Date: August 2, 2021 **(This document is subject to change at any given date/time in order to respond to evolving conditions).**

To: AdventHealth Orlando Researchers
From: AdventHealth Orlando IRB
RE: Updates from the IRB

IRB Remains Fully Operational

The IRB Administration and IRB Committees are currently functional and operating per standard practices.

Priority continues to be given to all inquiries, requests, applications and modifications related to COVID-19, and its impacts on research.

At this time, the AdventHealth Orlando IRB is NOT suspending research at AdventHealth due to the current Black Status related to the COVID-19 pandemic peak we are experiencing. The IRB and AHRI Leadership will continue to monitor our status and this position is subject to change as a result. You will be notified immediately of any changes.

All researchers are required to have knowledge of the current hospital status as relayed to all AdventHealth employees via CFD email updates. Maintaining the ability to keep our research up and running largely depends on researchers' keen awareness of AdventHealth Updates, study sponsors, CDC, state, and local policies and recommendations to keep our research participants and research staff safe.

We have new information and FAQs below.

1. How are research studies affected by the frequently changing hospital status updates?

Ethical principals in research and federal regulations for the protection of human research require changes in research be submitted to the IRB prior to implementation, **unless immediate action is needed to eliminate an immediate risk to the participant**.

All researchers are required to have knowledge of the current hospital status as relayed to all AdventHealth employees via CFD email updates. Should the current hospital status impact your ability to conduct your research per the IRB approved protocol, make any necessary updates to your study procedures, and submit your proposed change in research to the IRB of Record for review and approval.

Example: Black Status suggests there may be resource constraints that could affect your study participants schedule of procedures. The IRB would need to be made aware of any plans to deviate from a research protocol.

2. If I must make changes to accommodate the hospital's current status, how should I approach modifying study procedures?

Please remember any modifications to the IRB approved protocol requires IRB approval from the IRB of Record. As an example, for studies relying upon AdventHealth IRB: protocol amendment (submit Form HRP-203 Modification Application) or protocol exception request (submit FORM: HRP-230 Protocol Exception Request).

Research personnel training and education regarding changes. All research personnel should be notified of protocol and process changes put in place due to COVID. This may include changes to the consent process or study visits. If you

plan to conduct consent in a remote fashion, you are required to educate your teams about and follow the IRB HRP-183 Remote Consent Guidance.

IMPORTANT NOTE: If action is taken without IRB approval to eliminate an immediate risk to the participant, please report the action to the IRB of Record in accordance with their policies. See AH IRB policy 400.069 Prompt Reporting Requirements in Research. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine because of suspected or known exposures.

3. How should I educate current or potential participants about COVID-19 and how it pertains to their participation in research at AdventHealth?

The IRB currently has a COVID-19 information sheet for research participants (updated 7-30-21). The IRB continues to request that research teams share this education with their research participants. This could be provided prior to or at their next scheduled research visit in whatever medium you decide is best. The information sheet is posted on both the AHRI internal Sharepoint site and external facing website.

Investigators should have a plan to continue this education and questioning of their research participants as often as necessary and at time points that make sense per study.

All applicable documents should be revised as usual, e.g. protocol/supplement. If the changes are temporary in nature, you could outline the changes in the Modification Application only. Principal investigators are responsible to ensure that the entire study team receives proper training on any new procedures implemented. Regardless of whether an IRB of Record requires a submission or not, you should make plans to communicate to your participants, any COVID safety procedures that they can expect to undergo once they arrive at the study site.

4. How should I be thinking about participant safety monitoring?

Clinical research studies may require in-person study visits in order to conduct safety monitoring of the research participants. For example, participants in a drug treatment study may need to have regular examinations, interviews, or laboratory tests for specific possible side effects.

The Principal Investigator (PI) should consider contingency plans in the event that research participants are unable to attend scheduled study visits, especially those that impact participant safety.

Plans should continue to address study visit management due to participant quarantine and/or institutional research site or clinic closures. Follow any guidelines or instructions from the specific facility where participant interaction would occur.

Plans should include options in the event that the researcher and/or key personnel/research staff are unavailable to conduct research visits due to their own quarantine.

Researchers should plan for alternatives to in-person monitoring visits, if possible. For example, interviews could be conducted by phone or email; visits could be conducted at an alternative location for examinations or specimen collection. Or, perhaps the schedule of monitoring could be safely modified or delayed. Alternatively, the research site may plan to meet with their participants in a different location and one that keeps them from entering the hospital.

Continue to Review the research protocol(s) to determine which study visits, interventions, or tests are essential for participant safety. **Discuss options with the sponsor(s).**

Consider access to the research resources such as the test article (drug, biologic, device), lab test, imaging, and healthcare facility services. Consider telemedicine and shipping the test article directly to the participant.

Consider if the transfer of the participant to another research site for continued access to the research resources is in the best interest of the participant.

Please contact the IRB office if you have any questions.
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