IRBMED Guidance
PREP ACT Language for COVID-19 Research Informed Consent

I. **BACKGROUND**

One of the most critical and immediate needs during the COVID-19 pandemic is the conduct of clinical trials to support testing potential COVID-19 prophylactics and treatments. Engaging in these potentially life-saving clinical activities might put institutions and covered persons at risk for a liability claim.

II. **OVERVIEW**

To address liability considerations, on March 10, 2020 (effective date February 4, 2020), the Secretary of the Department of Health and Human Services (HHS) issued a Declaration pursuant to the Public Readiness and Emergency Preparedness (PREP) Act granting immunity to entities involved in the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing and use of the Covered Countermeasures to the COVID-19 virus.

This guidance document broadly describes the scope of the PREP Act and the information that study teams should include in the informed consent documents.

III. **THE COVID-19 DECLARATION APPLIES TO**

A. **Covered Persons:** distributers, program planners, qualified persons, and their officials, agents, and employees, as well as certain additional persons authorized to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures.

B. **Covered Countermeasures:** 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 Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use:

- approved, cleared, or licensed by FDA
- authorized for investigational use under IND or IDE
- used for emergency use

IV. **WORKFLOW FOR STUDIES THAT FALL UNDER ABOVE CRITERIA**

A. When working on the IRB application that propose to administer and use a drug, biologic, diagnostic device or vaccine to treat, diagnose, cure, prevent or mitigate COVID 19, the Study Teams must ensure that the following language has been included in the informed consent document(s):

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Ensure the following language is included in the applicable sections of the informed consent document:	
For standard consent document, in Section 5.2	*Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study.* *If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" please go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427*
For consent document on Expanded Access Use of an Investigational Agent, in Section 5.1	

B. NOTE: IRBMED will not be able to approve IRB application until the above language is included in the applicable informed consent documents.

V. **RESOURCES**

A. Notice of Declaration under the PREP Act https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf.

B. The Countermeasures Injury Compensation Program (CICP): https://www.hrsa.gov/cicp/about/index.html

C. Standard Informed Consent Template https://az.research.umich.edu/medschool/templates/standard-informed-consent-template

D. FDA Expanded Access Informed Consent Template https://az.research.umich.edu/medschool/templates/fda-expanded-access-informed-consent-template