OHSRP PROCEDURES RELATED TO COVID-19 RESEARCH AND THE PREP ACT

Background:

The Secretary HHS issued a Public Readiness and Emergency Preparedness (PREP) Act Declaration for certain COVID-19 countermeasures on March 10. The Declaration covers, covered countermeasures (described below). As an example, the PREP Act applies to NIH when it initiates a clinical trial studying therapeutic treatment of COVID-19 using a drug under an IND. When the PREP Act applies, the Declaration limits participants' legal right to sue covered persons. Covered persons in these situations includes the United States Government, which may include manufacturers, trial sponsors, healthcare providers (related to countermeasures) or others. While study participants right to sue for significant injuries (including death) is restricted under the Declaration, U.S.-located or other certain participants with a U.S. nexus may be able to seek compensation from HRSA's Countermeasure Injury Compensation Program (CICP) for certain serious physical injuries.

Human subjects protection regulations require that participants be informed if any of their legal rights are affected, and what recourse is available, so it is important for IRBs to be informed about the PREP Act. To comply with this, OHSRP has created new language to be incorporated into any intramural research program study consent form that utilizes a "Covered Countermeasure" by NIH.

Resources/Definitions:

The Secretarial declaration is available at:

https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf

Additional information about the PREP Act can be found at this FAQ website here

The CICP program is explained at: https://www.hrsa.gov/cicp/about/index.html

The definition of a covered countermeasure is:

> 42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7)
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> Covered Countermeasures are any 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.
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> Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Principal Investigator Responsibility:
Principal Investigators should make an initial determination as to whether their study includes a covered countermeasure. If so, only the language provided below must be used in the Research Related Injury section of the informed consent document. Revisions (by NIH IRBs or outside reviewing IRBs) will need to be approved by OHSRP before finalized.

Required Informed Consent Language:

If your study uses a COVID-19 covered countermeasure, substitute the following language in the research injury section of the informed consent document. For NIH studies that are conducted at NIH sites other than the Clinical Center, please adapt the first paragraph to be consistent with your site-specific language already approved by OHSRP.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care will be provided by the NIH, the NIH Clinical Center, or the Federal Government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures. Because this study is covered by the PREP Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427.