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Fast-Track Regulation
Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services
Virginia Administrative Code (VAC) citation(s)	12VAC35-180
Regulation title(s)	Regulations to Assure the Protection of Subjects in Human Research
Action title	Amend Regulations Following Periodic Review
Date this document prepared	~~October 9, 2018~~ REVISED ~~October 24, 2018~~ June 5, 2019

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 180 defines policy and review requirements to protect individuals who are participants in human research performed by facilities or programs operated, funded, or licensed by the department. Specifically, the regulation is designed to:

- Protect the rights and health of the participants in human research conducted in the public behavioral health and developmental services system;
- Ensure that participation in human research is voluntary and entered into with adequate knowledge of the research procedures, risks, and benefits; and
- Minimize the costs and intrusiveness of the administrative procedures to research organizations and the citizens of Virginia.

This action is the result of a periodic review. No comments were received during the review. The proposed amendments are not substantive and merely update language to mirror language in federal law,

the Code of Virginia, or in 12VAC35-115, *Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by the Department Of Behavioral Health and Developmental Services* ("Human Rights Regulations"). A cross-reference to the Human Rights regulations is added in two sections.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

"State Board" means the State Board of Behavioral Health and Developmental Services.

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.

The State Board approved promulgation of these amendments to 12VAC35-180 *Regulations to Assure the Protection of Subjects in Human Research* using the fast-track process at its meeting on October 3, 2018.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

There is no specific mandate associated with this regulatory change except the impetus of periodic review requirements. This rulemaking is expected to be noncontroversial and appropriate for the fast-track process because no comments were received during the review. None of these changes are controversial or establish any additional regulatory burdens. The action provides updated clarifications in the regulations that will be helpful to those in the system using services, those providing services, and entities conducting human research.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Section 37.2-203 of the Code of Virginia authorizes the State Board to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the commissioner and the department.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

This action is the result of a periodic review initiated on October 5, 2017. No comments were received during the public comment period held from October 30, 2017, through November 21, 2017. The periodic review found that the regulations were reasonable and consistent with the statutory requirements, with some minor revisions needed to better align with state and federal requirements.

This regulation needs to remain in place to ensure the health, safety, and welfare of the individuals involved in human research. Chapter 180 applies to the department and any person, entity, or organization offering services that are licensed, funded, or operated by the department; some of those service providers are small businesses. It also applies to any research review committee, as defined in the chapter, at one of these entities. Updated clarifications in the regulations will be helpful to those in the system using services, those providing services, and entities conducting human research.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Updated the title of the regulation to use the correct term "ensure" instead of "assure."

Updated definitions of:

- "Board," to mirror 37.2-100.
- "Community services board," to mirror 37.2-100, including deletion of the term "mental retardation."
- "Individual," to correct language to match federal research regulations [45 CFR 46.102(e)(1)] and [45 CFR 46.102(e)(5)].
- "Informed consent," to move substantive language from the definition section to Section 100, Informed Consent.
- "Research review committee," to add 'human research review committee' and 'institutional review board.'

Section 70, Elements of each committee's review process:

- In Subsection A 6, deletion of an unnecessary list of types of vulnerable people.
- Delete Subsection B as it is redundant with H.
    - Conforms to federal regulation (45 CFR 46.113) the possibility to suspend or terminate approval of research by adding a new paragraph F. 'Elements of each committee's review process:'
      F. The committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the committee requirements or that has been associated with unexpected serious harm to any individuals. Any suspension or termination of approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, the department or agency head, and the commissioner.
- Add a new Subsection I to comply with requirements of 12VAC35-115 ("Human Rights Regulations") regarding notification to the local human rights committee.

Section 80, Kinds of human research exempt from committee review:

- Collapsed item 2 into item 1, as item c, to make clear that such research must occur in an educational setting.

Section 100, Informed consent:

- Moved language from the definition of "Informed consent" to create a new subsection B, and edited it to comply with federal regulation [45 CFR 46.116].

