

Conduct and Submission of COVID-19 Research in Human Subjects

The following applies to newly initiated research and existing protocol modifications to collect COVID-19 data from human subjects.

Priority Review

The Office of Research Integrity (ORI) and Institutional Review Boards (IRB) provide priority screening and review to facilitate rapid approval of COVID-19 research.

Study Identification

If your research involves investigating any aspect of COVID-19, please enter “COVID-19” at the start of your Project Title in your IRB protocol application.

Please add COVID-19 to “Title of Project” and “Short Title Description” of your current IRB protocol.

For protocols being reviewed by an external IRB, please enter “RELIANCE COVID-19” before the PROJECT and SHORT titles.

Informed Consent Options

For options conducting remote consent, see the [UK ORI Best Practice Guide](#). For FDA-regulated research note questions 10 & 11 in the [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#) as a signed document is required.

The University of Kentucky Center for Clinical and Translational Science (CCTS) has shared a [video demo](#) of their process for obtaining remote consent of [UK COVID-19 Biobank](#) participants using REDCap.

Injury Language for COVID-19 Treatment Protocols

BACKGROUND:

On March 10, 2020, the HHS Secretary issued a [Public Readiness and Emergency Preparedness \(PREP\) Act Declaration](#) which was [amended effective March 27, 2020](#) that provides liability immunity (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from manufacture, distribution, administration or use of countermeasures to diseases, threats, and conditions determined by the Secretary to constitute a public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.

PREP limits legal rights to sue covered persons engaged in select COVID-19 countermeasures (including select treatment research) and provides compensation for eligible individuals who suffer injuries from use of covered products.

Covered countermeasures may include vaccines, drugs, or medical devices to be used to treat, diagnose, cure, prevent, or mitigate COVID-19.

Products must be:

- (a) a qualified pandemic or epidemic product;
- (b) a security countermeasure;
- (c) a respiratory protective device approved by NIOSH;
- (d) approved, licensed, or cleared by FDA;
- (e) authorized under an [Emergency Use Authorization \(EUA\)](#) issued by FDA;
- (f) described in an [Emergency Use Instructions \(EUI\)](#) issued by the CDC; or
- (g) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).

In addition to meeting the scope of the act, reasonable precautions must be taken to facilitate the safe use of covered countermeasures. See the [PREP Act Q&As](#) and [PREP Act Glossary](#) for detailed information.

CONSENT LANGUAGE:

The following statement should be added to the informed consent for applicable COVID-19 studies, in order to inform participants regarding their legal rights.

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 and recover losses from the researchers, healthcare providers, any study sponsor, distributor or manufacturer 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.

PARTICIPANT QUESTIONS:

If participants have questions about the Countermeasures Injury Compensation Program (CICP) direct them to the [CICP website](#) which provides [Requester FAQs](#), [Fact Sheet](#) and contact information.

COVID-19 Screening Procedures

COVID-19 screening procedures mandated by the institution or healthcare system do not need to be submitted as an IRB Modification Request unless the data is being collected as part of a research objective.

See ORI Resumption of Research FAQs for [reporting Positive COVID-19 tests to the IRB](#) and [Kentucky Public Health](#).

Adverse Events on FDA-regulated Clinical Trials

[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#) provides information on assessment of causality of Serious Adverse Events (SAE)s. Causality assessments may require comparison in arms for unblinded trials or comparison to external population.