



Periodic Review / Retain Regulation Agency Background Document

Agency name	Virginia Department of Social Services
Virginia Administrative Code (VAC) citation	22 VAC 40-890
Regulation title	Human Subject Research
Document preparation date	October 17, 2007

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 36 (2006) and 58 (1999).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.

This regulation is mandated by § 63.2-218 of the *Code of Virginia* and by 45 CFR Part 46.

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

No alternatives to the existing regulation were considered. This regulation was promulgated in response to § 63.2-218, which specifies that the State Board of Social Services shall promulgate regulations that effectuate the provisions of Chapter 5.1 (Human Research) of Title 32.1 (Health) of the Code of Virginia.

Public comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

A The regulation was published for public comment on August 20, 2007; the comment period expired September 10, 2007. No comments were received.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

This regulation requires that the department’s Institutional Review Board (IRB) review and give its approval, as appropriate, to any research sponsored by the department and its related entities (i.e., local departments of social services, department licensed facilities, and authorized contractors). It is necessary for the public safety and welfare of human subjects involved in research sponsored by or approved through the Department of Social Services and related entities.

The existing regulation meets the criteria set forth in Executive Order 36. The regulation is clear and concise and written in a manner that is easy to understand.

Result

Please state that the agency is recommending that the regulation should stay in effect without change.

The State Board of Social Services recommends that the regulation stay in effect without change.

Family impact

Please provide an analysis of the regulation’s impact on the institution of the family and family stability.

This regulation is wholly supportive of the institution of the family and family stability by virtue of its intentional, directed review of all Department-related research protocols, to ensure the protection of the privacy and confidentiality of all information provided by human subjects involved in department-related research. A major feature required in IRB-approved research is “Informed Consent,” that is, the right by each subject who participates in a research study to know the purposes of the research; any reasonable, foreseeable risks or discomforts to the subject; any benefits reasonably expected from the research; a statement of the confidentiality of records identifying the subject; and a statement that participation is voluntary and will involve no penalty or loss of benefits to which the subject is entitled and that the subject may withdraw his consent and discontinue participation at any time, without prejudice.