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Fast-Track Regulation
Agency Background Document

Agency name	State Board of Social Services
Virginia Administrative Code (VAC) Chapter citation(s)	22 VAC40-890
VAC Chapter title(s)	Human Subject Research Regulations
Action title	Update Human Subject Research Chapter
Date this document prepared	December 14, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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.

The Virginia Department of Social Services follows federal regulations (Title 45 CFR Part 46; also known as the Common Rule) for the Protection of Human Subjects to ensure protection of all human subjects participating in research conducted or sponsored by the Department. In addition to updating certain definitions and terms to be congruent with those that appear in other state Code (e.g., § 32.1-162.16), the Department will amend the 22 VAC 40-890-30 and 22 VAC 40-890-80 to be congruent with recent revisions to the Common Rule. The Revised Common Rule expands the list of types of research posing minimal risk to human subjects that qualify for either an exemption from IRB review or an expedited review in which only the Chair (or one other IRB member) conducts the review. The Common Rule eliminates the need for a continuing review for ongoing research initially approved under an expedited review process. Other changes affect IRB reporting requirements and the required minimum number of IRB

members. Amendments to the existing chapter are to provide language aligned with § 63.2-218 of the Code of Virginia.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

CFR stands for Code of Federal Regulations
COV stands for Code of Virginia
VAC stands for Virginia Administrative Code

Statement of Final Agency Action

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 of Social Services approved the fast track regulation for 22VAC40-890, Human Subject Research Regulations, on December 14, 2022.

Mandate and Impetus

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, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "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."

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

A periodic review as conducted in 2019 and the recommendation was to amend the regulation. The fast track action aligns the regulation federal regulation and state code, updates citations and makes technical changes for clarity. Those subject to the regulation will not be substantively impacted by the changes. It is not expected to be controversial and therefore, it is appropriate for the fast track rulemaking process.

Legal Basis

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

1) The promulgating agency is the Virginia Department of Social Services, 2) upon the legal authority identified in § 63.2-218 of the Code of Virginia, 22VAC40-890, and 45 CFR 46, with 45 CFR 46 derived from three sections of the U.S. Code: 5 USC Section 301; 42 USC Section 289; and 42 USC Section

300v-1(b). Section 63.2-218 authorizes the State Board of Social Services to adopt regulations necessary relative to human research.

Purpose

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 is intended to solve.

The regulatory changes are needed to 1) provide congruence of language between § 63.2-218 Code of Virginia and the regulations contained in 22VAC40-890; 2) ensure that the provisions contained in the COV for the health, safety and welfare of citizens are in alignment with those provisions contained in the regulations; and 3) prevent any confusion in the execution of regulations as relates to the law in the COV.

Substance

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.

Revisions clarify definitions of local departments of social services, facilities, and contractors, for congruence with language of the COV. Definitions of "Human research", "Informed consent", and "Legally authorized representative" are expanded to align with definitions of these key terms contained in the Code of Virginia § 32.1-162.19.

22VAC40-890-30 regarding categories of research that are exempt from review is outdated. In addition to categories listed in this section, 45CFR46.104(d) adds to the list of categories of research that may be exempt from IRB review.

Section 22VAC40-890-50 regarding Informed Consent is revised to align with COV § 32.1-162.18(a), which includes the requirement of a witness for signatures of informed consent by the research participant, or the participant's legally authorized representative. Exceptions to this chapter apply to provisions in both sections B and C.

22VAC40-890-60 regarding the Human Research Review Committee (also known as the Institutional Review Board, or IRB), is revised to clarify the minimum number of members as stated in Departmental Guidance. The number is changed from seven (7) to "at least five (5) members" to be congruent with federal regulations (45CFR46.107).

22VAC40-890-70 regarding the Review and Approval Process refers to annual review of ongoing research. Low-risk research that was eligible for expedited review pursuant to 22VAC40-890-80 no longer requires a continuing review.

22VAC40-890-80 regarding categories of research that are eligible for expedited review is outdated. The proposed revision reflects the appropriate, current reference to 45CFR46.110. The current federal regulation (45 CFR 46.110) expands the list of categories of research that may be eligible for expedited review. The list of exempt research categories is approved by the U.S. Secretary of Health and Human Resources and is subject to review and revision every eight years.

22VAC40-890-90 regarding annual reporting on IRB activities will now require additional information about IRB approvals of research conducted by local agencies, affiliated facilities and contractors on behalf of the Department, including the manner in which research findings will be disseminated.

Issues

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.

