CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Getting Started in Clinical & Translational Research at UMMS

I.   Institution-Specific Guidance and Requirements

Institutional Review Board (IRB) Guidance

What is considered human research? What requires IRB review? Who can serve as Principal Investigator? Answers to these and other common questions, as well as important Investigator documents, can be found on IRB home page at: http://www.umassmed.edu/ccts/irb/

- ✓ **Investigator Manual (HRP-910)**: This resource answers common questions and guides investigators through requirements specific to the conduct of human research at UMMS.
- ✓ **Investigator Guidance**: These documents provide regulatory guidance for investigators conducting Human Research.
- ✓ There may be additional obligations depending on your source of funding. *(See section III below.)*

IRB Required Training

UMMS requires that any individual involved in the design, conduct or reporting of research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training at https://www.citiprogram.org/. UMMS also requires CITI's Good Clinical Practice (GCP) online training for all investigators and staff involved in clinical trials, as defined by NIH.

- ✓ If you already have an existing account with CITI from a prior institution, add the **University of Massachusetts Worcester** as an additional affiliation*.* Do not delete your existing affiliations.
- ✓ *IMPORTANT:* To fulfill the UMMS human research training requirements, select **Biomedical Research Investigators and Key Personnel** (question 1 during step 7 of Learner Registration).
- ✓ If you must also complete **Good Clinical Practice** (GCP) training, select the **Required** course for question 4.
- ✓ UMMS requires that re-training take place every **three years**. Please refer to the Investigator Manual (HRP-910) for more information. (*See URL above under IRB Guidance.*)

HIPAA Privacy Rule

The HIPAA Privacy and Security Rules apply if your research study uses Protected Health Information (PHI) belonging to UMass Memorial Medical Center (UMMMC) or another HIPAA covered entity. For more information and to access HIPAA forms, visit http://www.umassmed.edu/ccts/human-research/privacy-and-security/.

Conflicts of Interest

Financial Conflicts of Interest (FCOI)

- ✓ The UMMS Policy for Promoting Objectivity in Biomedical Research was implemented to comply with federal FCOI reporting and training requirements. Please visit the Office of Research Financial Conflict of Interest site at http://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/ to learn more.
- ✓ Training on FCOI is mandated for all investigators working on sponsored research projects every 4 years. UMMS FCOI training is available through the Collaborative Institutional Training Initiative (CITI) accessible at https://www.citiprogram.org/. Visit the Office of Research FCOI training page for information on how to register.
- ✓ Project specific forms and New Investigator FCOI Policy and Agreement packet available on the FCOI Forms page.

Other Conflicts of Interest

- ✓ The UMMS Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures, important COI forms and link to the COI system for disclosures are available on the Research Funding Policies and Procedures page at https://umassmed.edu/research/sponsored-programs/policies-guidance--forms/policies.

II.   Protocol Development and Resources

Many resources are available to investigators conducting human research at UMMS. Join the Center for Clinical and Translational Science (CCTS) by signing up at http://www.umassmed.edu/ccts/about/membership/. You will receive notices about core services, lectures and funding opportunities. Resources include:

- ✓ **Clinical Research Center**: Access to comfortable space for subject visits, touchdown space for monitors, and a lab processing and packaging/shipping area. Regulatory support is available.
- ✓ **Conquering Diseases Programs**: Components include a Biorepository, a Clinical Research Volunteer Database, a Community Resource Center, and assistance with clinical study recruitment.

- **Research Electronic Data Capture (REDCap)**: REDCap is a secure web application for building and managing online surveys and databases.
- **Quantitative Methods Core (QMC)**: Housed in the Department of Quantitative Health Sciences, QMC is designed to help UMMS investigators with support in biostatistics, experimental design and data management.
- **Investigational Drug Service (IDS)**: Investigational pharmacists facilitate subject safety for clinical trials at UMMS. IDS responsibilities include, but are not limited to: receipt, storage, control and accountability of investigational drugs.
- **UMCCTS Informatics**: Informatics resources to support a wide variety of clinical and translational research. https://umassmed.edu/informatics.

III.   Funding and Contracts

Institutional requirements for UMMS New and First-Time Investigators
New and First-Time Investigators submitting sponsored project applications should visit:
https://umassmed.edu/research/sponsored-programs/policies-guidance--forms/new-investigator-requirements1/

Assistance with agreements is available
- **UMCCTS Office of Clinical Research (OCR)** handles: industry-sponsored Clinical Trial Agreements (CTAs); investigator-initiated; industry-sponsored clinical research.
- **UMMS Research Funding Services (RFS)** handles: federal and non-federal grants and agreements; industry-sponsored basic research.
- **UMMS Office of Technology Management (OTM)** handles: Material Transfer Agreements (MTAs)
- Contact information for the appropriate office can be found at http://www.umassmed.edu/ccts/human-research/Clinical-Research-Agreements-and-Budgets/

IV.   Research Review Process

e-IRB

All research involving human participants must be reviewed by IRB. UMMS uses an electronic Institutional Review Board (eIRB) system to manage all IRB processes. Before you can submit your study, you must request access as a new user by visiting the IRB home page and clicking *eIRB Data Request* on the left navigation panel. For questions or problems obtaining your login for eIRB, please contact the IRB at irb@umassmed.edu or call 508-856-4261.
- To log in to eIRB, go to the IRB home page and click on the gold eIRB button on the bottom left corner.

Ancillary Reviews

Some research may require review by a specific department or committee in addition to the IRB. It is the responsibility of the Principal Investigator to ensure that appropriate reviews are obtained prior to study initiation. Visit http://www.umassmed.edu/ccts/human-research/ancillary-reviews/ to learn more about these ancillary reviews.
Additional departmental reviews may include:
- UMMS Department of Emergency Medicine, UMass Memorial Acute Care Operations Committee (ACOC), UMass Memorial Cancer Research Office, Students as Study Subjects Ad Hoc Advisory Group
Additional institutional reviews may include:
- UMMS Radiation Safety Department, UMMS Institutional Biosafety Committee, UMMS Conflict of Interest

V.   Other resources
Become part of the community:
- Learn about funding sources, such as NIH and foundations. Request to be added to the Office of Research mail list by contacting Research Funding Services at 6-2119 or email a request to research.funding@umassmed.edu.
- Sign up to become a member of the CCTS (http://www.umassmed.edu/ccts/about/membership/) and get information about funding, core services and lectures relevant to clinical and translational research.
- Help other researchers find you by completing the research profile page at http://profiles.umassmed.edu/Profiles/search/
- Looking for funding sources for your research? Create a Community of Science-Pivot account to access an online database base of key word driven funding opportunities. Registration is available on the Funding Opportunity page https://umassmed.edu/research/sponsored-programs/the-award-lifecycle/finding-funding/
- Join the Clinical Research Professionals Group (CRPG) to learn about training and educational opportunities. Request to be added to the email list by emailing HRPeducation@umassmed.edu.

*Need more help? Contact CCTS@umassmed.edu for general questions or clinicalresearch@umassmed.edu for specific questions related to clinical trials.