

1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 *An Act to amend and reenact § 32.1-162.19 of the Code of Virginia, relating to human research review*  
3 *committees.*

4 [H 2567]  
5 Approved

6 **Be it enacted by the General Assembly of Virginia:**  
7 **1. That § 32.1-162.19 of the Code of Virginia is amended and reenacted as follows:**

8 § 32.1-162.19. Human research review committees.

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

16 B. No human research shall be conducted or authorized by such institution or agency unless the  
17 committee has reviewed and approved the proposed human research project giving consideration to (i)  
18 the adequacy of the description of the potential benefits and risks involved and the adequacy of the  
19 methodology of the research; (ii) if the research is nontherapeutic, whether it presents more than a  
20 minimal risk to the human subjects; (iii) whether the rights and welfare of the human subjects involved  
21 are adequately protected; (iv) whether the risks to the human subjects are outweighed by the potential  
22 benefits to them; (v) whether the risks to subjects are minimized by using procedures that are consistent  
23 with sound research design and that do not unnecessarily expose subjects to risk and, whenever  
24 appropriate, by using procedures already being performed on the subjects for diagnostic or treatment  
25 purposes; (vi) when some or all of the subjects are likely to be incapable of making an informed  
26 decision regarding consent or are otherwise vulnerable to coercion or undue influence, such as children,  
27 prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged  
28 persons, whether additional safeguards have been included in the study to protect the rights and welfare  
29 of these subjects; (vii) whether the informed consent is to be obtained by methods that are adequate and  
30 appropriate and whether the written consent form is adequate and appropriate in both content and  
31 language for the particular research; (viii) whether the persons proposing to conduct the particular  
32 human research are appropriately competent and qualified; and (ix) whether the criteria for selection of  
33 subjects are equitable. The committee shall require periodic reports from each existing human research  
34 project to ensure that the project is being carried out in conformity with the proposal as approved.

35 C. The regulations of an institution or agency may authorize the committee to conduct an expedited  
36 review of a human research project which involves no more than minimal risk to the subjects if (i)  
37 another institution's or agency's human research review committee has reviewed and approved the  
38 project or (ii) the review involves only minor changes in previously approved research and the changes  
39 occur during the approved project period.

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

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