Code of Virginia
Title 32.1. Health
Chapter 5.1. Human Research

§ 32.1-162.19. Human research review committees

A. Each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee. The committee shall be composed of representatives of varied backgrounds to ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. No member of the committee shall be directly involved in the proposed human research or have administrative approval authority over the proposed human research except in connection with his responsibilities as a member of the committee.

B. No human research shall be conducted or authorized by such institution or agency unless the committee has reviewed and approved the proposed human research project giving consideration to (i) the adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research; (ii) if the research is nontherapeutic, whether it presents more than a minimal risk to the human subjects; (iii) whether the rights and welfare of the human subjects involved are adequately protected; (iv) whether the risks to the human subjects are outweighed by the potential benefits to them; (v) 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; (vi) 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; (vii) whether the informed consent is to be obtained by methods that are adequate and appropriate and whether the written consent form is adequate and appropriate in both content and language for the particular research; (viii) whether the persons proposing to conduct the particular human research are appropriately competent and qualified; and (ix) whether the criteria for selection of subjects are equitable. The committee shall require periodic reports from each existing human research project to ensure that the project is being carried out in conformity with the proposal as approved.

C. The regulations of an institution or agency may authorize the committee to conduct an expedited review of a human research project which involves no more than minimal risk to the 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.

D. Every person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in this section.

E. Each human research review committee of a state institution or agency shall ensure that an overview of approved human research projects and the results of such projects are made public

on the institution's or agency's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq.).

1979, c. 38, § 37.1-236; 1986, c. 274; 1992, c. 603; 2002, c. 754;2007, c. 413.

The chapters of the acts of assembly referenced in the historical citation at the end of this section(s) may not constitute a comprehensive list of such chapters and may exclude chapters whose provisions have expired.