Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Department of Mental Health, Mental Retardation and Substance Abuse Services (as of 7/1/09, Department of Behavioral Health and Developmental Services)
Virginia Administrative Code (VAC) citation	120 VAC 35-180
Regulation title	Regulations to Assure the Protection of Participants in Human Research
Action title	Minor revisions to regulations to update language and eliminate unnecessary regulatory provisions
Date this document prepared	6/15/09

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.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

The regulations govern human research activities that involve individuals receiving services from providers that are licensed, operated, or funded by the Department of Mental Health, Mental Retardation and Substance Abuse Services. Public comments received during the periodic review of these regulations that began on April 1, 2008 indicated that the some of the language used in the existing regulation was generally out-of-date and should be clarified in order to be consistent with the Department's other regulations. The periodic review found that the regulations were reasonable and consistent with the statutory requirements; however minor revisions are being proposed to make the regulatory language more person-centered; to change the name of the Department; and to eliminate selected provisions of the requirements that are no longer needed.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 2, 2009, the State Mental Health, Mental Retardation and Substance Abuse Services Board reviewed the recommended changes to 12 VAC 35-180-10 et seq. and adopted the revised regulations for the fast track rulemaking process.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Virginia Code § 37.2-402 requires that the Board adopt regulations regarding human research. The current version of these regulations became effective in 2004.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed changes in the human research regulations is to eliminate unnecessary review requirements; reflect the Department's name change approved by the 2009 General Assembly; and updated the regulatory provisions to provide a more person-centered focus.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Executive Order 36 allows state agencies to use a fast-rack rulemaking process to expedite regulatory changes that are expected to be non-controversial. The changes being made in the Human Research regulations eliminate unnecessary review provisions; reflect the Department's name change approved by the 2009 General Assembly; and update the regulatory provisions to provide a more person-centered focus. None of these changes are controversial or establish any additional regulatory burdens.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

There are no substantive changes being proposed to the existing regulations.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages of the proposed changes to the public are:
(1) Correcting unnecessary and confusing regulatory language
(2) Adjusting section titles and language to clarify the role of the Review Committees.
(3) Eliminating activities that place unnecessary restrictions on the Review Committee and the organization conducting the research

The primary advantage to the agency is that the proposed changes will:
(1) Clarify the role of the State Board and Commissioner
(2) More clearly describe the department's responsibilities
(3) Remove the board's review responsibilities.

Other pertinent matters of interest to the regulated community, government officials and the public
(1) Change the name of the Department
(2) Add a requirement that certain agreements now permitted by the regulation between entities conducting research be in writing.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

None of the proposed revisions are more restrictive than applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is particularly affected by the proposed changes to the regulation.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no known adverse impacts on small businesses. The proposed changes in the existing regulations are intended to eliminate unnecessary restrictions, reduce reporting requirements, clarify the expedited review procedures, and eliminate confusing regulatory language.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	None
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	Community services boards, private providers of mental health, mental retardation and substance abuse services and state facilities.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	It is estimated that less than 100 entities could be affected by these regulations. It is further estimated that a maximum of 25-30 of these entities are small businesses. It should be noted that regulated entities would only be affected by the proposed changes if they become involved in human research outside of Federally funded initiatives.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	The proposed changes will not result in any additional costs.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Revision of the existing regulation is the least burdensome alternative. Virginia Code § 37.2-402 requires that the Board adopt regulations regarding human research. The intent of these revisions is to make minor revisions to make the regulatory language more person-centered; to change the name of the Department; and to eliminate selected provisions of the requirements that are no longer needed.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory changes will have no adverse impact on the family.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10		Department of Mental Health, Mental Retardation and Substance Abuse Services	Replaced with Department of Behavioral Health and Developmental Services through out the regulations -- 2009 General Assembly action.
10		Uses "person(s),"human subject" or "subject(s)"	Replaced with "individual(s)" reflective of person-centered regulatory language through

			out the regulations
10		Contain definitions for both "Human Research" and "Research"	Eliminated the definition of "Research" as confusing since the regulations only apply to "Human Research." Added "human" to research to ensure consistency of defined terms throughout the regulations
10			Added CSB definition
40A		Policy	Editorial revisions and clarification
40B			Added a provision to assure adequate protection for individuals
40C-E			Inclusion of 40 B required renumbering
40F			Editorial revisions and clarification
50		Certification Process	Adjusted section title and regulatory language to reflect that the Department requires human research be conducted in affiliation with a Research Review Committee, pursuant to §32.1-162.19
60		Composition of research review committee	Editorial revisions and clarification
70A &B		Elements of each committee's review process	Editorial revisions and clarification
70C			Now requires establishment of a lead institution and written responsibilities
70D,E & F			Editorial revisions and clarification
70 G			Now requires written reports of suspension or termination due to protocol violations
70H & I			Editorial revisions and clarification
80		Kinds of human research exempt from committee review	Editorial revisions and clarification
90A & B		Expedited review procedures for certain kinds of human research involving no more than minimal risk	Editorial revisions and clarification
90C		Limited the type of activities that could be considered for expedited reviews	Section C is eliminated because it places unnecessary restrictions on the Review Committee's authority to conduct an expedited review.
100A-D		Informed Consent	Editorial revisions and clarification
100E		Allowed for alternatives when written consent is secured through oral presentation	Removed unnecessary and confusing regulatory language to clarify what is required when written consent is secured through oral presentation.
100F			Editorial revisions and clarification
110A		Committee records	Editorial revisions and clarification
110B			Record retention requirements modified to meet current LOV requirements
120		Mandatory reporting	No change
130		Role of the department, commissioner, and the board	The board's review responsibilities removed and the department responsibilities more clearly described
140		Applicability of federal policies	Editorial revisions and clarification

Enter any other statement here