~~participant~~ subject. When cooperating institutions conduct some or all of the research involving some or all of the ~~participants~~ subjects, each cooperating institution is responsible for safeguarding the rights and welfare of human ~~participants~~ subjects and for complying with this chapter, except that in complying with this chapter institutions may enter into joint review, rely upon the review of

another qualified committee, or make similar arrangements aimed at avoiding duplication of effort. Such arrangements may be made by the committee chairperson with the approval of a majority of the members present at a meeting of the committee. If a given institution or agency does not have a research review committee, this arrangement shall be approved by the chief executive officer of the institution, or his designee.

D. The committee shall consider research proposals within 45 days after submission to the committee's chairman. 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.

E. The committee shall develop a written description of the procedure to be followed by a ~~participants~~ subject who has a complaint about a research project in which he is participating or has participated.

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

G. The committee shall require periodic reports to ensure that the project is being carried out in conformity with the proposal. The frequency of such reports should reflect the nature and degree of risk of each research project.

H. The committee shall ensure compliance with the Health Insurance Portability and Accountability Act of 1966 regarding the use and disclosure of PHI created for research. In particular, authorization shall be obtained for the use and disclosure of PHI created for the purpose of research, except as otherwise permitted by 45C.F.R.164.512(i).

12VAC35-180-80. Kinds of research exempt from committee review.

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

1. Research conducted in established or commonly accepted educational settings, involving commonly used educational practices, such as:

a. Research on regular and special education instructional strategies; ~~or~~

b. Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.

2. Research involving solely the use and analysis of the results of s~~tandardized psychological,~~ educational~~,~~ tests, whether cognitive, diagnostic, aptitude, or achievement ~~tests~~, if ~~information taken~~ the data from ~~these sources~~ such tests ~~is~~ are recorded in such a manner so that ~~participants~~ subjects cannot be ~~reasonably~~ identified, directly or through identifiers linked to the ~~participants~~ subjects.

3. Research involving survey or interview procedures, unless:

a. Responses are recorded in such a manner that ~~participants~~ the subjects can be identified, directly or through identifiers linked to the ~~participants~~ subjects; and

(1) The ~~participant's~~ subject's responses, if they became known outside the research, could reasonably place the ~~participant~~ subject at risk of criminal or civil liability or be damaging to the ~~participant's~~ subject's financial standing, employability, or reputation; or

(2) The research deals with sensitive aspects of the ~~participant's~~ subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct ~~or family planning~~.

4. Research involving solely the observation (including observation by ~~participants~~ subjects) of public behavior, unless:

a. Observations are recorded in such a manner that ~~participants~~ subjects can be identified, directly or through identifiers linked to the ~~participants~~ subjects, and either:

(1) The observations recorded about the individual, if they became known outside the research, could reasonably place the ~~participant~~ subject at risk of criminal or civil liability or be damaging to the participant's financial standing, or employability, or reputation; or

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

5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information

taken from these sources is recorded in such a manner that ~~participants~~ subjects cannot be identified, directly or through identifiers linked to the ~~participants~~ subjects.

6. Research involving solely a combination of any of the activities described in this section.

12VAC35-180-90. Expedited review procedures for certain kinds of research involving no more than minimal risk.

A. The committee may conduct an expedited review of a human research project which involves no more than minimal risk to the ~~participants~~ subjects if (i) another institution's or agency's human research review committee has reviewed and approved the project or (ii) the review involves only minor changes in previously approved research and the changes occur during the approved project period. Under an expedited review procedure, the review may be carried out by the committee chairperson and one or more experienced reviewers designated by the chairperson from among members of the committee. In reviewing the research, the reviewers may exercise all of the ~~authorities~~ authority of the committee except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in 12 VAC 35-180-70 of this chapter.

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.

C. Research activities involving no more than minimal risk and in which the only involvement of human ~~participants~~ subjects will be in one or more of the following categories (carried out

through standard methods) may be reviewed by the research review committee through the expedited review procedure.

1. Collection of hair and nail clippings, in a nondisfiguring manner; nonpermanent teeth at a time of natural loss or if patient care indicates a need for extraction; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from ~~participants~~ subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the ~~participant~~ subject or an invasion of the ~~participant's~~ subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture or less invasive procedures, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra-gingival and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate ~~participants'~~ subjects' behavior and the research will not involve stress to ~~participants~~ subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

12VAC35-180-100. Informed consent.

