OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

ORD Guidance Document: Applicability of the Exclusion of VHA Research From the Paperwork Reduction Act

Date: July 19, 2023

This is a new guidance document.

For questions on the content of this guidance, email the VHA Office of Research and Development through FIND Pro.

Purpose: To establish guidance to implement Section 181 of the Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022 (Cleland-Dole Act), which allows an exclusion from the requirements of the Paperwork Reduction Act (PRA) for information collection as part of research activities conducted within the Veterans Health Administration (VHA). This guidance defines the scope of VHA research activities to which Section 181 applies, including VHA research activities with current clearance by the Office of Management and Budget (OMB) or in the process of obtaining OMB clearance.

Background: The Cleland-Dole Act was signed into law on December 29, 2022, under Division U of the Consolidated Appropriations Act of 2023 (P.L. 117-328). Prior to passage of the Cleland-Dole Act, voluntary or mandatory collections of information as defined by the PRA requesting the same information using identical questions from ten or more members of the public in a VHA research activity required OMB clearance unless it met a research exemption. A "collection of information" is defined in the PRA per 5 CFR 1320.3(c), as the following:

> ""[T]he obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit.
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> 'Collection of information' includes any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information. As used in this Part, 'collection of information' refers to the act of collecting or disclosing information, to the information to be collected or disclosed, to a plan and/or an instrument calling for the collection or disclosure of information, or any of these, as appropriate."

The research exemption in the PRA allows collections of information, such as interviews and surveys of research subjects, to be excluded from the requirement to obtain PRA clearance if the information is obtained from individuals under treatment or clinical examination in connection with research to prevent a clinical disorder. However, many VHA research activities do not fall under this PRA's research exemption. The Cleland-Dole Act includes a revision of the PRA's applicability to research activities conducted within VHA by adding a research exclusion for VHA research. Section 181 of the Cleland-Dole Act specifies that the PRA *"...shall not apply to the voluntary collection of information during the conduct of research by the Veterans Health Administration, including the Office of Research and Development, or individuals or entities affiliated with the Veterans Health Administration."*

This guidance document provides information on the applicability and implementation of Section 181 of the Cleland-Dole Act. The PRA no longer applies to research activities conducted by VHA that were previously subject to OMB clearance. The Cleland-Dole Act's exclusion from the PRA is specific to VHA research; it does not apply to non-research activities conducted within VHA or any or collections of information as defined by the PRA requiring OMB clearance conducted by the Department of Veterans Affairs (VA). ORD provides guidance on the following questions:

1. What types of research activities conducted by VHA are excluded from the PRA by the Cleland-Dole Act?
2. Does Section 181 of the Cleland-Dole Act only apply to research conducted or funded by ORD?
3. Are quality assurance and quality improvement activities considered "research" activities that are excluded from the PRA?
4. If a quality improvement activity uses the word research to describe its activities for collections of information, is the quality improvement activity required to apply the PRA?
5. How are "individuals or entities affiliated with the Veterans Health Administration" defined for purposes of deciding whether the PRA applies, according to Section 181 of the Cleland-Dole act?
6. Can another federal agency or department be considered "individuals or entities affiliated with the Veterans Health Administration" for purposes of deciding whether the PRA applies according to Section 181 of the Cleland-Dole act?
7. What actions are required by a VA Facility or VA Investigator if a VHA research activity currently has OMB clearance since the PRA no longer applies?
8. What actions are required to be taken by a VA Investigator if a VHA research activity is currently in the process of obtaining OMB clearance?
9. Does the Cleland-Dole Act require VHA to document when a VHA research activity is not required to apply the PRA?
10. If the activities conducted by VHA are not a research activity, how is it determined whether the PRA applies requiring OMB clearance?

1. **What types of research activities conducted by VHA are not required to apply the PRA according to the Cleland-Dole Act?**

   ORD's policies define research for any research activity conducted within VHA. As defined in VHA Directive 1200.05(3), Paragraph 3.cc, "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...." In addition, clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research as also described in the Directive. Activities that meet the definition of research under ORD policies constitute research for purposes of applicability of Section 181 of the Cleland-Dole Act.

   Any research activity conducted within VHA requires approval by the VA Facility's Research and Development (R&D) Committee. This approval is in addition to any other applicable committees or subcommittees, such as an Institutional Review Board (IRB). Any VHA research activity approved by the VA Facility's R&D Committee is excluded from the PRA. The most common types of VHA research activities to which the PRA would have previously applied (unless the research exemption was met) were research studies using collection instruments obtaining information directly from ten or more living human subjects who were not federal employees, including, but not limited to, surveys, questionnaires, or interviews.

