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Veterans Health Administration (VHA) Office of Research and Development (ORD) Guidance: Implementation of the Public Readiness and Emergency Preparedness Act (PREP Act) for COVID-19 Research Activities

DATE: August 17, 2020

This is a new guidance document.

For questions on the content of this guidance, email the VHA Office of Research and Development at vhacoordregulatory@va.gov.

Scope: The scope of this guidance is for application of the Public Readiness and Emergency Preparedness Act (PREP Act) to COVID-19 research activities effective February 4, 2020, through October 1, 2024.

Regulatory Background

Under 38 U.S.C. § 7303(a), the Secretary of VA is authorized to "carry out a program of medical research in connection with the provision of medical care and treatment to veterans . . . to include biomedical research, mental illness research, prosthetic and other rehabilitative research, and health-care-services research."

The Secretary of the Department of Health and Human Services (HHS) declared under the PREP Act, 42 USC § 247d-6d(a)(1) effective February 4, 2020, through at least October 1, 2024, "liability immunity for activities related to medical countermeasures against COVID-19." 85 Fed. Reg. 15,198, preamble (March 17, 2020).

The plain language of 42 U.S.C. § 247d-6d(a)(1), states, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure."

The declaration that is described by subsection (b) is the Public Health Emergency declaration made by the Secretary HHS on January 31, 2020.
https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

The following questions are addressed in this Guidance:

1. Does the PREP Act apply to all VHA COVID-19 research involving a covered COVID-19 countermeasure?
2. What is a covered COVID-19 countermeasure?
3. Who are the "covered persons"?
4. What liability protections are available for "covered persons"?
5. What types of loss/harm to study subjects are covered by the Prep Act?
6. If a study subject suffers a loss as a result of participation in a COVID-19 trial involving a countermeasure, does he/she have any recourse for care?

7. If a study subject suffers a loss as a result of participation in a COVID-19 trial involving a countermeasure, can the study subject file a federal tort claim against VA and recover damages?
8. Can a subject in a COVID-19 study involving a covered COVID-19 countermeasure sue a covered person other than VA for damages for injuries or harm under State law?
9. Is the research informed consent form of a COVID-19 countermeasure study required to contain information regarding the PREP Act?
10. Does the PREP Act information need to be part of the "Key Information" at the front of the consent form?
11. What is the language that has been approved by ORD and OGC to be included in the informed consent form of studies to which the PREP Act applies?
12. Can the approved VA PREP Act consent form language be modified by the IRB?
13. If a commercial IRB is serving as the reviewing IRB for a COVID-19 study involving covered COVID-19 countermeasures, who is responsible to provide the VA approved PREP Act language?
14. Does the PREP Act impact VA's Cooperative Research and Development Agreements (CRADAs)?
15. Does the PREP Act impact other non-CRADA agreements regarding COVID-19 studies using covered COVID-19 countermeasures (e.g., DOD is the sponsor)?
16. Our agreements (e.g., CRADAs, grant agreements, subcontracts) do not mention or use the terminology of covered COVID-19 countermeasures, so how does this apply?
17. Is the R&D Committee required to approve the enrollment of non-Veterans participating in COVID-19 research studies involving a covered COVID-19 countermeasure?

1. Does the PREP Act apply to all VHA COVID-19 research involving a covered COVID-19 countermeasure?

Yes. This provision applies to all VHA COVID-19 research involving a covered countermeasure begun on/after February 4, 2020 through October 1, 2024 (unless amended).

2. What is a covered COVID-19 countermeasure?

A covered COVID-19 countermeasure includes: an antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product. (§ 247d-6d(i)(1)(A)).

3. Who are the "covered persons"?

As it applies to VHA, all VHA employees involved in the distribution, application and/or administration of the COVID-19 countermeasure are included in the definition of covered person for the sake of this declaration. As defined in the HHS declaration, "covered persons" include, "the United States as well as manufacturers, distributors, prescribers, administrators, and dispensers of such countermeasures, including agents and employees."

4. What liability protections are available for "covered persons"?

"Covered persons" are immune from lawsuits and liability under federal and state law with respect to all claims for loss except for death or serious physical injury proximately caused by willful misconduct. § 247d-6d(d)

5. What types of loss/harm to study subjects are covered by the Prep Act?

Any conceivable loss that a research subject would incur is covered by the PREP Act. The loss described by the statute includes death, physical, mental or emotional injury, illness and a host of related injuries as well as property damage or loss. § 247d-6d(a)(2)(A).

6. If a study subject suffers a loss as a result of participation in a COVID-19 trial involving a countermeasure, does he/she have any recourse for care?

Yes. VA medical facilities, including joint VA-DoD Federal health care centers, must provide necessary medical treatment (i.e., not just emergency treatment) to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Regardless of Veteran status, a research subject participating in R&DC approved research studies will be treated for his/her injury at no cost for the care. (38 CFR 17.85 and VHA Directive 1200.05 para 24). This care may be provided by the local VA medical facility or arrangements may be made for contracted care at another facility.

7. If a study subject suffers a loss as a result of participation in a COVID-19 trial involving a countermeasure, can the study subject file a federal tort claim against VA and recover damages?

