Date: May 19, 2020

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

Updates made to Q1, 1st Wave; Q3

To: AdventHealth Orlando Researchers
From: AdventHealth Orlando IRB
RE: Updates from the IRB - Tiered Plan to Re-Open Non-Essential Studies During COVID-19 Pandemic

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.

To prepare for a tiered Re-Opening of non-essential studies, first and foremost, all are required to follow and incorporate AdventHealth's re-open mandates as distributed to employees i.e. Central Florida Division Team Member Email Updates.

Please be reminded that the IRB will be one of the determining bodies for whether studies deemed non-essential can be re-opened due to the COVID-19 pandemic.

As COVID-19 continues to be a threat, personnel shortage and shortage of personal protective equipment (PPE) and supplies demands that the research enterprise continue to uphold its civic duty and introduce a tiered or "wave" approach to minimize the risks to research subjects, research staff, and minimize the consumption of protective equipment that are much in need in the clinical care setting.

We have new information and FAQs below.

General FAQs

1. How will studies with a Non-Essential status be assessed by the IRB to be re-opened at AdventHealth Orlando?

Ethical principals in research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. The federal and state governments, local municipalities and AdventHealth Orlando have put into place a re-opening plan which includes a staged and controlled approach. To follow suit, the IRB will consider re-opening Non-essential research studies in waves. (This will include new study submissions as discussed in Question 4.) The timing of each wave will vary based on re-opening plans described above.

Effective May 19, 2020, the 1st Wave has been opened. You may now submit a Modification Application to request to open your study(s) for that wave. See Question 3 below. All waves are described below.

1st Wave OPEN – (A) Studies determined by AHRI to be essential* but enrollment and/or other activities were paused by the department or industry sponsor. (*This is only for studies where there is no option or availability for treatment outside the research. **OR** (B) Studies deemed non-essential where currently enrolled subjects must now report for in-person safety follow ups which are vital to the subjects' well-being e.g. device studies where follow up must occur in-person with the sponsor's vendor and study nurse. For these studies, the essential study activity necessary for the active subjects will be permitted. However, enrollment to new subjects remains paused.
2nd Wave - low risk population** with/without direct benefit to subjects, and proper measures in place
3rd Wave - high risk population** with direct benefit to subjects, and proper measures in place
4th Wave– high risk population** with no direct benefit to subjects, and proper measures in place

**Based on CDC Guidelines for those at high risk for COVID-19

2. What should I take into consideration if I plan to re-open my study(s) deemed Non-Essential?

All principal investigators and study teams must consider the following prior to requesting to re-open a non-essential study as it pertains to the waves above:

A. **Your participant population**
    i. 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):
        i. Over 60 years of age
        ii. Individuals With underlying health conditions, including heart disease, lung disease, or diabetes
        iii. Individuals With weakened immune systems
        iv. Pregnant
        v. Caregivers of children with underlying health conditions

B. **Your study location**
   What measures is your building or research facility taking to screen all people prior to entry?

C. **Your 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.

D. **Your plans to decrease potential exposure for nonclinical research personnel**

E. **Reduce face-to-face contact with research participant.** 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.

F. **Your 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

G. **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.

H. **Abide by all recommendations and actions** of the appropriate public health authorities and AdventHealth.

I. **Ensure every day that study personnel who will interact with participants** are symptom-free and have not had possible exposure to COVID-19.

3. When my study meets the open wave(s) criteria, how do I request to lift the pause on my study?

Once your study is eligible to request a lift on enrollment pause, you must submit a Modification Application form to the IRB of Record per their policies. Regardless of whether an IRB of Record requires a submission or not, the following applies: ****Lifting a pause on a study indicates the principal investigator's commitment to follow all guidelines above.**** 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. May I submit a new study to the IRB?

For new studies submitted to the IRB, the IRB will make a determination on whether the study fits into the category(s) of waves currently accepted for review as discussed in question 1 above. If the study does not meet the current open wave(s) you could receive approval but will not be able to start your study. This will be noted in your approval letter. Once your study fits into the current wave(s), you must submit a Modification Application.

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

IRB does not believe this is necessary.

6. 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.

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7. 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).

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.

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8. 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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