Protection of Participants in Human Research

22VAC30-40-10. 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 Board of Rehabilitative Services for the Department of Rehabilitative Services.~~

"Commissioner" means the Commissioner of the Department of Rehabilitative Services.

"Department" means the Department of Rehabilitative Services.

"Human participant" 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.

"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.

"Independent living center" means a consumer-controlled, community-based, cross disability, nonresidential private nonprofit agency that:

1. Is designed and operated within a local community by individuals with disabilities; and

2. Provides an array of independent living services.

"Institution" means the department, any center of independent living, sheltered workshop, the Woodrow Wilson Rehabilitation Center, 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 or participant's environment that are performed for research purposes.

"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 definition, 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 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.

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

"Private information" includes information about the human participant's behavior that occurs when an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by the human participant which the participant 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 human 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.

"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.

"Research investigator" means the person, whether professional or student, who conducts the research.

"Sheltered workshop" means a facility-based community rehabilitation program that provides directly or facilitates the provision of one or more of the following vocational rehabilitation services to individuals with disabilities to enable them to maximize their opportunities for employment, including career advancement:

1. Medical, psychiatric, psychological, social, and vocational services that are provided under one management;

2. Testing, fitting, or training in the use of prosthetic and orthotic devices;

3. Recreational therapy;

4. Physical and occupational therapy;

5. Speech, language, and hearing therapy;

6. Psychiatric, psychological, and social services, including positive behavior management;

7. Assessment for determining eligibility and vocational rehabilitation needs;

8. Rehabilitation technology;

9. Job development, placement, and retention services;

10. Evaluation or control of specific disabilities;

11. Orientation and mobility services for individuals who are blind;

12. Extended employment;

13. Psycho-social rehabilitation services;

14. Supported employment services and extended services;

15. Services to family members when necessary to the vocational rehabilitation of the individual;

16. Personal assistance services; or

17. Services similar to the services described in subdivisions 1 through 16.

"Voluntary informed consent" means the knowing, written consent of an individual, or the individual's legally authorized representative, 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 in writing:

1. A statement that the study involves research, and a reasonable and comprehensible explanation to the human participant of the procedures that the researcher will follow and their purposes, including identification of any procedures which are experimental; the expected duration of the human participant'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 description of any attendant discomforts and risks to the human participant which may reasonably be expected and a statement that there may be other risks not yet identified;

3. A description of any benefits to the human participant or to others which may reasonably be expected;

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

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 human participant is otherwise entitled, and the human participant may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

7. An explanation of who to contact for answers to pertinent questions about the research and human research participants' rights, and who 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 it consists 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.

. 22VAC30-40-70. Elements of each committee's review process.

A. No human research shall be conducted or authorized by the Department of Rehabilitative Services, any independent living center, any sheltered workshop, or the Woodrow Wilson Rehabilitation Center unless the 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 are adequately protected;

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

5. Whether the voluntary informed consent is to be obtained by methods that adequately and appropriately fulfill the requirements of these regulations and whether the written consent form is adequate and appropriate in both content and language for the particular research and for the particular participants of the research;

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

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

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

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

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

C. Research must be approved by the committee which has jurisdiction over the participant. When cooperating institutions conduct some or all of the research involving some or all of the participants, each cooperating institution is responsible for safeguarding the rights and welfare of human participants 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. The committee chairperson may make such arrangements with the approval of a majority of the members present at a meeting of the committee.

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 research 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 human participant who has a complaint about a research project in which he is participating or has participated.

F. Any participant 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. The frequency of such reports should reflect the nature and degree of risk of each research project.

22VAC30-40-130. Role of the department~~, commissioner,~~ and the ~~board.~~commissioner.

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. ~~The board shall be kept informed of all reviews of violations of research protocol.~~

C. The commissioner shall arrange for the printing and dissemination of copies of these regulations.

22VAC30-40-140. Applicability of state policies.

Nothing in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated ~~by the board~~ in response to § 32.1-162.19 §37.1-84.1 of the Code of Virginia.

22VAC30-40-150. Applicability of federal policies.

Human research at institutions which is 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 ~~and the board~~ annually of their compliance with the policies and regulations of federal agencies.

I certify that this regulation is full, true, and correctly dated

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James A. Rothrock, M.S., L.P.C.
Commissioner
Department of Rehabilitative Services

Date:_____