

# University Hospitals Institutional Review Board

## FAQs Regarding Human Research Procedures Related to Coronavirus COVID-19

### **Do I need to amend my protocol to reflect clinical screening procedures for coronavirus COVID-19?**

No. New mandatory clinical screening procedures are not considered part of the “IRB approved procedures” for your protocol and therefore do not necessarily trigger the need for an amendment to the protocol. These screening procedures do not constitute a change in IRB-approved research procedures unless you choose to incorporate the data collected under the mandatory screening into your study plan as part of the research.

### **I am a PI of an investigational drug/device trial. Do I need to pause my trial?**

No, if there is a potential benefit from the trial that outweighs any additional risk from COVID-19, trials with investigational treatments, including drugs and devices, should continue.

### **What changes am I allowed to make to my protocol right now in light of COVID-19? Can I cancel study visits?**

Any changes in IRB-approved research procedures must be reported to the IRB and may not be implemented prior to review and approval by the IRB *except when necessary to eliminate apparent immediate hazards to the subject*. This is permitted by both the Common Rule (38 CFR §16.108(a)(3)(iii)) and FDA regulations (21 CFR §56.108(a)(4)) in order to prevent investigators from delaying the initiation of safety changes to eliminate apparent immediate hazards to subjects.

University Hospitals also has a responsibility to ensure the safety of its staff. As such, interim measures to eliminate immediate hazards to staff, which may involve deviating from approved study procedures prior to securing IRB approval, may be warranted. Examples of modifications or safety changes include, but are not limited to:

- cancelling non-essential study visits
- conducting phone visits in lieu of in-person visits
- conducting safety screening (initiated by the Principal Investigator) prior to in-person visits occurring
- other changes as deemed appropriate to eliminate immediate hazards to subjects because of the risk of exposure to this highly communicable disease.

All modifications must be authorized by the Principal Investigator and, unless an immediate hazard is apparent, the funding agency or sponsor must also provide prior approval. In all

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cases, the funding agency or sponsor must be notified of any modifications within one(1) business day. If it is anticipated that changes made to the study to eliminate apparent immediate hazards will be sustained for a duration that would allow time to submit an amendment to cover such changes, then approval of a protocol amendment must be sought.

In some cases, these protocol changes may involve the Principal Investigator temporarily stopping subject recruitment or placing a temporary hold on all study procedures. If you are conducting an FDA regulated, investigator initiated research study and you are the holder of the IND or IDE, you will also need to notify the FDA of any modifications.

**If I make any modifications to the Protocol do I need to document them?**

Yes. All changes should be documented in your regulatory binder. Be sure to include details about communication with the funding agency, sponsor, or FDA as well as justifications for any changes made. You should also submit an RNI (Reportable New Information) form through SpartaIRB to document that you informed the IRB of the alternative procedures.

**If I am considering pausing or modifying study procedures for a study that uses an external IRB (ex: Advarra), do I need to notify the IRB of Record?**

The regulations allow implementation of a change to study procedures without prospective IRB approval when it is necessary to avoid imminent hazards to subjects; however, each IRB makes its own decisions with regard to the approval process. The UH IRB does not have the authority to make decisions on behalf of external IRBs.

For other issues related to COVID-19 procedures, please visit [the Novel Coronavirus COVID-19 page on the UH Digital Workplace](#)

**Please note that the Clinical Research Center is actively working to develop options for virtual visits. We will communicate these options as soon as they are available.**

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For additional IRB information or guidance,  
please contact the [UH IRB Administration Office](#) at  
**216-844-1529** or [UHIRB@UHhospitals.org](mailto:UHIRB@UHhospitals.org)

*Distributed by the Clinical Research Center at University Hospitals Cleveland Medical Center. Send comments, suggestions or feedback to [John Dannug](#).*