- Added cross-references to regulation and code related to the Human Rights Regulations:
  - In D of Section 100, a cross-reference for providers to an existing section in the Human Rights Regulations: "Prior to participation by an individual in any human research project, the provider shall meet the requirements of 12VAC35-115-130."
  - In Section 120, in regard to reporting, "in accordance with § 37.2-402 of the Code of Virginia and this chapter."

Other non-substantive, clarifying edits throughout.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

This action is the result of a periodic review, which included a public comment period. The proposed amendments will provide clarity for better protection of individuals involved in research, interested stakeholders, and the system overall by providing updated language to mirror language in federal regulations [45 CFR Part 46], the Code of Virginia (§ 32.1-162.16 et seq. and § 37.2-402), and 12VAC35-115. There are no disadvantages to the regulatory action.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

In Section 90, Expedited review procedures for certain kinds of human research involving no more than minimal risk: Current language remains that requires two rather than one additional experienced reviewers to work with the committee chair during an expedited review. This current and unchanged requirement is more restrictive than federal requirements [45 CFR 46.110].

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to

either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no state agencies particularly affected by this action.

Localities Particularly Affected

There are no localities particularly affected by this action.

Other Entities Particularly Affected

There are no other entities particularly affected by this action.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no costs to the agency.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues to other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	Updating language to be consistent and current with both the Code of Virginia and regulation helps to ensure support of individuals receiving services and their authorized representatives.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs. 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.
Benefits the regulatory change is designed to produce.	Updating language to be consistent and current with both the Code of Virginia and regulation helps to ensure support of individuals receiving services and their authorized representatives.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	People and entities likely to be affected are: • Individuals receiving services and their authorized representatives; • Providers of services that are licensed, funded or operated by the department; and • Research review committees.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no way to estimate the exact number of people who will be affected. DBHDS licenses approximately 1,300 service providers. This type of research is rare in the behavioral health and developmental services system, and the framework within which the research can be conducted is narrow. Thus, few individuals receiving services would be affected, and the impact to the provider is negligible.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs. 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.
Benefits the regulatory change is designed to produce.	Updating language to be consistent and current with both the Code of Virginia and regulation helps to ensure support of individuals receiving services and their authorized representatives.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

There are no viable alternatives to this regulatory proposal. Revision of the existing regulation is the least burdensome alternative. Code of Virginia § 37.2-402 requires that the State Board adopt regulations regarding human research. The intent of these revisions is to make minor revisions to bring the regulatory language fully in line with current requirements in federal and state code and regulation.

No comments were received during the review. The regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. As long as the Commonwealth allows human research, there is a continued need for the regulation. The regulation provides a straightforward framework for the conduct of

research. The regulation incorporates but does not fully overlap, duplicate, or conflict with federal or state law or regulation. The last period review was in 2009. Since that time, technology, economic conditions, or other factors have had no impact on Virginia's need for the regulation.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

This regulation needs to remain in place to ensure the health, safety, and welfare of the individuals involved in human research. There is no reason to delay the adoption of these changes by using the standard process. The structure set out in the regulation is in accordance with other applicable federal and state laws and regulations. It is not legally possible to minimize compliance and reporting requirements. This type of research is rare in the behavioral health and developmental services system, and the framework within which the research can be conducted is narrow. Thus, the impact to the provider is negligible and the edits represent only existing statute or regulation.

Public Participation

If an objection to the use of the fast-track process is received within the 30-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: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.

If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.

For changes to existing regulation(s), please use the following chart:

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
10			Unless otherwise indicated, changes are to update to current code or regulatory language, to conform to style guidelines, to streamline, or to provide clarification.
		Note, title: Regulations to Assure the Protection of Subjects in Human Research	Note: The title of the regulation is updated from 'assure' to use the proper term 'ensure.'
		"Board" means the Board of Behavioral Health and Developmental Services.	• "Board," to mirror 37.2-100, after 'the,' insert: 'State'
		"Community services board" or "CSB" means a public body established pursuant to § 37.2-501 of the Code of Virginia that provides mental health, mental retardation, and substance abuse services to individuals within each city or county that established it. For the purpose of these regulations, community services board also includes a behavioral health authority established pursuant to § 37.2-602 of the Code of Virginia.	• "Community services board," to mirror 37.2-100, after 'CSB means,' strike: 'a' And insert: 'the' After 'mental,' strike: 'retardation' And insert: 'developmental'
		"Health information" means any information, whether oral or recorded in any form or medium that: 1. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and	
		"Human research" means any systematic investigation, including research development, testing, and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research	• After 'Human research shall not,' strike: 'be deemed to'

