



**Description of Amendment #3 (July 13, 2023) to
VHA Directive 1200.05(3): Requirements for the Protection of Human
Subjects in Research**

Description of Amendment: Three revisions are present in the July 13, 2023, technical amendment to VHA Directive 1200.05. The amendment is described in the following table as follows with revisions highlighted in red.

- Paragraph 2: Revised summary of changes.
- Paragraph 5.g.(21): Added a new paragraph requiring VA Investigators to ensure that collection instruments for a research activity involving obtaining information directly from research subjects are reviewed by the IRB or VA Facility Research and Development Committee (as applicable) prior to research approval. Includes a policy statement that the Paperwork Reduction Act does not apply to VHA research activities involving these collections of information.
- Paragraph 28: Added a reference to 38 U.S.C. § 7330D.

VHA Directive 1200.05(2)	VHA Directive 1200.05(3) Amended (July 13, 2023)
<p><u>Paragraph 2: SUMMARY OF MAJOR CHANGES:</u></p> <p>New Paragraph 2.e.</p>	<p><u>Paragraph 2: SUMMARY OF MAJOR CHANGES:</u></p> <p>e. Amendment dated July 13, 2023, adds paragraph 5.g.(21) and references 38 U.S.C. § 7330D.</p>
<p><u>Paragraph 5. RESPONSIBILITIES:</u></p> <p>g. VA Investigators. Each VA investigator is responsible for:</p> <p>New Paragraph 5.g.(21)</p>	<p><u>Paragraph 5: RESPONSIBILITIES:</u></p> <p>g. VA Investigators. Each VA investigator is responsible for:</p> <p>(21) Ensuring that collection instruments for a research activity involving obtaining information directly from research subjects, such as surveys, questionnaires, and interview guides, have been reviewed by the IRB or VA Facility Research and Development Committee (as applicable) prior to research approval. NOTE: The Paperwork Reduction Act does not apply to VHA human subjects research activities involving these collections. See 38 U.S.C. § 7330D (the codification of Cleland-Dole § 181). Please refer to the ORD Guidance Document: <i>Applicability of the Exclusion of VHA Research from the Paperwork Reduction Act</i>.</p>



VHA Directive 1200.05(2)	VHA Directive 1200.05(3) Amended (July 13, 2023)
<u>Paragraph 28. REFERENCES</u> New reference for Paragraph 28.g.	<u>Paragraph 28. REFERENCES</u> g. 38 U.S.C. 7330D, Coordination of toxic exposure research.

This is the third amendment to VHA Directive 1200.05 since it was signed on January 7, 2019. The amended VHA Directive 1200.05(3) is located at:

https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171.

It will also be available in FIND Pro and at the following links:

<http://vaww.va.gov/vhapublications/>

<http://www.va.gov/vhapublications/>.

Please send any questions regarding this amendment to the ORD Regulatory Mailbox at VHACOORDRegulatory@va.gov.