Required Items and Training for Study Team Members

A Tallahassee Memorial HealthCare IRB Guidance Document

Purpose

This document provides guidance on the required items and training needed to participate in research at Tallahassee Memorial HealthCare (TMH). If you have questions regarding the training requirements and additional items needed, please contact the IRB Office at IRBOffice@tmh.org.

Cayuse Account

All members of the study team will require a Cayuse account. To request an account for a new user, please send the required information below via email to IRBOffice@tmh.org.

You must include the following information in your request:

1. Name: (first, last)
2. Licensure/Credentials: (MD, RN, PhD, etc.)
3. E0 or DR number: (if affiliated with TMH)
4. Institution: TMH, private practice, or University (if part of a TMH residency program, please select TMH)
5. Division: (within TMH or your Institution)
6. Title: Please indicate your job title (Research Coordinator, Director, MD, RN, etc.)
7. TMH Email: (if applicable)
8. Preferred Email: (do NOT use your personal email)
9. Office Phone Number: (do NOT use your personal phone number)
10. Office or Institution Mailing Address: (do NOT use your personal mailing address)

PLEASE NOTE: Your Cayuse username **will be** your TMH email address if you have one. However, if the email address you primarily use is NOT your TMH email address, you may provide your preferred email address (your username will still be your TMH email address) which will be utilized by Cayuse for ALL email notifications, announcements, requests, etc.

Conflict of Interest

Training: All study team members are required to complete the COI training prior to initial submission and every 3 years thereafter.

COI training module can be found: https://webapp.tmh.org/researchtraining/

Disclosure: All study team members will be required to complete a COI Disclosure at the following time points during the lifetime of each study:

- Initial Submission: to ensure there are no outstanding conflicts at the time of Initial Review
- Continuing Review: to ensure there are no new conflicts that may have developed over the previous approval period
- Personnel Addition: when a new study team member is added they will be required to submit a COI Disclosure form

If a study team member becomes aware of a new conflict during an ongoing study, they must submit a Modification to the IRB with a COI Disclosure form explaining the potential conflict.

COI Disclosure forms are reviewed by the TMH Conflict of Interest Committee and may result in language needing to be added to the Informed Consent Form, a management plan being implemented, or removal from the study team if the conflict cannot be managed.

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CITI Training

All study team members (Principal Investigators, Co-Investigators, Research Coordinators, etc.) must complete TMH required research training **prior** to IRB Review.

Cayuse integrates with CITI training to allow the IRB to review CITI training completion for all study team members. Please ensure the email address affiliated with your CITI training account is the email address you provided as your "preferred" email address (i.e., the email address where you receive Cayuse emails) to the IRB when signing up for your Cayuse account. If these email addresses do NOT match, please revise the CITI training email address to align with your Cayuse account.

If you have completed CITI training via another organization, please "affiliate" with TMH for IRB staff to compare the completed modules with the required modules and ensure TMH requirements have been met.

To complete the training, or affiliate with TMH follow the below instructions:

Access the CITI Program: https://www.citiprogram.org/index.cfm?pageID=14

1. Select: Register
2. Select: Tallahassee Memorial HealthCare
3. Select: Agree to Terms of Service
4. Select: Affirm affiliation with TMH
5. Enter personal information
6. Create Username, Password, Security Answer
7. Select USA, answer contact question
8. Indicate if you want CE credits (if selecting yes, provide contact info)
9. Answer questions to select curriculum: See the table below

CITI Module Questions	PI	Co-Investigator	Research Coordinator/Nurse
Q1: Human Subjects Research (HSR)	Biomedical Researchers	Biomedical Researchers	Research Coordinators
Questions 2, 3, 4	Not at this time		
Q5: Good Clinical Practice	**If research is FDA regulated (drug or device):** Good Clinical Practice for Clinical Trials involving Drugs & Devices **All other research:** GCP – Social & Behavioral Research Best Practices for Clinical Research		