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## Exempt Action: Final Regulation Agency Background Document

<b>Agency name</b>	Virginia Department for Aging and Rehabilitative Services
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	22VAC30-40
<b>VAC Chapter title(s)</b>	Protections of Participants in Human Research
<b>Action title</b>	Chapter 728 (2020) Amend Human Research Regulations
<b>Final agency action date</b>	September 3, 2020
<b>Date this document prepared</b>	September 3, 2020

Although a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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.*

This action amends three sections in 22VAC30-40 (Protections of Participants in Human Research) to address a legislative change to the listing of covered entities as derived from § 51.5-132 of the Code of Virginia. With the revisions made through Chapter 728 of the 2020 Acts of Assembly (original legislation: HB1148), 22VAC30-40 will specifically identify area agencies on aging (AAAs) as covered entities subject to the department's human research review committee (HRRC).

### 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, internal staff review, petition for rulemaking, periodic review, or board decision). "Mandate" is defined as "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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*

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The 2020 Acts of Assembly, Chapter 728, adds AAAs to listing of entities subject to the department's HRRC. Changes are needed to sections 10 (Definitions), 30 (Applicability), and 50 (Certification process) to account for the explicit inclusion of AAAs in § 51.5-132 of the Code of Virginia.

### **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.*

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The Commissioner of the Department approved the amendments to the Protections of Participants in Human Research (22VAC30-40) on September 3, 2020.