2. **Does Section 181 of the Cleland-Dole Act only apply to research conducted or funded by ORD?**

   No, Section 181 of the Cleland-Dole Act does not apply solely to research conducted or funded by ORD. Section 181, exclusion from the PRA, applies to any research activity conducted within VHA that meets the definition of research according to ORD policies, which requires approval by the VA Facility's R&D Committee, in addition to any other applicable committees or subcommittees.

3. **Are quality assurance and quality improvement activities considered "research" activities that are not required to apply to PRA?**

   No, quality assurance and quality improvement activities are not research and are required to apply the PRA if they include collections of information requiring OMB clearance under the PRA. See VHA Office of Research & Development Program Guide 1200.21 ("VHA Operations Activities That May Constitute Research") at https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf for information about quality assurance and quality improvement activities.

4. **If a quality improvement activity uses the word "research" to describe its activities for collections of activities, is the quality improvement activity required to apply the PRA?**

   An activity that does not meet the definition of research according to ORD policies cannot classify itself as "research" for purposes of not applying the PRA if it involves a collection of information requiring OMB clearance. For example, a quality improvement activity that does not meet the definition of a systematic investigation designed to develop or contribute to generalizable knowledge cannot be categorized as "research" when it does not meet the definition. Any research activity as defined by ORD policies require review and approval by the VA Facility's R&D committee, including any applicable committees and subcommittees. The VA Facility's R&D Committee cannot approve an activity as research when it is not a research activity under ORD policies.

5. **How are "individuals or entities affiliated with the Veterans Health Administration" defined for purposes of deciding whether the PRA applies according to Section 181 of the Cleland-Dole Act?**

   The Cleland-Dole Act states that the PRA *". . . shall not apply to the voluntary collection of information during the conduct of research by the Veterans Health Administration, including the Office of Research and Development, or individuals or entities affiliated with the Veterans Health Administration*." The phrasing, "*individuals or entities affiliated with the Veterans Health Administration*" is operationalized by VHA as those individuals or entities that VHA have entered into a written agreement (e.g., contract) that are conducting the research on behalf of VHA and acting as agents of the VHA.

6. **Can another federal agency or department be considered "individuals or entities affiliated with the Veterans Health Administration" defined for purposes of deciding whether the PRA applies according to Section 181 of the Cleland-Dole act?**

   If VHA is entering into a written agreement with another federal agency or department that is subject to the PRA, the specific activity in that agreement remains subject to the PRA for the non-VA federal agency or department unless the non-VA federal agency or department is conducting the research on behalf of VHA. In addition, some federal agencies, such as the National Institutes of Health (NIH), also have a PRA exemption for research activities conducted by their agencies (21st Century CURES Act, H.R. 34-114th Congress (2015-2016). https://www.congress.gov/bill/114th-congress/house-bill/34).

7. **What actions are required by a VA Facility or VA Investigator if a VHA research activity currently has OMB clearance since the PRA no longer applies?**
   No actions are required by a VA Facility or VA Investigator for an activity currently under OMB clearance because the PRA no longer applies under Section 181 of the Cleland-Dole Act. No documentation will be received from OMB, ORD, or the VHA PRA office.

8. **What actions are required by a VA Investigator if a VHA research activity is in the process of obtaining OMB clearance?**
   Any activity taken by a VA Investigator to obtain OMB clearance will no longer be required to be completed because the PRA no longer applies as a result of the passage of the Cleland-Dole Act. No documentation will be received from OMB, ORD, or the VHA PRA office. If any communications are received from OMB, please email the VHA PRA office and notify ORD through the FIND Pro tool. For assistance notifying ORD, please review this guide.

9. **Does the Cleland-Dole Act require VHA to document when a VHA research activity is excluded from the PRA?**
   ORD, the VHA PRA office, and/or the VA Facility's R&D Committee are not required to document when a VHA research activity is not required to apply the PRA. Any VHA research activity that meets the definition of research as defined by ORD's policies does not apply the PRA.

10. **If the activities conducted by VHA are not a research activity, how is it determined whether the PRA applies and requires OMB clearance?**Different program offices may have their own mechanism for determining whether the activity requires application of the PRA and OMB clearance. If your program does not have a mechanism, please send queries to: VHACOPRA@VA.GOV.

References:

VHA Directive 1200.05(3): Requirements for the Protections of Human Subjects in Research located at https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171

Consolidated Appropriations Act of 2023 (P.L. 117-328)