

RESEARCH COUNCIL INFORMATION & SUBMISSION INFORMATION

Research Council Overview

The purpose of the Research Council is to provide administrative oversight of all human subjects research studies at TMH. The Council represents TMH and is responsible for determining the impact a research study will have on the organization and whether a study may be conducted at TMH.

Research Council meets every month on the 2nd Wednesday of the month. Submissions of proposed new studies must be received no later than end of business the Friday prior to the Research Council meeting.

How to Submit to Research Council

- Create the study in Cayuse.
 - o You do not have to complete the entire submission, nor do you have to press the “submit” button. We can access the study without it being complete.
 - o The following must be attached:
 - Protocol
 - COI Disclosure Forms
 - ICF in its current state (doesn’t have to be final)
 - Pharmacy, Lab, and/or Radiology approval if applicable
- Email TMH IRB Office (IRBOffice@tmh.org) to indicate you would like your study added to the agenda. You must include the completed Research Council Worksheet.

TMH RESEARCH COUNCIL
STUDY OVERVIEW WORKSHEET

IRB NUMBER:

PI:

REQUEST TO CEDE: Yes/No. If yes, indicate IRB of Record.

PROTOCOL SUMMARY: BRIEFLY describe the proposed research. Alternatively, copy the summary from the Protocol.

FEASIBILITY ASSESSMENT

IT:

Briefly describe the IT requirements including if an electronic data capture system will be used, and if elements of PHI will be sent out of TMH. Alternatively, copy this information from the Protocol.

PHARMACY:

Indicate if Pharmacy approval is needed. If so, please provide documentation of approval.

LAB:

Indicate if Lab approval is needed. If so, please provide documentation of approval.

RADIATION SAFETY OFFICER:

Indicate if Radiation Safety Officer approval is needed (i.e., radiation procedures are being performed for research purposes only). If so, please provide documentation of approval.

CONFLICTS OF INTEREST:

Indicate if ANY members of the listed study team have a positive conflict of interest. Additionally, provide all completed COI Disclosure forms.

NUMBER OF ACTIVE RESEARCH STUDIES:

Indicate the number of active/open research studies and the enrollment status (i.e., enrolling, closed to enrollment – treatment ongoing, closed to enrollment – long-term follow-up, etc.) for the listed PI.