
In the context of rapidly evolving circumstances regarding COVID-19, and HHC’s focus on social distancing and the health and well-being of the community, Research Administration, in consultation with Institutional Review Board and Senior HHC Leadership, is providing this following guidance regarding human subjects-related research visits, screening, enrollment and regulatory compliance.

These procedures are being implemented with the primary focus to minimize the risk of exposure and infection with COVID-19 in research participants, researchers, and the larger community, and to ensure ongoing access to research which may provide essential support and care to participants.

Interactions with Research Participants
In light of the evolving Infection Control guidelines that are in effect in all HHC locations mandating how clinical interactions are to be conducted, enrollment, screening and follow up treatment/monitoring for some studies may require modifications.

- **Non-Essential Research Visits** (‘NO potential direct drug or device therapeutic benefit OR safety risk’)
  1) Active Research Participants:
     a. Studies requiring face-to-face interaction with participants with no potential direct drug or device therapeutic benefit or safety monitoring requirements are to be suspended until further notice.

     b. Studies not requiring face-to-face research interactions with active research participants may continue with telephone contact, remote monitoring, or remote data collection.

  2) Enrollment of New Research Participants:
     a. Enrollment of new research participants in a clinical trial or other human subject-related research will be allowed ONLY if the enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 HHC infection control measures in place.

- **Essential Research Visits** (‘potential direct drug or device therapeutic benefit or safety risk’)
  1) Active research participants:
     o Studies requiring face-to-face interaction with participants (that involve the administration of drugs or monitoring of devices that cannot be performed remotely) with potential direct drug or device therapeutic benefit or safety monitoring requirements may continue with the following additional guidance:
       - All active research participants must be screened remotely (by phone, teledicine, video, ...) for risk, signs and symptoms of COVID-19, as directed by the current HHC infection control protocol, by research staff prior to the research visit, with repeat screening by research staff at the time of the face-to-face visit. Those who screen positive on either occasion will require local triage as per HHC protocol.

       o Studies not requiring face-to-face research interactions with active research participants may continue with telephone contact, remote monitoring, or remote data collection.

  2) Enrollment of new research participants: Enrollment of new research participants in a clinical trial or other human subject-related research will be allowed only if;
participation in the trial provides a potential for a direct therapeutic benefit (drug or device) to participants, as determined above, or;

- the enrollment and longitudinal participant management can be conducted entirely remotely for the duration of the COVID-19 HHC infection control measures in place.

**IRB Review of Modifications Related to COVID-19**

- Addition of screening procedures related to COVID-19 **does not** require IRB approval. This is public health surveillance.

- The HRPP/IRB interprets the substitution of telephone, web conferencing, and secure electronic communication to conduct data collection procedures normally done in-person as a temporary change not requiring review. These methods may be added when possible and practical for mitigating research risks related to COVID-19 to subjects or others.

- Any addition of study procedures **related to research** does require IRB review and approval.

- Refer to the FDA (21 CFR 56.108 (a)(4)) and OHRP (45 CFR 46.108 (3)(iii)) for information regarding implementing changes in research prior to IRB approval in order to eliminate apparent hazards to participants. 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. HHC IRB encourages investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants. Such changes without IRB approval must be reported to the IRB within 5 business days.

- If a research participant is unable to complete a required study related activity per the IRB approved protocol this is a protocol deviation and should be reported to the IRB by the investigator per standard process. This may include prospective deviations to ensure ongoing treatment.

- Investigators conducting research protocols **not overseen by the HHC IRB** should consult with the external IRB regarding management of protocol deviations and amendments per their recommendations. External IRBs (such as WIRB, NCI CIB, ADVARRA) have likely provided guidance.

**Privacy Reminders**

Privacy protections, including those under the HIPAA Privacy Rule, are not set aside during an emergency. As some employees may transition to work remotely, please be reminded of these key privacy considerations:

- Do not store electronic research data on unsecure devices in order to work remotely.
- The IRB encourages the use of HHC-approved VPN access and other remote services while working at home instead of storing data directly on your devices.
- Do not take home physical research records or data (paper consent forms, case report forms, questionnaires/surveys, etc.). All physical records must continue to be stored in IRB-approved, secure locations.
- For additional guidance, please contact the Office of Compliance and Integrity at 860-972-1573.

**Study Sponsors and Monitors**

Principal investigators and research staff are asked to contact study sponsors to notify them of these revised standards and make appropriate arrangements to accommodate these changes. All sponsor and monitor visits for clinical trials or other human subject-related research, whether for site qualification, site initiation, or monitoring visits, should be postponed, consistent with the Visitor Restriction Policy. Consideration for remote visits should be based on study need and resource availability.
**HRPP Office Operations**
The HHC IRB remains fully functional and operating at our standard capacity. We will utilize our VMR capabilities to hold full board meetings virtually and will work remotely if necessary using our web-based site, IRIS. We do not anticipate any negative impacts on our procedures or timelines due to the public health emergency.

**Impact on federally-funded research**
Due to the potential exceptional impact of the declared public health emergency, NIH has alerted the research community of short-term administrative flexibilities that will apply to NIH applicants and recipients:

- [Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19](#) (3/12/2020)
- [General Frequently Asked Questions (FAQs) - Proposal Submission and Award Management Related to COVID-19](#) (3/10/2020)
- [NIH LATE APPLICATION POLICY Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19)](#) (3/10/2020)

We are thankful for your patience, partnership, and thoughtful approaches as we adapt to a novel disruption to the conduct of studies while maintaining key protections for our research participants. We are available to personally answer any questions and provide ongoing guidance. As always, please reach out to the IRB/HRPP office at 860.972.2893 for your research-related inquiries.

Best Regards,

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