		regulation pursuant to 45 CFR 46.101(b). "Individual" means a human subject pursuant to 45 CFR 46.102 (f) about whom an investigator (whether professional or student) conducting research obtains (i) data through interaction with the individual; or (ii) protected health information. "Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of an individual who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary for such consent shall include: 1. A reasonable and comprehensible explanation to the individual of the proposed procedures or protocols to be followed, and their purposes, including descriptions of any attendant discomforts, risks and benefits reasonably to be expected, how the results of the human research will be disseminated, and how the identity of the individual will be protected; 2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual together with their side effects, risks, and benefits; 3. A description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified; 4. An instruction that the individual may withdraw his consent and discontinue	• After '(ii),' strike: 'protected health' And insert: 'identifiable private information.' This change is made to match the language in federal research regulations, which is broader. • "Informed consent," to include a phrase in #1, 4, and 6 to comply with federal regulation. Specifically, for 1. [45CFR46.116(a)(1)] ; 4. [45CFR46.116(a)(8)]; and 6. [45CFR46.116(a)(7)]: • After the first sentence, move all text to a newly created Subsection B of Section 100, with amendments described here. • "A statement that the study involves research, and a" before the existing 'reasonable and comprehensible explanation' ….

		participation in the human research at any time without prejudice to him or fear of reprisal; 5. An explanation of any costs or compensation that may accrue to the individual and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols or any medical care that may be available if an injury occurs; and; 6. An offer to answer and answers to any inquiries by the individual or, if applicable, his legally authorized representative concerning the procedures and protocols and a description of the ways in which concerns may be raised or questions asked; "Institution" or "agency" means any community services board or any facility or program operated, funded, or licensed by the department. "Interaction" includes communication or interpersonal contact between investigator and the individual who is the subject of the human research. "Research review committee" or "committee" means a committee of professionals to provide complete and adequate review of human research activities pursuant to § 32.1-162.19 of the Code of Virginia.	• After ‘means,’ insert: the department, • After ‘contact between,’ insert ‘the’ before ‘investigator. • "Research review committee,” to mirror the Human Rights Regulations, after ‘or “committee”’ strike: ‘committee’ And insert: ‘ "institutional review board" ‘ After ‘professionals,’ strike: ‘to’ And insert: ‘that’
30		This chapter shall apply to the Department of Behavioral Health and Developmental Services, any community services board, and any facility operated, funded or licensed by the department which conducts or which proposes to conduct or	• In two places (after ‘by the department’ and ‘conducts or’), strike: ‘which’ And insert: ‘that’

		authorize human research in which individuals participate as human subjects.	
60		A. Each research review committee shall have at least five members, appointed by the head of the institution or agency, with varying backgrounds to ensure the competent, complete and professional review of human research activities commonly conducted by the institution or agency. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its advice and counsel in safeguarding the rights and welfare of individuals who are the subjects of human research. In addition to possessing the professional competence necessary to review specific human research activities, the committee must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews human research that has an impact on individuals who are institutionalized or are otherwise vulnerable, including individuals who reside in mental health facilities or state training centers, the committee shall have in its membership one or more persons who are primarily concerned with the welfare of these individuals and who have appropriate experience to serve in that capacity. D. No member of a	• In Subsection A, after 'including individuals who reside in,' strike: 'mental health facilities and state training centers' And insert: 'state facilities'