Issues associated with the regulatory change include 1) greater clarity in the regulations to adhere to the language used in the COV (advantage) and, for researchers, congruence with updated federal regulations in regards to human subject research (advantage); and 2) said clarity will prevent any confusion when executing the regulations or developing Guidance (advantage); updates to the regulations regarding review of human subject regulation will reduce administrative burden for the VDSS IRB (advantage). There are no foreseen disadvantages to these revisions of clarification.

Requirements More Restrictive than Federal

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.

None of the regulatory changes proposed are more restrictive than Federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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

None.

Localities Particularly Affected

None.

Other Entities Particularly Affected

None.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, 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. Keep in mind that this is the proposed 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	None
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.	None
For all agencies: Benefits the regulatory change is designed to produce.	More categories of research studies that pose no more than a minimal risk to human subjects will be eligible for expedited review instead of full board review by the IRB and other studies will qualify for exemption from review. Ongoing low-risk research that was originally approved under an expedited process will not require an annual continuing review by the IRB. This reduces the administrative burden on the VDSS IRB Chairperson, who is also the IRB Coordinator. There are no costs associated with IRB reviews and other determinations.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Pursuant to § 63.2-217, because there are no potential costs, savings, fees or revenues, copies of the fiscal analysis were not shared separately with local boards.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	Universities and for-profit research organizations that conduct human subjects research and program evaluations that involve DSS clients or DSS client data.
Agency's best estimate of the number of such entities that will be affected. 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.	Per year, approximately 10 research organizations will be impacted. The VDSS IRB does not collect information regarding the small business status of these entities.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. 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.	None
Benefits the regulatory change is designed to produce.	Less administrative burden for both the IRB and researchers during reviews of new and ongoing low-risk research.

Alternatives to Regulation

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.

All proposed regulatory changes aim to clarify existing regulations in alignment with existing COV, and do not deviate substantially from existing Virginia and Federal code, regulations, guidance or practice.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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.

Again, all proposed regulatory changes aim to clarify existing regulations in alignment with existing COV, and do not deviate substantially from existing Virginia and federal code, regulations, guidance or practice.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, 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.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Virginia Department of Social Services is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Dr. Gail Jennings, 801 East Main Street, Richmond, VA 23219-2901, Phone: (804)615-4000, Email: gail.jennings@dss.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

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. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
22VAC40-890 Human Subject Research Regulations		The term “local agencies” is used throughout.	Term is changed to “local departments” throughout the chapter to align with COV § 63.2-100. The intent is to make terminology more consistent in the Code and regulations.
22VAC40-890-10 Definitions		"Committee" means the human research review committee which reviews and approves human research activities related to this chapter. "Facility" means any agency licensed by the department including, but not limited to, adult and child day and residential facilities. "Human research" or "research" means any formal and structured evaluation involving individuals in a special project, program, or study. "Informed consent" means the knowing and voluntary agreement of the participant exercising free choice, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. "Legally authorized representative" means a person with authority to consent on behalf of a prospective participant to include (i) the parent or parents having custody, (ii) the legal guardian, or (iii) any person or judicial or other person or body authorized by law or regulation, including an attorney in fact appointed	For clarification, the term “Committee”, which is the human research review committee, refers specifically to the Department’s Institutional Review Board (IRB) by name. There is no substantive impact. The following definitions are updated to be consistent with other Code sections: The definition for “Facility” is updated to mean any person licensed by the department, as defined in COV § 63.2-1701(A). The definition for "Human research" is updated to align with the definition used in COV § 32.1-162.16. The definition for "Informed consent" is aligned with the definition used in COV § 32.1-162.16. The definition includes basic elements of information necessary to obtain informed consent. The definition for “Legally authorized representative” is updated to align with the definition used in COV § 32.1-162.16. Updating these definitions has no substantive impact.

		under a durable power of attorney, to the extent the power grants the authority to make a decision related to human research. The attorney in fact shall not be employed by the person or department conducting the human research. No official or employee of the department, facility or local agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.	
20 Applicability		The chapter applies to VDSS, local departments of social services or departments of welfare, etc.	Reference to "departments of welfare" is removed in order to align with § 63.2-100. No substantive impact.
30 Research exempt from chapter		2. Research conducted in established or commonly accepted educational settings involving commonly used educational practices, provided that participants cannot be identified, directly or through identifiers, for: a. Regular and special education instructional strategies; b. The effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods; or c. Educational tests. 4. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office. 5. Research involving solely the collection or study of existing data, documents, or records, if these sources are publicly available or if the information taken from these sources is recorded in such a manner that participants cannot be	This section is being updated to align with the federal regulations in 45 CFR 46.104(d) that were updated in 2018 to broaden the categories of research that would be eligible for exemption from IRB review. Current exemption #2 is being repealed because it is covered under 45 CFR 46.104(d)(1). Remaining subsections are renumbered. No substantive impact. Current subsections #4-6 are being repealed because they are covered under 45 CFR 46.104(d)(2), (d)(4), and (d)(5). No substantive impact. A new subsection #3 is added for research that is exempt pursuant to 45 CFR 46.104(d). The intent is to align with federal regulation. The impact would be to eliminate the requirement for IRB review for certain categories of research that pose no more than minimal risk to subjects. This change will reduce the administrative burden for the IRB in terms of conducting reviews. It will also reduce the burden on researchers to submit applications for their studies to undergo reviews.