A. No human research may be conducted in this Commonwealth in the absence of ~~voluntary~~ informed consent subscribed to in writing by the ~~participant~~ subject or by the ~~participant's~~ subject's legally authorized representative except as provided for in subsection F of this section. If the subject is capable of making an informed decision, then it shall be subscribed to in writing by the subject and witnessed. If the subject is incapable of making an informed decision, as

defined in § 54.1-2982, at the time consent is required, then it shall be subscribed to in writing by the person's legally authorized representative and witnessed. If the ~~participant~~ subject is a minor otherwise capable of rendering ~~voluntary~~ informed consent, the consent shall be subscribed to by both the minor and his legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective ~~participant~~ subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the ~~participant~~ subject or the representative shall be in language understandable to the ~~participant~~ subject or the representative.

If two or more persons who qualify as legally authorized representatives have equal decision-making priority under this chapter inform the principal investigator or attending physician that they disagree as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.

B. No individual shall participate in research unless this requirement is met for each individual. The giving of informed consent by a legally authorized representative shall be subject to the provisions of subsection C of this section. No ~~voluntary~~ informed consent shall include any language through which the ~~participant~~ subject waives or appears to waive any of his legal rights, including any release of any individual, institution or agency or any agents thereof from liability for negligence. Notwithstanding the informed consent by a legally authorized representative, no person shall be forced to participate in any human research if the investigator conducting the human research knows that participation in the research is protested by the prospective subject. In the case of persons suffering from organic brain disease causing progressive deterioration of

cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which the legally authorized representative has given informed consent shall not consititute the use of force. Each ~~participant~~ subject shall be given a copy of the signed consent form required by 12 VAC 35-180-40 (A) of this chapter, except as provided for in 12 VAC 35-180-100 (F).

C. No legally authorized representative may consent to nontherapeutic research unless it is determined by the committee that such nontherapeutic research will present no more than a minor increase over minimal risk to the ~~participant~~ subject. A legally authorized representative may not consent to participation in human research on behalf of a prospective 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 prospective subject, whether expressed orally or in writing. A legally authorized representative may not consent to participation in human research involving nontherapeutic sterilization, abortion, psychosurgery, or admission for research purposes to a facility or hospital as defined in § 37.1-1. No nontherapeutic research shall be performed without the consent of the ~~participant~~ subject.

D. The committee may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent set forth in 12 VAC 35-180-10 of this chapter, or waive the requirements to obtain informed consent provided the committee finds and documents that:

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

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

3. The research could not practicably be carried out without the omission, waiver or alteration; and

4. Whenever appropriate, the ~~participants~~ subjects ~~will~~ shall be provided with additional pertinent information after participation.

E. Except as provided in subsection F of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 12 VAC 35-180-10 of this chapter. This form may be read to the ~~participant~~ subject or the ~~participant's~~ subject's legally authorized representative, but in any event, the investigator shall give either the ~~participant~~ subject or the legally authorized representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent required by 12 VAC 35-180-10 of this chapter have been presented orally to the ~~participant~~ subject or the ~~participant's~~ 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 ~~participant~~ subject or the legally authorized representative. Only the short form itself is to be signed by the participant 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 shall be given to the ~~participant~~ subject or the representative, in addition to a copy of the short form.

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

12VAC35-180-110. Committee records.

A. An institution or agency, or when appropriate a committee, shall prepare and maintain adequate documentation of committee activities, including the following:

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

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 controverted 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.

7. Statements of significant new findings provided to ~~participants~~ subjects.

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.

Statutory Authority

12VAC35-180-120. Mandatory reporting.

Each research review committee shall 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, including any significant deviations from the proposals as approved.

12VAC35-180-130. Role of the department, commissioner, and the board.

A. The commissioner shall establish and maintain records of institutional assurances, annual reports, and summary descriptions of research projects to be reviewed by the board.

B. The commissioner shall review communications from committees reporting violations of research protocols which led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of the rights of human research ~~participants~~ subjects. The board shall be kept informed.

C. The commissioner shall arrange for the printing and dissemination of copies of this chapter.

12VAC35-180-140. Applicability of state policies.

Nothing in this chapter shall be construed as limiting in any way the rights of ~~participants~~ subjects in research under regulations promulgated by the board in response to §37.1-84.1 of the Code of Virginia.

12VAC35-180-150. Applicability of federal policies.

Human research at institutions or agencies which are subject to policies and regulations for the protection of human ~~participants~~ subjects promulgated by any agency of the federal government shall be exempt from this chapter. Such institutions or agencies shall notify the commissioner and the board annually of their compliance with the policies and regulations of federal agencies.