		committee shall participate in the committee's initial or continuing review of any project in which the member is directly involved or for which he has administrative approval authority, except to provide information requested by the committee. The committee shall be responsible for determining whether a member has a conflicting interest. The committee member shall be replaced in the case of conflicting interests resulting in a decrease of the committee below five persons. E. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.	• In Subsection D, after 'shall be replaced,' strike: 'in the case' And insert: 'if the' After 'of conflicting interests,' strike: 'resulting' And insert: 'results' • In Subsection E, after 'of complex issues,' strike: 'which' And insert: 'that'
70		A. No human research shall be conducted or authorized by an institution or agency unless a research review committee has reviewed and approved the proposed human research project giving consideration to: 1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the human research; 2. The degree of the risk, and, if the human research is nontherapeutic, whether it presents greater than minimal risk; 3. Whether the rights and welfare of the individuals who are the subjects of the human research are adequately protected; 4. Whether the risks to the individuals who are the	

		subjects of human research are outweighed by the potential benefits to them; 5. Whether the risks to individuals are minimized by using procedures that are consistent with sound human research design and that do not unnecessarily expose individuals to risk and, whenever appropriate, by using procedures already being performed on individuals for diagnostic or treatment purposes; 6. When some or all of the individuals are likely to be incapable of providing informed 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 individuals; 7. 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 human research and for the individuals who are the particular subjects of the human research; 8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified; 9. Whether criteria for selection of individuals to participate as human research subjects are equitable; and 10. Whether the human research conforms with such other requirements of the department, where	• In Subsection A 6, after 'undue influence,' strike: 'such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons,' This is an unnecessary and limiting list of types of vulnerable people.

		applicable. B. Each committee shall review approved projects to ensure conformity with the approved proposal at least annually.	• Delete Subsection B as it is redundant with H, and reletter C – E, and change I to J. • Add a new subsection as newly lettered Subsection F to explain the committee's authority to suspend or terminate approval of research [45 CFR 46.113]: F. The committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the committee requirements or that has been associated with unexpected serious harm to any individuals. Any suspension or termination of approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, the department or agency head, and the commissioner. • Add a new Subsection I to comply with requirements of 12VAC35-115 ("Human Rights Regulations") regarding notification to the local human rights committee: I. Prior to participation by individuals in any human research project, the institution or agency shall inform and provide a copy of the research review committee approval to the local human rights committee established pursuant to 12VAC35-115-10 et seq. Once the research has been initiated, the institution or agency shall update the local human rights committee periodically on the status of the individual's participation.
80		Human research activities in which the involvement of individuals as subjects is limited to one or more of the following categories are exempt from this chapter unless the human research is covered by other sections of this chapter: 1. Human research conducted in established or commonly accepted educational settings, involving commonly used educational practices, such as:	

		a. Research on regular and special education instructional strategies; or b. Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods. 2. Human research involving solely the use and analysis of the results of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in such a manner so that individuals cannot be identified, directly or through identifiers linked to the individuals. 3. Human research involving survey or interview procedures, unless responses are recorded in such a manner that the individuals can be identified, directly or through identifiers linked to the individuals; and either: a. The individual's responses, if they became known outside the human research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation; or b. The human research deals with sensitive aspects of the individual's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct. 4. Human research involving solely the observation (including observation by individuals who are the subjects of human research) of public behavior, unless observations are recorded in such a manner that individuals can be identified, directly or through identifiers linked to the individuals, and	• Collapse item 2 into item 1 (as newly lettered item 1 c), to make clear that such research must occur in an educational setting: 2. c. • Renumber items 3-6.