		identified directly or through identifiers linked to the participants. 6. Research and demonstration projects covered under 45 CFR 46.101(b)(5) 45 CFR 46.104(d)(5) which are conducted by or subject to the approval of the commissioner, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.	
40 Policy		E. Where the human research activity exposes to risk others not participating, all must give their signed voluntary informed consent.	A technical change is made replacing "to risks" with "risks to."
50 Informed consent		A. No human research may be conducted without voluntary informed consent signed by the participant or by the participant's legally authorized representative, except as provided for in subsection C of this section.	The voluntary informed consent must also be witnessed in order to align with 45CFR46.117. In practice, the IRB and researchers have been complying with this federal regulation. Code citations are updated.
60 Human research review committee		A. The department shall establish a department committee, consisting of seven members, appointed by the commissioner.	The committee composition is being changed to consist of at least five members. This change will align with federal regulations in 45CFR46.107. The IRB currently has 10 members.
70 Review and approval process		F. The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports	A new provision adds circumstances in which continuing review of research is not required. This includes: 1) research eligible for expedited review in accordance with 22VAC40-890-80; or 2) research that has progressed to the point that it involves only one or

		shall be consistent with the nature and degree of risk of each research project. The committee shall also require a report from the research project at the conclusion of the project.	both of the following, which are part of the IRB-approved study: 1) data analysis, including analysis of identifiable private information or identifiable biospecimens, or 2) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. To align with federal regulations in 45CFR46.109(f)(1). No substantive impact.
80 Expedited review of human research participants		A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the participants if: 1) the research review committee affiliated with another state department, local agency department, licensed facility or institution has reviewed and approved the project; or 2) the review involves only minor changes in previously approved research and the changes occur during the approved project period.	In Subsection A, the second condition is being removed and placed in its own section (C). This second condition also appears in the federal regulation in 45CFR46.110. New subsections that align with federal regulations in 45CFR46.110 are being added for clarification. The remaining subsection (B) is renumbered. Subsections B and C refer to a list of DHHS-approved categories of research that qualify for expedited review. This list is subject to periodic review by DHHS. The list includes but is not limited to: (1) Collection of data from voice, video, digital, or image recordings made for research purposes; (2) Research on individual or group characteristics or behavior (including, but not limited to, research on cultural beliefs, practices and social behavior); (3) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies that otherwise do not qualify for exemption from review in 45CFR46.104(d); (4) continuing review of ongoing research previously approved by the convened IRB if the study has reached a later stage (study enrollment closed, study intervention completed, and only long-term follow-up is occurring; or research activity restricted to data analysis only). Subsection D states who may conduct the expedited review (either the IRB Chairperson or another experienced member of the IRB) and what their

			authority is to disapprove research. In accordance with 22VAC40-890-70 and 45CFR46.110(b)(2), research may only be disapproved under a non-expedited (full board) review. The IRB has been implementing this provision in practice. Subsection F states that research where identification of subjects and/or their responses would potentially place them at risk or be damaging to their financial standing, employability, reputation, etc. would only qualify for expedited review if reasonable and appropriate measures are taken to minimize risk of invasion of privacy and breach of confidentiality of data. This provision appears in the DHHS-approved list of categories approved for expedited review. The intent is to align with federal regulations in 45CFR46. No substantive impact.
90 Reporting		The report should include a description of each human research project in which the agency participated; The report should include results of the research after its conclusion.	The report should include description of each human research project in which the local department, facility or contractor participated, including the name and contact information for the approving research review committee; For clarification. No substantive impact. The report should include results of the research after its conclusion, including a description of how the research will be shared beyond the local department, facility or contractor. For clarification. No substantive impact.

If a new VAC Chapter(s) is being promulgated and is not replacing an existing Chapter(s), use Table 2.

Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace

New chapter-section number	New requirements	Other regulations and law that apply	Intent and likely impact of new requirements

*If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is identical to the emergency regulation, complete Table 1 and/or Table 2, as described above.*

*If the regulatory change is replacing an **emergency regulation**, but changes have been made since the emergency regulation became effective, also complete Table 3 to describe the changes made since the emergency regulation.*

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current emergency requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage