OCRICC Guidance Document for Investigators & Research Teams
INFORMED CONSENT FORM

INVESTIGATORS & RESEARCH TEAMS: PLEASE READ CAREFULLY

The Office of Clinical Research and Innovative Care Compliance (OCRICC) is responsible for providing administrative approval to conduct research in all of the Froedtert ThedaCare Affiliates. The purpose of this document is to provide guidance for research teams on how to prepare and submit the ICF for OCRICC review.

Turn-around time for administrative approval may be impacted if the ICF guidelines are not followed. Should you have any questions or concerns involving this ICF guidance please contact the OCRICC clinical consultant assigned to your study.

1. **General:**
   - If any modifications or revisions are made to the FT/MCW IRB ICF template, OCRICC will need to review and approve the modifications.
   - Some studies defer to a Central IRB (CIRB). OCRICC will review the ICF language and any modifications or revisions made to the existing FT/MCW IRB template.
   - It is the study team's responsibility to have a thorough verbal informed consent discussion that includes a detailed discussion about out-of-pocket costs to the participant. In order to make sure that participants understand their out-of-pocket expenses and what may or may not be covered by their insurance, study teams should encourage patients to check with their insurer for details. Uninsured participants should be informed that they are responsible for all costs not provided free by the study.

2. **Costs to Subjects (Section D1 of ICF)**
   - Do not modify the template language in D1 of the ICF, except for identifying items or services that the study/sponsor will pay for or that the participant receives for free. This should include any costs that the participant is liable for.
     - It is the responsibility of the research staff to update the ICF with any services identified by OCRICC as non-billable during the MCA review.
     - It is the responsibility of the study staff to make sure that all services identified in the protocol, schedule of events, and the CTA provided for free are listed.
   - Words like extra, non-essential, or optional cannot be used when referring to billable items or services.
   - If conflicts or non-compliant language is used, it will cause delays while clarification is obtained from the study team.

   Acceptable Section D1 Examples:

   <u>WHEN ALL ACTIVITIES DESCRIBED ARE RESEARCH-ONLY AND BEING PAID BY THE STUDY</u>
   There are no costs to you for any of the activities in this study. All costs will be paid by the study. If you have questions regarding study costs, please contact Dr. XXXXX

   <u>WHEN SOME ACTIVITIES DESCRIBED ARE RESEARCH AND SOME ARE BILLABLE AS ROUTINE CARE COSTS</u>
   Some of / Most of the medical care that you will receive in this study is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care will be billed to you or your

insurance carrier. You will be responsible for co-pays and deductibles for any services billed to your insurance. Activities / costs that are part of the study will not be billed to you or your insurance company. These are:

- *Study drug*
- *EKGs*
- *MRI scan at 6 months*
- *Clinic visits at 36, 42, and 48 weeks*

Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you join this study. If you have questions regarding study costs, please contact Dr. XXXXXX

WHEN ALL ACTIVITIES DESCRIBED ARE ROUTINE CARE AND WILL BE BILLED TO INSURANCE

All of the medical care that you will receive in this study is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care will be billed to you or your insurance carrier. You will be responsible for co-pays and deductibles for any services billed to your insurance. Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you join this study. If you have questions regarding costs, please contact Dr. XXXXXX

3. Subject Injury Language (Section D5 of ICF)

- If the sponsor has modified the template language or IRB review is deferred to a central IRB and you are using their ICF, ensure the following or it will require clarification/modifications and result in delays:
  - It must be clear in the ICF that the study/sponsor is liable or the patient/patient's insurance is liable. Language saying that the study/sponsor will cover costs only if the participant's insurance does not pay **is not acceptable**.
  - If the study/sponsor is going to reimburse the participant for any costs associated with subject injury, that will need to be coordinated with MCW and the participant. FT will bill for any services provided by an FT affiliate according to the MCA.

4. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION (Section E of ICF)

- MCW/FT IRB PHI template language cannot be modified and must be used even if a study is using a central IRB template.
- All the types of information you are using or collecting for the research project should be listed.
- If you will need a report with specific data elements, make sure the types of information you list include all the data elements required.
- Statements in the ICF cannot restrict access to medical records, even if the study is blinded to the participant.