Date: March 13, 2020

General FAQs #2, #3 UPDATED March 19, 2020 2:00 p.m.

(This document is subject to change at any given date/time).

To: AH Researchers
From: AH IRB
RE: Coronavirus: COVID-19 - Updates from the IRB

IRB Remains Fully Operational

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

If AdventHealth elects to transition to remote operations, the IRB Administrative Office has mitigation processes in place for remote review and to maintain IRB oversight.

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

To prepare and reduce the risk of COVID-19, please follow AdventHealth's updates as distributed to employees i.e. Central Florida Division Team Member Email Updates.

We have new information and FAQs below.

General FAQs UPDATED March 19, 2020 2:00 p.m.

1. How should I plan for this rapidly evolving situation?

All principal investigators and study teams should immediately develop a COVID-19 mitigation plan. The plan should consider the following, at a minimum

1) **The study population and the location**. It is no longer appropriate to assume that populations and locations with few reported cases are relatively free of COVID-19 presence. It is also important to consider the possible impact of the study on care providers and their facilities, who will likely be dealing with significant increases in visitors and patients.
2) What measures your building or research facility is taking to screen people prior to entry.
3) Those at increased risk of severe illness from COVID-19. People at higher risk, as defined by the CDC, include any of the following (note that these are changing criteria):
    a. Over 60 years of age
    b. Individuals With underlying health conditions, including heart disease, lung disease, or diabetes
    c. Individuals With weakened immune systems
    d. Pregnant
    e. Caregivers of children with underlying health conditions
4) **Have a protocol for noncontact screening** for subjects with possible active COVID-19 infection prior to approaching potential research participants. Individuals with active symptoms should be avoided.
5) **Avoid all participants with confirmed COVID-19 infection**
6) **Decrease potential exposure for nonclinical personnel**
7) **Reduce face-to-face contact with research participants**. For example, this may be accomplished by including barriers between research personnel and participants, and/or using technology (e.g., telephone, facetime, email, intercoms) to conduct interviews.
8) **Contingency plans when subjects are unable/unwilling to be seen for scheduled visits.** This could also be accomplished using technology (e.g., telephone, facetime, email) to conduct interviews

2. Will research continue as usual at AdventHealth Orlando?

BY 5:00 p.m. on THURSDAY, March 19, 2020, ALL PRINCIPAL INVESTIGATORS WILL BE REQUIRED TO evaluate each of their active or future research projects that currently include in-person visits/contact and determine whether their research activity can continue or should be paused based on increased risk of exposure to COVID-19. This will include identifying whether each study is "essential" or "non-essential" and an attestation that the principal investigator agrees.

Ethical principals in research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. Some studies will have to be temporarily paused due to increased risk. We expect that principal investigators will need to pause all studies/activities that are considered "non-essential" as follows:

a. there is little to no prospect of direct benefit to participants and involves in-person contact (unless other arrangements are made as described in this document)
b. are NOT conducted during or as part of routine clinical care

Examples of essential studies:

a. Studies where a participant may directly benefit from participation
b. Studies where there is no option or availability for treatment outside the research .

3. What should I do if I have a study(s) that is "non-essential"?

You will need to make the IRB of Record aware of whether the study will be paused OR defend why the study should remain open. If AH IRB is the IRB of Record, promptly submit a Modification Form in IRBNet to notify the IRB. The IRB expects that you include whether subjects will be informed, but does not require approval of the method, such as phone scripts or letters. Sponsors, funders, etc. should also be made aware per your usual routine when study changes are implemented.

4. How will I know when I can resume my paused study?

Further updates will cover when paused studies can be resume.

FAQs for Ongoing Studies (updated March 18, 2020)

1. Can I still interact with my research subjects?

You should have a compelling reason why in-person interactions need to occur or continue.

In-person visit requirements. If there is a compelling reason you cannot postpone in-person interactions, you should:

- **Screen all participants for possible exposure** to the novel coronavirus COVID-19 or symptoms of exposure to respiratory illnesses before scheduling (and immediately before the occurrence of) any in-person interactions.
- **Ensure that hand sanitizer, hand washing facilities and/or cleaning wipes** are readily available for participants and study personnel, when in-person interactions will occur.
- **Abide by all recommendations and actions** of the appropriate public health authorities and AdventHealth.
- **Ensure every day that study personnel who will interact with participants** are symptom-free and have not had possible exposure to COVID-19.

2. Do I need to modify my consent form to include the risks of COVID-19 if there will be in-person interactions?

At this time, IRB does not believe this is necessary.

3. 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 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 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.

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.

4. 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).

> The notification to the IRB may be a full protocol amendment, but it does not have to be. The notification of the change in research plans may also be a memo, letter, or other document that explains the changes being made, and provides enough information for the IRB to assess the relative risks resulting from the changes. The amendment or plans document will proceed through IRB review as per the usual process.

If action is taken without IRB approval to eliminate an immediate risk to the participant, please report the action to the IRB of Record. 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.

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5. When should I update Clinical Trials.gov Registration?

Some studies registered at the federal site ClinicalTrials.gov are modifying their research procedures to include testing for SARS-CoV-2 and/or assessment of COVID-19 symptoms. The ClinicalTrials.gov information for the study should be updated to include these new procedures, if they are done for research purposes. If they are being added as public health surveillance activities in coordination with public health authorities, the protocol, consent forms and registration information does not need to be modified. The federal requirement about modifications is that any research-related changes that are communicated to the subjects (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration with 30 days after IRB approval of the modification.

Please contact the IRB office if you have any questions.
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