

***GUIDANCE ON THE EFFECT OF COVID-19 TO
NEW AND ONGOING RESEARCH***
LEGACY HEALTH IRB GUIDANCE: MARCH 30, 2020

Effect of COVID-19 on new and ongoing research: During this COVID-19 crisis, research does not necessarily need to be halted or suspended or put on hold, but investigators may need to make significant changes in research quickly to accommodate social distancing and other requirements for the safety of subjects and study staff. Keep in mind that the COVID-19 has had the unusual effect of making many minimal risk activities in research now greater than minimal risk, even though the specific research procedures have not changed, for it is daily life that has changed -- and procedures that were once without risk now may pose unacceptable risks in the research context.

Assessment of needed changes in ongoing research: PI's and sponsor should assess their research procedures quickly and thoroughly and determine whether they should make changes that will comply with social distancing and other requirements posed by COVID-19 and submit those proposed changes to the IRB. For example, the following changes may be needed because of COVID-19:

- Decreasing or eliminating the number of protocol-required visits of subjects to the clinic or facility because the visit itself now poses risks that were once normal, thereby utilizing telemedicine or other means to remain in contact with subjects;
- Adding pre-screening procedures to prevent recruitment or enrollment of subjects that may have been exposed to COVID-19
- Conducting home visits or arranging for other methods of blood draws or other procedures that are required by the study but reduce the risk of contagion;
- Allowing flexibility for out-of-window procedures;
- Using remote consenting or other methods to provide subjects with new or updated information about the study;
- Stopping or moving in-person focus groups or interviews or surveys to remote procedures, yet still ensuring that confidentiality or privacy is not degraded by any change;
- Delaying or re-scheduling procedures that are required under the protocol but area not time-sensitive that can be done at a later time;
- Shipping investigational drugs or devices directly to research participants if that is possible and consistent with protocol requirements and sponsor agreement.

Prompt review of changes to research by the IRB: Most changes to research that result from COVID-19 concerns can be processed quickly via expedited review, as long as the change does not introduce greater than minimal risk to subjects. Consequently, when a COVID-19 prompted change is required, investigators should submit a change in research or an amendment or modification as soon as possible, signed by the investigator, explaining that the change is needed because of COVID-19 risks to subjects or staff or others. These requests will be given priority at Legacy Health IRB and every attempt will be made to review and approve them through expedited review.

COVID-19 effects as causing "immediate hazards" to subject safety in research: Please note that if the needed change is time sensitive, and there is not enough time for IRB review, FDA Guidance provide that:

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. 21 CFR 56.108(a)(4). In such a case, the IRB should be promptly informed of the change

following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare. FDA Information Sheets. (Emphasis added.)

Also, FDA regulations provide that:

Each IRB shall ... (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. 21 CFR 56.108(a)(4). (Emphasis added.)

DHS regulations 45 CFR 46.108(a)(3)(iii) has similar language, requiring the IRB to establish and follow written procedures for:

Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. 45 CFR 46.108(a)(3)(iii) (Emphasis added.)

Consequently, Where an investigator or a sponsor thinks that the study needs to be changed to “eliminate apparent immediate hazards” e.g., COVID-19 risks, to research subjects, these changes can be implemented and then reported to the IRB for review and approval or acknowledgment as soon as possible to ensure that the change is consistent with ensuring the subjects' continued welfare. This may occur because of the need to retain subjects on study drug or monitor the device in a treatment study, or to continue to provide medical care to subjects consistent with the protocol but also with standard care.

Notification/Submission to the IRB of COVID-19 induced change: IRB notification of a change made to “eliminate apparent immediate hazards” to subjects can be done via submitting a revised protocol, consent form, etc., as long as the change is clear and provides the information needed for IRB review of the change and especially the risks that the change poses or eliminates. The standard LRI modification/amendment form or the standard deviation form may be used for submission to the IRB. The change will then be processed via expedited review or full board review. Submissions should be clear about whether the change has already been implemented or whether it is a prospective change being submitted.

“Re-consent” of subjects for changes in research: Any changes in research may require notification to subjects of the changes. Commonly, subjects are “re-consented” via revised consent forms or by addendum to consent forms. The regulations do not technically require “re-consent”, as the rule is instead that “subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)).” Consequently, COVID-19 changes that occur quickly or before IRB review of the change may still require that that subjects be apprised quickly of the changes. The information about the change and how it was presented to subjects should also accompany any submission for review by the IRB.

Questions, answers and guidance from the IRB: Please contact the following persons for IRB related questions via email or phone (503-413-2491) at Legacy Research Institute:

Paul Newton, JD, CIP

Senior Research Regulatory Specialist

pwnewton@lhs.org

Valerie Stallings

Administrative Assistant

vstallin@lhs.org

