DETROIT MEDICAL CENTER

Clinical & Translational Research Office

DMC RESEARCH REVIEW PROCESS

INSTRUCTIONS FOR RESEARCH APPLICATION

Concurrent submission to the DMC Clinical Research Office (CRO) and the associated IRB for parallel review is highly recommended.

1) Click on the DMC Application for Research Authorization links:
    - Go to www.dmc.org
    - Under "FOR HEALTH PROFESSIONALS" select "CLINICAL & TRANSLATION RESEARCH OFFICE"
    - Scroll to the bottom of the page and select "Application/Logon"
    - Click on blue box (Click here to log in to the application)
        - If you are a new user, select the blue box that states "Create Account".
        - If you are a returning user, select the blue box that states "Username" and type in user name, and then type in password in "Password" field. Select blue box "Log In"
        - If you have forgotten your password, please select "Lost Password?" link and follow directions

2) Required Documents:

- Initiate the submission only if **all the study documents** are ready for submission

Please upload the following documents for the research study submission:

RETROSPECTIVE CHART REVIEW

- Protocol
- IRB submission form(s) *(signed copy)*
- IRB submission appendices *(if applicable)*
- HIPAA form *(signed copy, if applicable)*
- Consent Form (*if applicable)*
- Data Collection Form(s)
- Clinical Trial Agreement (CTA) *(if applicable)*
- Award Letter *(if funded, if applicable)*
- Budget *(if applicable)*
- IRB approval letter *(when available)*

- IRB approval document(s) (*when available*)

PLEASE NOTE: Additional documents may be requested.

REGISTRY/SURVEY/QUESTIONNAIRE STUDY

- Protocol
- IRB submission form(s) *(signed copy)*
- IRB submission appendices *(if applicable)*
- HIPAA form *(signed copy, if applicable)*
- Consent form (*if applicable)*
- Data Collection Form(s)
- All surveys/questionnaires/instruments
- Clinical Trial Agreement (CTA) *(if applicable)*
- Award Letter *(if funded, if applicable)*
- Budget *(if applicable)*
- IRB approval letter *(when available)*
- IRB approval document(s) (*when available*)

PLEASE NOTE: Additional documents may be requested.

CLINICAL TRIAL/INTERVENTION STUDY

- Protocol
- Investigator Brochure
- IRB submission form(s) *(signed copy)*
- IRB submission appendices *(if applicable)*
- HIPAA form *(signed copy, if applicable)*
- Consent form(s)
- Assent form(s)
- Data Collection Form(s)
- All surveys/questionnaires/instruments
- Clinical Trial Agreement (CTA)
- Award Letter *(if funded, if applicable)*
- Budget
- 1572 (*PI signed*)
- IND/IDE letter
- Financial Disclosure Form (FDF) for all investigators
- Nursing Research Council (NRC) approval letter *(if applicable)*
- DMC Clinical Trials Policy Coverage Analysis Checklist for Clinical Research Studies
- Data Sharing Agreements *(if applicable)*
- Sub-Award documentation *(if applicable)*
- IRB approval letter *(when available)*
- IRB approval document(s) (*when available*)

PLEASE NOTE: Additional documents may be requested.

3) DMC Billable Events:

- If the research study includes DMC Billable Events (i.e. DMC services including DMC staff), the PI must submit the DMC Clinical Trials Policy Coverage Analysis Checklist for Clinical Research Studies. This research study will be reviewed and approved by Tenet NRBO (National Research Budget Office)
- DMC CRO staff and/or Tenet NRBO will complete a Cost Analysis and a Hospital Time Analysis to assure compliance with DMC/Tenet policy/procedure and federal regulations
- DMC CRO staff will discuss the specific billing procedures and monitoring for the study with the PI and his/her staff

4) Facility Research Committee (FRC):

- Clinical intervention studies, prospective registries, or any research which requires a consent form/information sheet will be reviewed by the hospital FRC in which the research will be conducted
- *Tenet Policy COMP RCC 4.47 - The FRC shall review each proposed study in order to determine whether individual research studies are appropriate for the Tenet Facility. The FRC evaluates each study's impact on the organization, including staffing, patient safety, supplies and reimbursement*
- *DMC CRO determines which studies are applicable for DMC FRC review and approval*
- *PIs and his/her study teams will be notified of applicable deadlines for FRC research document(s) submission for DMC FRC review*
- *DMC CRO presents all research studies to the DMC FRC*
- Retrospective Chart Reviews are exempt from FRC review and will be reviewed/approved by the DMC staff

5) DMC Research Review Authorization Letter:

- DMC Research Review Authorization Letters are emailed to the PIs and his/her study coordinator
- Following DMC CRO approval, the IRB of record should be emailed the DMC Research Review Authorization Letter
    - The above is a responsibility of the PI and his/her study team
- The Research Review Authorization Letter will prompt the IRB of record to finalize their approval, when appropriate.
- *No research may begin at the DMC until the study is fully executed. PIs will receive this confirmation via email*

6) eCATS - Tenet contract management system:

- Research study documents and facility agreements will be reviewed via eCATS
- Once the study is approved via the eCATS process, the Investigator will be notified with a request to sign the facility agreements.
- Following execution of the agreements, the research study will be activated (i.e. fully executed – ready to begin at the DMC)

IMPORTANT: Research cannot commence until the agreements are fully executed.

7) DMC Research Review Fees*

- **Please review the institutional master research agreement(s) for specific charges**
- **Please note: DMC administrative review fees will be waived for research studies that list resident, fellows, medical students in most cases.**

Please note – Fees are subject to periodic review and may change.

Invoices are automatically generated and sent within 4 weeks of the execution study agreement between the Investigator and the DMC.

Please make check payable to "Detroit Medical Center" and please do include the invoice(s).

Please mail check/payment to:
Detroit Medical Center Clinical Research Office
2nd Floor Orchestra Place – Accounts Receivable
3663 Woodward Ave
Detroit, MI 48201
Attention: Research Review

DMC Clinical Research Office Contact Information:
Leah Maddern, BS, BA
Senior Research Administrator, DMC Clinical Research Office
Phone: 313-578-2386
Fax: 313-578-2392
Email: lmaddern2@dmc.org

Mary Montie, PhD
Director, DMC Clinical Research Office
Phone: 313-578-2381
Fax: 313-578-2392
Email: mmontie@dmc.org