		either: a. The observations recorded about the individual, if they became known outside the human research, could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation; or b. The human research deals with sensitive aspects of the individual's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct. 5. Human research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information taken from these sources is recorded in such a manner that individuals cannot be identified, directly or through identifiers linked to the individuals. 6. Human research involving solely a combination of any of the activities described in this section.	
90		B. Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of human research proposals which have been approved under the procedure.	• In Subsection B in two places (after 'committee' and after 'proposals'), strike: 'which' And insert: 'that'
100		A. No human research shall be conducted in the absence of informed consent subscribed to in writing by the individual or by the individual's authorized representative except as provided for in subsection F of this section. If the individual is capable of providing informed consent, written consent must be provided by the individual and witnessed. If the individual is	• In the first sentence in Subsection A after 'individual's,' insert: 'legally'

		incapable of making an informed decision, as defined in § 54.1-2982 of the Code of Virginia, at the time consent is required, written consent must be provided by the individual's legally authorized representative and witnessed. If the individual is a minor otherwise capable of rendering informed consent, the consent shall be provided by both the minor and his legally authorized representative. An investigator shall seek such consent only under circumstances that provide the individual who is the prospective subject or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the individual or, if applicable the individual's legally authorized representative shall be in language understandable to the individual or the representative. If two or more persons who qualify as legally authorized representatives have equal decision-making priority under this chapter inform the principal investigator or attending physician that they disagree as to participation of the individual in human research, the individual shall not be enrolled in the human research that is the subject of the consent.	• Create a new Subsection B, using the list pulled from the definition of "Informed consent" in section 10 with amendments as listed above (see Section 10). • Strike and update the lettering of the remaining paragraphs, to create newly lettered: C-G.

			• In newly lettered Subsection C (previously part of A): After 'Notwithstanding the informed consent by,' correct a typo to separate 'a' and 'legally.' After 'except as provided for in subsection,' update cross-reference from F to H. • In Subsection C (newly lettered D), Added cross-references to code and regulation for providers to an existing section in the Human Rights Regulations: "Prior to participation by an individual in any human research project, the provider shall meet the requirements of 12VAC35-115-130." • In newly lettered H (previously F), after 'the requirement in subsection:' Update the cross-reference to A from E.
110		B. The records required by this chapter shall be retained for at least three years, and records relating to human research which is conducted shall be retained for six years after completion of the human research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner. An overview of approved human research projects and the results of such projects shall be made public on the website of the institution or agency conducting the human research unless otherwise exempt from disclosure under the Virginia Freedom of Information Act, (§ 2.2-3700 et seq. of the Code of Virginia).	• In the first sentence of Subsection A, after 'or when appropriate a committee,' insert: ',' • In Subsection B, after 'relating to human research,' strike: 'which' And insert: 'that'
120		Each research review committee shall submit to the governor, the General Assembly, and the	• In Section 120, in regard to reporting, insert Code of Virginia reference for clarity at the end of the sentence:

		commissioner or his designee at least annually a report on the human research projects reviewed and approved by the committee, including any significant deviations from the proposals as approved.	"in accordance with § 37.2-402 of the Code of Virginia and this chapter"
130		The commissioner shall assure that the department's human rights program, through procedures described in 12VAC35-115, protects the rights of individuals who are admitted to a state hospital, training center, or other facility operated, funded, or licensed by the department to refuse to participate as a subject of human research and assure that written and informed consent is received from individuals or their legally authorized representative prior to their participation as a subject of human research.	• Clarifying amendments in four places: After 'The commissioner shall,' strike: 'assure' And insert: 'ensure' After 12VAC35-115, insert: '-130 Research' After 'are admitted to a state,' strike: 'hospital, training center' And insert: 'facility' After 'human research and,' strike: 'assure' And insert: 'ensure' After 'that written,' strike: 'and'
140		Nothing in this chapter shall be construed as limiting in any way the rights of individuals in human research under regulations promulgated by the State Board of Behavioral Health and Developmental Services pursuant to § 37.2-400 of the Code of Virginia.	• After 'the rights,' insert: 'under regulations promulgated by the State Board of Behavioral Health and Developmental Services pursuant to § 37.2-400 of the Code of Virginia' After 'individuals,' insert: 'participating' After 'human research,' strike: 'under regulations promulgated by the State Board of Behavioral Health and Developmental Services pursuant to § 37.2-400 of the Code of Virginia'
150		Human research at institutions or agencies which are subject to policies and regulations for the protection of individuals promulgated by any agency of the federal government shall be exempt from this chapter.	• After 'or agencies,' strike: 'which' And insert: 'that'