McLaren HEALTH CARE

Initial Submission Checklist

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

Tips for a "stellar" IRB submission:

- Use this checklist to ensure a complete submission package and avoid delays from submission to IRB approval. 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).
- Proof-read the submission to ensure there aren't inconsistencies between sections or between the application and attachments.
- Do a final check for completeness to reduce turnaround for your review.

Utilize MHC research website for eProtocol access instructions, training requirements, policies, forms and templates found at https://www.mclaren.org/main/research

Do not submit this checklist to the IRB. Not everything in this checklist will apply to your study. Contact the MHC IRB if you have questions or concerns before submitting.

BEFORE SUBMITTING APPLICATION TO IRB

☐ **Determine if your project is human subject research.** Submit Request for Determination of Human Subject Research Form. Medical residents are required to submit this form.

☐ **Determine who will be the Principal Investigator, Co and Sub-Investigators.** Every research study requires a Principal Investigator (PI). This person takes full responsibility for the conduct of the study and is qualified by training and/or experience to conduct the study. Per Graduate Medical Education Department medical residents are not allowed to PI. Individuals who are affiliated with MHC can serve as PIs. Unaffiliated individuals can only serve as sub or co-investigators or team member and must receive approval by the IRB office.

☐ **Identify the study team including their role and responsibilities**. All research team members must be listed on the IRB application. Research team member include those "Individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals, who recruit participants, obtain consent, or who collect study data."

☐ **Complete required training**. All research personnel listed on the study must complete CITI Human Subject Research training. In addition, all investigators must complete CITI Conflict of Interest training.

☐ **Obtain department, committee or other approvals**.

- Medical Residents require review of their protocol by Ph.D. advisors overseeing their project PRIOR to SUBMISSION to the IRB.
- All prospective interventional studies must get Protocol Review Committee (PRC) approval.
- All prospective observational studies must go through an Administrative Review.
  For both PRC review and Administrative Review contact McLaren Center for Research Innovation (MCRI) at mcri@mclaren.org
- Some studies require Service Agreements

☐ **Determine if other departments that will assist with your research study, i.e. medical records, lab, radiology, etc**. Have department manager sign Project Impact Statement Form.

☐ **Become familiar with research policies and regulations**. Primary investigator must be familiar with applicable research policies and regulations.

☐ **Obtain eProtocol ID and password**. To gain access to electronic IRB system to submit application. Individual or group training available by calling IRB office.

DOCUMENTS TO SUBMIT WITH APPLICATION

Please upload all applicable items in the within eProtocol. To find templates and forms go to: https://www.mclaren.org/main/irb-templates and https://www.mclaren.org/main/irb-forms

Individual/Committee review approval:

☐ Protocol Review Committee approval letter. Required for all prospective interventional studies. Approval letter must be submitted at the time of initial submission or application will be returned. Contingent approval letters will not be accepted.

☐ Administrative Review approval letter. Required for all prospective observational studies. Approval letter must be submitted at the time of initial submission or application will be returned. Contingent approval letters will not be accepted.

☐ Scientific Validity and Scholarly Review Form. Required for all other studies that don't undergo Protocol Review committee or administrative review. Make sure appropriate signatures are obtained per form instructions.

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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 and MHC_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 eProtocol 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. Proof read and spell check.

HIPAA Authorization:

☐ Stand- alone HIPPA document if not combined within the main ICF

☐ Waiver or Alteration of HIPAA Authorization (form within eProtocol 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
- 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
- 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

☐ Case report forms (CRF)

☐ IRB approval letters and/or letters of support from collaborating or cooperating sites

☐ Training/Certification

☐ Conflict of Interest – Management Plan. Any researcher COI decision memos/management plans must be uploaded

☐ Unaffiliated Independent Agreement. The IRB will inform you if this is needed

☐ Collaborating Institutional Agreement. The IRB will inform you if this is needed

☐ CV Required for individuals not affiliated with McLaren Health Care. CV must be signed

☐ Other. Examples Letters of Support, Data Transfer Agreements, Certificates of Confidentiality, Translation Certification, Non-English versions of material for participants, etc.

What to expect after submitting your IRB submission through eProtocol

- The IRB Staff will assess the completeness of your application.
- 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.
- **Timelines:** We process expedited review and exempt studies on a rolling basis. Studies requiring full board review are placed on the full board agenda once the application is complete. Full board IRB meetings are held the first and third Friday of month. Studies are placed on the agenda one week before the scheduled meeting.