No. Typically, the liability, if any of the United States for damage to or loss of property, or personal injury or death is governed exclusively by the provisions of the Federal Tort Claims Act (FTCA). However, the PREP Act supersedes the FTCA. Thus, any claim under the FTCA by VA subjects involved in COVID-19 research with COVID countermeasures would likely be barred. The study subject can seek benefits through the DHHS Health Resources & Services Administration Countermeasures Injury Compensation Program (CICP). https://www.hrsa.gov/cicp/index.html

8. Can a subject in a COVID-19 study involving a covered COVID-19 countermeasure sue a covered person other than VA for damages for injuries or harm under State law?

No. The statute includes a provision expressly pre-empting states from enforcing laws that are in conflict with requirements of the Act (42 USCS § 247d-6d(b)(8), but does allow application of state law in the willful misconduct provision as in FTCA cases. § 247d-6d(e)(2).

9. Is the research informed consent form of a COVID-19 countermeasure study required to contain information regarding the PREP Act?

It depends on when the study was approved with relation to this guidance. The Prep Act applies whether or not the language is in the consent form. ORD believes that it could be reasonable to conclude that a reasonable person may want to know of their limited ability to sue if he/she suffers a loss or is injured or harmed, as a result of participating in a COVID-19 countermeasure study; correspondingly, it could be reasonable to conclude that such information is information that a reasonable person would want to have in order to make an informed decision about whether to participate in such research per 38 CFR §16.116(a)(4). As such, ORD is requiring that research informed consent forms for a VA COVID-19 countermeasure study approved after issuance of this guidance must contain the language in FAQ# 11 below. However, research informed consent forms for a VA COVID-19 countermeasure study approved prior to issuance of this guidance are not required to contain information about the PREP Act; nevertheless, ORD encourages that the consent forms for those studies be modified to include the language.

10. Does the PREP Act information need to be part of the "Key Information" at the front of the consent form?

No. The PREP Act information may be placed where other liability language is noted in the consent form.

11. What is the language that has been approved by ORD and OGC to be included in the informed consent form of studies to which the PREP Act applies?

The following language is to be used:

A new public health law under the Public Readiness and Emergency Preparedness Act (PREP Act) was issued by the Department of Health and Human Services on March 10, 2020. This law limits your ability to sue if you are in a COVID-19 research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP). For more information about this program, please contact the Health Resources and Services Administration's CICP by phone at 855-266-2427 or online at https://www.hrsa.gov/cicp/about/index.html.

VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the local VAMC or arrangements may be made for contracted care at another facility. In case of research related injury resulting from this study, you should contact your study team. If you have questions about medical treatment for any study related injuries, you can call the operator at this VA Medical Center and ask for medical administration.

You still have the right to hold VA responsible for negligence that is not related to a COVID-19 research study.

12. Can the approved VA PREP Act consent form language be modified by the IRB?

No. OGC has provided this language and it can only be altered with their prospective concurrence.

13. If a commercial IRB is serving as the reviewing IRB for a COVID-19 study involving covered COVID-19 countermeasures, who is responsible to provide the VA approved PREP Act language?

ORD provided the OGC approved PREP Act language to the current ORD-approved commercial IRBs (i.e., WIRB and Advarra). Investigators are required to ensure that the language is not altered by the commercial IRB personnel. If any new commercial IRBs are approved by ORD and serve as a reviewing IRB for a COVID-19 study involving COVID-19 countermeasures, ORD will provide the required consent form language to that IRB as well.

14. Does the PREP Act impact VA's Cooperative Research and Development Agreements (CRADAs)?

Yes, since most of VA's CRADAs contain a section covering the indemnification and liability of the collaborator for costs associated with a subject's injury, and VA's liability, the PREP Act will impact CRADA language. Contact OGC's Health Care Law Group STAR. If unsure of STAR attorney assigned to the VA medical facility, click here.

15. Does the PREP Act impact other non-CRADA agreements regarding COVID-19 studies using covered COVID-19 countermeasures (e.g., DOD is the sponsor)?

Yes, since other agreements tend to include indemnification and liability provisions. Contact OGC's Health Care Law Group STAR. If unsure of STAR attorney assigned to the VA medical facility, click here.

16. Our agreements (e.g., CRADAs, grant agreements, subcontracts) do not mention or use the terminology of covered COVID-19 countermeasures, so how does this apply?

VA agreement language refers to these covered COVID-19 countermeasures as test articles (drugs or devices) used in COVID-19 research. The language in the agreement may be changed from test article to specifically highlight covered COVID-19 countermeasures as determined by OGC.

17. Is the R&D Committee required to approve the enrollment of non-Veterans participating in COVID-19 research studies involving a covered COVID-19 countermeasure?

Yes. The R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans in VA approved research as required by VHA Directive 1200.01, Paragraph 13.a. The R&D Committee should evaluate who will be responsible for paying for any study-related costs and medical care or treatment for non-Veterans included in research activities involving VA hospital inpatient or

outpatient treatment. The Prep Act does not currently provide funding for payment of research-related injuries.