Research Integrity – Human Research Protection Program (HRPP)
Interim MHC Policy on Human Subject Research During COVID-19 Pandemic

Effective Date: April 23, 2020

Due to the evolving COVID-19 outbreak, the Research Integrity Department and the McLaren Health Care Institutional Review Board (MHC IRB) are providing guidance related to human subject-related research visits. Effective immediately, this temporary policy is being implemented to protect research participants, researchers, and the larger McLaren Health Care community from risk of infection from COVID-19, as well as to ensure ongoing access to research which may provide essential support to participants.

Scope of Interim Policy

- The policy covers all McLaren Health Care Investigators and extends over all exempt and non-exempt human subject research under the auspices of McLaren Health Care.

- This policy does not apply to IRB-approved study activities that do not involve direct participant/subject contact (e.g. chart reviews, online surveys, remote interviews).

- This policy is intended to remain in effect only for the duration of the Public Health Emergency (PHE) related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act, State of Michigan Governor's Executive Order No. 2020-21, No. 2020-42 and CDC guidelines.

- If your study is regulated by a non-MHC IRB you should consult directly with that IRB for reporting, modifications and any additional requirements as they relate to COVID 19. In addition, you are still responsible for any McLaren Health Care institutional requirements.

- Studies that are not directly related to COVID-19 research may halt enrollment.

Procedure of Interim Policy

1. **Investigators can choose to either - Place a 'Study' Hold or Continue Research with Modifications**

    - **Place a 'Study' Hold:** Principal Investigators can voluntarily hold all clinical research activities. They must do so if they it can be done safely without risk to participants.
    - Please notify currently enrolled subjects promptly. The means by which you notify them is up to you (letter, email, phone call etc.) but be sure to document the method, the subjects who were notified, and when.

- The IRB office should be notified of the hold placed on your research via a modification form.
- The Sponsor and FDA (If PI is IND/IDE holder) should be notified if required.

➢ **Continue Research with Modifications:** Principal Investigator may implement any of the following procedures to:

- **Stop Study Enrollment:** Investigators who stop study enrollment to protect the safety of research subjects from COVID-19 investigators **do not need to notify the IRB.**

- **Conduct Research Visits Without Person-to-Person Contact:** Convert in-person visit to an electronic platform (e.g., telehealth).
  - In drafting the alternative procedures, keep in mind the parameters of your current approval. For example, if you were approved to collect data that were not connected in any way to the subject's identity, you will want to ensure the same protection electronically.

  - Modification for the change instituted must be submitted to the MHC IRB. **You do not have to wait for IRB approval to institute this safety measures**.

  - However, upon review of the modification the IRB may request revisions if safety of the subject is deemed to be in jeopardy.

2. **Implementing a Different Subject Safety Process**:
   - If the Principal Investigator decides to implement a different process [other than one of the options listed above] to ensure subject safety, a Modification to the IRB must be submitted clearly identifying the process chosen.

   - The IRB will review the information and assess the risk associated with the study against the potential benefit to the subjects and assess if the study may continue as requested.

3. Guidance on Deviation from Protocols and Current HRPP/IRB Policy

This Interim MHC Policy may require you to deviate from your currently IRB-approved protocol in order to ensure subject safety. Please note that modifications may be implemented per the Interim MHC Policy ***without first obtaining IRB review and approval*** when the modification is necessary to eliminate apparent immediate hazards to the subject [45 CFR 46.108 (a)(3)(iii) and 21 CFR 56.108(a)(4)].

- This policy allows for unavoidable, protocol-specific deviations as *necessitated by the impact of the current COVID-19 public health emergency only*.

- The only deviations allowed are those that are necessary to eliminate immediate hazard to a subject, such as cancelling a research visit due to COVID-19. For all other protocol modifications even if temporary, please submit a modification form.

- Current HRPP/ IRB policy permitted deviations must be submitted during continuing review. However, COVID-19 related protocol deviations[2] *should not be saved* for the next continuing review but instead submitted as they occur. It is acceptable to submit an aggregate of COVID-19 deviations on one modification form.

[2]Note since deviations are normally reported only annually on continuing review form, during this PHE please utilize the modification form to report deviations.

4. Guidance Regarding Non-COVID-19 Changes to Approved Research

- All modifications not related to the Interim MHC Policy on Human Subject Research During COVID-19 Pandemic need to be submitted to the IRB and approved prior to implementation, per current policy.

- The incorporation of a COVID-19 screening procedure and follow up does NOT require IRB approval.

- Please submit COVID-19 related modification(s) separate from all other types of modifications if required.

5. Principal Investigator Responsibility

- It is the responsibility of the PI to make appropriate notifications to sponsors and/or federal agencies.

6. Study Sponsors

- If applicable, sites should discuss any remote monitoring plans with sponsor.

- Principal Investigators are responsible for communicating with and establishing plan for continued supply of investigational product, adverse event assessment, etc. when in-person visits are not feasible. Such plans should be communicated to the IRB via completion of a modification form.

Signature on file — April 23, 2020

Dr. Michael McKenna — Date
Executive Vice President/Chief Medical Officer
Institutional Official