



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Corrections
Virginia Administrative Code (VAC) citation	6VAC15-26
Regulation title	Regulations for Human Subject Research
Action title	Amend as necessary the 6VAC15-26, which establishes conditions, standards and procedures for review and approval of human subject research, on an informed consent basis, of offenders and employees of the Department of Corrections.
Date this document prepared	November 19, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

6VAC 15-26 Regulations for Human Subject Research establish conditions, standards and procedures that facilitate the Department of Corrections' review and approval of human research, on an informed consent basis, of offenders and employees. These regulations apply to any individual group, or agency conducting research using human participants within the Virginia Department of Corrections, including any facility, program or organization owned, operated, funded, or licensed by the department.

Legal basis

Under the authority of §53.1-5.1 of the Code of Virginia, the Board of Corrections plans to amend promulgates these regulations pursuant to the APA , and under the provisions of Code of Virginia §32.1-162.16 et seq. for human research.

Need

The Board is recommending amendments to the Regulations for Human Subject Research to increase efficiency in the committee review process. Updating regulations should enable the Department of Corrections to ensure compliance with legislatively mandated requirements.

Substance

Amendments to these regulations will further define and clarify requirements for obtaining informed consent for human subject research and establishment of human research review committees. Individuals affected include all parties interested in submitting proposals for human subject research to the Department of Corrections, offenders, and department employees who consent to participate in research, and each organizational unit of the department that conducts or proposes to conduct, or authorizes research using human participants. The regulations should not affect one entity more so than another, nor should they impose any monetary demand upon the department.

Alternatives

The board could not consider any other alternative than to amend these regulations for human subject research.

Public participation

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do via the Regulatory Townhall website , www.townhall.virginia.gov or by mail, email or fax to John Britton, Department of Corrections Research and Management Services, (804)674-3268 ext: 1241, FAX (804)674-3590, john.britton@vadoc.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

The Department of Corrections is using a participatory approach to amend this regulation and will solicit communications from representatives of the Department of Corrections, as well as informed parties within state government as necessary. On technical issues, the agency may consult with experts.

Family impact

The proposed amendments do not strengthen or erode the authority or rights of parents in education, nurturing and supervision of their children. There will be no impact on economic self-sufficiency, self pride, marital commitment or disposable family income.