McLaren HEALTH CARE

Overview for Submitting a New Application to the MHC IRB

Pre-Submission to Submission	Pre-Review	Designated Review	Full-Board Review
☐ **Determine if your project is human subject research Not** sure or if you think your project is not human subject research you must complete Request for Determination of Human Subject Research Form via iRIS. If you are certain your project is human subject research, you may proceed with submitting a formal application to the IRB. (your department/program policies may require other steps) ☐ **Complete required training**. All research personnel listed on the study must complete CITI HumanSubject Research training. In addition, all investigators must complete CITI Conflict of Interest training. (do not submit certificate with application) ☐ **Who can be a McLaren PI?** * Employees, physicians with MHC privileges. Unaffiliated individuals must work under MHC PI and sign an *Unaffiliated Individual Investigator Agreement (see * below)* ☐ Become **familiar with research policies, regulations, and templates** found at https://www.mclaren.org/main/research-integrity ☐ **IRB applications are submitted via an electronic platform called iRIS**. See iRIS application access instructions and training at https://www.mclaren.org/main/iris-research ☐ **Obtain department, committee, or other approvals**. All prospective interventional studies must get Protocol Review Committee (PRC) approval. Some studies require Service Agreements, DUA or CIA. For both PRC review and Administrative Review contact McLaren Center for Research Innovation (MCRI) at mcri@mclaren.org. Submit approval letters and agreements with application. ☐ **Gather and complete required IRB submission material**.** Email hrpp@mclaren.org with questions. ☐ **Documents –** Attach and upload all materials in iRIS. PIs must sign off on application.	☐ **The IRB Analyst will assess the completeness of your application.** Submissions that don't meet minimal submission standards will be returned. ☐ **If necessary, you will be contacted to provide additional information in your IRB submission application to assist with IRB review.** If this is your first time submitting, you should expect there will be some requested revisions/clarifications. Such a request is often prompted by missing materials, incorrect protocol template or application, missing documents, inconsistencies, missing ancillary review and approval letters etc. *This may impact review timeline.* ☐ **Determine if other departments that will assist with your research study**, i.e., medical records, lab, radiology, etc. IRB will request you have manager sign Project Impact Statement Form. *This may impact review timeline.* ☐ **IRB Analyst will assign completed protocol application to IRB Reviewer(s) for DESIGNATED REVIEW or FULL board REVIEW**	☐ **One or more IRB Members reviews submission applications and documents.** The Reviewer may request additional information from the investigator related to materials submitted, revisions, need for additional information etc. *This may impact review timeline.* ☐ On rare occasions submission are sent to a **consultant for additional review**. *This may impact review timeline.* ☐ IRB Analyst will monitor IRB member(s) requests, responses, and outcome determinations. ☐ **IRB Analyst will publish approval or determination** with investigator via iRIS.	☐ **One or more IRB Members reviews submission applications and documents**. The Reviewer may request additional information from the investigator related to materials submitted, revisions, need for additional information, etc. *This may impact review timeline.* ☐ **IRB Analyst will monitor IRB member(s) request, responses**. ☐ **IRB Analyst will assign completed protocol application to a full board meeting 1 week prior to scheduled meeting date.** Full board IRB meetings are held the first and third Friday of each month. Studies are placed on the agenda one week before the scheduled meeting. *Investigators are encouraged to be available for questions by board.* ☐ **Investigator notified of full board review outcome via iRIS.** *Contingent approvals may delay study start date timelines.*

Who can be a Principal Investigator at McLaren Health Care? *

There may be persons without direct or formal association to MHC who request authorization to use MHC facilities, data, or patient populations in order to conduct a research study. Individuals may, of course, collaborate with affiliated investigators to conduct investigations of mutual interest. McLaren Health Care is supportive of human subject research conducted by investigators who are unaffiliated with MHC. However, at the same time the MHC HRPP must be mindful of risk and liability concerns and the impact on MHC resources. Only the following individuals are *allowed to be a principal investigator at MHC*:

- Employees of MHC
- Physicians with MHC hospital privileges (Medical residents and fellows should consult GME office)
- Attending physicians teaching medical residents:
    - who do not have privileges at an MHC institution,
    - whose private practice is not owned by MHC, and
    - whose private practice is an MHC GME designated teaching site
- MHC Employee who is a student seeking a degree at a university requiring a research project and the MHC employee-student plans to conduct the research at MHC (and if that university has an IRB, the MHC IRB will be the IRB of record)
- Agents of MHC which includes all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility (per HRPP policy) Medical students are not allowed to be principal investigators

Unaffiliated Researchers

MHC HRPP will allow unaffiliated individuals to participate in research studies only under the supervision of an MHC PI. The unaffiliated individual must sign an *Unaffiliated Individual Investigator Agreement. The MHC PI must agree to assume oversight and responsibility according MHC policy MHC_RP0125 Investigator Responsibilities.* Lack of oversight may be considered non-compliance. We reserve the right to approve or deny requests for approval on a case-by-case basis.

Common study documents or material:**

- **Study protocol**
- **Recruitment materials**
- **Informed Consent Documents:**
    - Write consent form using IRB template, including any parental consent forms
    - Assent form for children under 17 and under, refer to consent policy MHC_RP0115 andMHC_RP0116 for when assent is required
    - Preamble, information sheet and/or verbal script if documentation of informed consent waived
    - Waiver of consent or documentation of consent (form within iRIS application)

  Reminder: For each consent form, use the most current version template. Must be written at 10th grade reading level. Define all medical and technical terms. Proofread and spell check.

- **HIPAA Authorization:**
    - Stand- alone HIPPA document if not combined within the main ICF
    - Waiver or Alteration of HIPAA Authorization (form within iRIS application)

- **Other Study Documents:**
  Note: Not all the following documents may apply to your study

- Final research study protocol
- Project Impact Statement Form. Obtain manager signature for every department impacted.
- Tables, charts, diagrams referenced in the IRB Application – paste these items into a Word document(s) and reference the attachment in the relevant application section(s)
- Investigator's drug brochure (IB)
- Verification of IND number (one of these): Sponsor protocol with IND number or communication from the FDA
- Drug information pamphlet or package insert
- Device manual Information for Use (IFU). Required for all device studies.
- Verification of IDE number (one of these): Sponsor protocol with IDE or communication from the FDA
- Recruitment materials, including copies, flyers, posters, print media, audio/video, online content, scripts, ads, notices, etc.
- Telephone scripts
- Pamphlets and study handouts, i.e., appointment/reminder cards, calendars, etc.
- Questionnaires and survey instruments (excluding standard questionnaires, such as the PHQ-9)
- Focus group or interview guides
- Data collection sheets

Tips for a "stellar" IRB submission:

- ✓ Applications should be complete and review ready. Incomplete applications may be sent back to the investigator to complete.
- ✓ Check the version date of forms and templates to ensure that you are using the current version. Use of old forms and templates can delay processing and exclude your project compliant with changing regulations and other considerations.
- ✓ Use easy to interpret document files names (include version dates in your file name).
- ✓ Proofread the submission to ensure there are not inconsistencies between sections or between the application and attachments.
- ✓ Do a final check for completeness to reduce turnaround for your review.

Questions and help: **IRB office number: 248-484-4950 | IRB email box: hrpp@mclaren.org**