HUMAN RESEARCH PROTECTION

Human Subjects' research and COVID-19

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Please refer to the IRB webpage for current forms and information:

https://www.hhrinstitute.org/researcher-resources/ohsr/

1) Are the IRB Office and IRB operating as usual?

Yes, they are fully operational. Voice messages and email messages will continue to be monitored frequently.

Effective immediately:

- Please **submit via email** all IRB forms, requests, supporting documentation, and any other paper-based items to the IRB Office, rather than inter-office mail and/or in-person drop-off. The drop-off box outside of IRB Office will no longer be monitored. The IRB office is lightly staffed, and that could change without notice to a no in-person staffing situation.
- Highest IRB priority is being given to all inquiries, requests, applications, and modifications related to COVID-19 and to their impact on ongoing research.
- Researchers are strongly encouraged to use phone calls and emails for communication rather than in-person meetings.
- **Continuing review reports will be emailed** rather than mailed through inter-office mail. To ensure timely review and re-approval, please **return completed forms via email** to the IRB Office prior to their due date to ensure timely review and re-approval.
- Approval letters and other communications from the IRB will be sent out via email to the study PI and named study coordinator; the IRB Office will no longer send out hard copies of materials, approvals, or other communications.

2) How do I submit my paper-based materials?

Effectively immediately, send all submission materials as electronic documents to: tschmidt@hhrinstitute.org or chanson@hhrinstitute.org

3) Can I still interact with my research participants?

Per HHRI Communications (March 16, 2020):

> HHRI sponsored and staffed clinical research programs need to stop activities that involve face-to-face participant interaction (including enrollment) in HHS clinical locations on the downtown campus as soon as can be safely accomplished. Interaction with participants to ensure their safety if there is an emergency related to their participation is permitted. If face-to-face participant interaction is required by

a clinical protocol to continue to follow a participant for safety reasons, research programs should contact the IRB to discuss how that will be done.

All other HHRI sponsored and staffed clinical research activities that involve face-to-face participant interaction need to stop this by Tuesday, March 17, 2020. If HHRI clinical research programs have a unique need to continue research visits they should discuss this directly with HHRI leadership (for example, projects that involve a COVID-19 research question). We anticipate clinical research protocols to begin to adopt new strategies to interact with participants so that projects can continue during these "no face-to-face" interaction periods. These changes are encouraged, but must be approved by the IRB prior to adoption.

HHRI is working with the IRB and consulting regulatory guidance to determine to what extent this temporary stoppage of participant interaction in clinical research is a reportable event to regulatory agencies and/or sponsors. Research teams do not need to contact the IRB to report this stoppage as a change in protocol. However, any subsequent project modifications to implement remote participant interaction (or other changes) that have not been previously approved do require a submission to the IRB. The temporary stoppage is an institution-wide policy being implemented in response to the declaration of a State of Emergency by the governor and the guidance being provided by the Minnesota Department of Health in response to the COVID-19 crisis.

We will continue to update you with new information and guidance as it becomes available.

4) What about clinical research of HHS investigators who are conducting non-sponsored investigator-initiated research that involves face-to-face interaction (including enrollment)?

In concert with policies of HHRI and the policies being implemented by HHS to reduce the risk of participant and/or staff exposure to COVID-19, non-sponsored or investigator-initiated projects should discontinue all face-to-face interaction (including but not limited to enrollment) during this time, as soon as this can safely be accomplished. Please see FAQ #3.

5) If my study is using an external IRB, what do I need to report to the Hennepin Healthcare IRB office?

- If your study is relying on an external IRB (e.g., Advarra, Vanderbilt University, etc.), you will follow the reporting requirements of that external IRB.
- You will need to work with the external IRB (either directly or via the lead study team or coordinating center) to submit any study protocol modifications such as changing study and/or consenting procedures.

6) How does the HHRI stoppage of face-to-face interactions impact studies relying on an external IRB (ceded studies)?

- HHRI's announcement requiring stoppage of activities that involve face-to-face participant interaction (including enrollment) DOES apply to studies relying on an external IRB if Hennepin Healthcare study activities involve face-to-face participant interaction.
- You will need to work with the external IRB (either directly or via the lead study team or coordinating center) to submit any modifications to the study protocol activities for your site. You will also want to verify the reporting policy for the external IRB for what must be reported (e.g., halting enrollment, changing study procedure to eliminate apparent immediate hazard, etc.).

- This stoppage requirement does not apply where interaction is required to ensure participant safety, or if there is a need to eliminate apparent immediate hazard related to their participation. Please see FAQ #3.

7) Are there suggestions for alternatives for in-person visits or monitoring of patient safety?

- Some clinical studies require in-person study visits (e.g., to conduct safety monitoring of the participants). Researchers should plan for alternatives to in-person visits or monitoring of patient safety. These might include (but not limited to):
    - Phone calls, including use of telemedicine options
    - Use of digital technology to record symptoms (e.g., cell phone photo of a healing surgical wound)
    - Visits from appropriately screened and trained study staff, visiting nurses, home health aides, etc., to conduct study procedures
    - Provision of study medications through an appropriate home delivery mechanism. You should first consult with the entity providing the medication (e.g., HHS Department of Pharmacy) to ensure compliance
- Modifications to visits or safety monitoring procedures should be approved in advance by the IRB, except when necessary to eliminate apparent immediate hazard to a participant and there is not sufficient time to obtain IRB approval. Follow the IRB Prompt Reporting Guidelines to determine how to report to the IRB.

8) How do I make changes to study procedures?

- For changes related to COVID-19, you may submit **319 FORM - Temporary Study Modification in Response to COVID-19**.
- Please use "COVID-19 RELATED SUBMISSION" in the email subject line.
- Modification requests must be approved by the IRB before you change study procedures (including consenting processes) for new or existing participants.

9) What is the procedure for temporary halt to study enrollment?

- If you are halting study enrollment to comply with the institution-wide policy (please see FAQ #3 and #4) being implemented in response to the declaration of a State of Emergency by the governor and the guidance being provided by the Minnesota Department of Health in response to the COVID-19 crisis, you do not need to report the temporary halt to the Hennepin Healthcare IRB; however, please document all actions in your study records.
- For ceded studies, please contact the External IRB to ensure compliance with their reporting requirements.
- IMPORTANT: You DO need to report to the IRB if a request to temporarily halt study enrollment is from an external funding agency or the study's Data and Safety Monitoring group.

10) Do protocol deviations as a result of the institution's response to COVID-19 need to be reported?

Yes, if investigators deviate from their approved protocol to eliminate apparent immediate hazard, please keep track of these deviations and report them to the IRB in accordance with the IRB's Prompt Reporting Guidelines.

11) A continuing review report is due soon. Does it still need to be submitted and should information regarding changes to research be included?

Yes, all continuing review reports must be submitted on-time. You should continue to submit any protocol deviations in accordance with the IRB's Prompt Reporting Guidelines. In addition, you may submit **319 FORM - Temporary Study Modification in Response to COVID-19** to request changes to study procedures, if applicable.

12) Has the process for single patient emergency use been changed?

No, the procedure for single patient emergency use of an experimental drug or device remains unchanged. Reporting forms are on the HHRI IRB website.

13) What is the contact information for the IRB?

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