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.

Food and Drug Administration (FDA) Guidance for Covid-19 Therapeutic Trials

FDA Drug Development Inquiries for Drugs to Address the COVID-19 Public Health Emergency
CDER is committed to supporting the development of novel drugs, and the potential repurposing of existing therapies, to address the Coronavirus Disease 2019 (COVID-19) public health emergency. The Office of New Drugs (OND) within CDER is expediting this effort, working with potential drug sponsors to rapidly move products into clinical trials, while assuring that the trials are properly designed and are appropriately safe.

Coronavirus Treatment Acceleration Program (CTAP)

CTAP recommends that requests for initial feedback on new COVID-19 related drug development programs be sent to the COVID19-productdevelopment mailbox.

FDA Guidance for Clinical Trials During Covid-19

In March 2020, the FDA issued Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic. The guidance has been updated several times with current information and questions and answers ranging from provision of investigational product informed consent for isolation patients.

In September 2020, the FDA issued guidance for investigators and sponsors regarding the measurement and analysis of COVID-19-related symptoms in clinical trials evaluating drugs to prevent or treat COVID-19 in outpatient adult and adolescent subjects. Since daily assessment of all COVID-19 related symptoms may not be feasible or may be burdensome for subjects, the guidance provides a set of common COVID-19 related symptoms and approach to measurement.

Informed Consent Options

For options conducting remote consent, see the Remote Informed Consent webpage and brief remote

consent video . 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.

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, 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 to the IRB for review unless the data is being collected as part of a research objective.

Positive or presumptive positive SARS-CoV-2 results must be reported to public health authorities in the state of Kentucky. They may not accept results that come from a lab which is not certified by the federal CLIA program or state equivalent. If you obtain a positive result, report it to the state of Kentucky and, if required, UK HealthCare. If the test is not a recognized/verified test, you should tell the participant about the result and the limits of that test, then encourage them to get a valid test from a healthcare facility. Find instructions under the "Healthcare Providers" section under "Resources" on the Kentucky Public Health COVID-19 website: https://govstatus.egov.com/kycovid19.

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.

The FDA guidance for investigators and sponsors regarding the measurement and analysis of COVID-19-related symptoms provides a set of common COVID-19 related symptoms and approach to measurement.