UMass Worcester Human Research Protection Program (HRPP) Newsletter

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UMass Worcester
UMass CCTS
Human Research Protection Program
ACC 7th Floor

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Visit us on the web:
http://www.umassmed.edu/ccts/human-research/

No more delays: New Human Subject Regulations take effect January 21, 2019

Updates to federal Human Subject Research regulations, better known as the "Revised Common Rule," are scheduled to take effect on January 21, 2019. The UMMS Human Research Protection Program will be using the flexibility afforded by these changes. What does this mean for UMMS researchers?

- **FDA regulated research and research funded/supported by the Department of Justice:** Research in these categories will experience the least amount of change: new research under these categories will utilize the new consent template, but are not subject to any other changes at this time.
- **Non-FDA regulated research and research not funded/supported by the Department of Justice:** New research studies in these categories will be eligible for new exemption categories and longer approval periods, and will continue to use a new consent template (posted 12/2017).

Please note: Although not subject to continuing review requirements, exempt projects will still require prior IRB review and approval of substantive changes and will require a closure form.

For more information and resources, see:
https://www.umassmed.edu/ccts/irb/what-you-should-know-about-the-2018-regulations/
Please monitor the IRB website and notifications for news and updates—stay tuned!

HRPP QUALITY CORNER: Spotlight on...

What is the Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement (QA/QI) program?

The Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement (QA/QI) program is a component of the UMass Center for Clinical and Translational Science. The program is independent of the IRB, and helps study teams and investigators by conducting routine post-approval monitoring of ongoing research to evaluate adherence with institutional requirements and federal regulations. If there are review findings, the QA/QI manager shares those findings with investigators and study team, and provides direct education on the findings, including how to avoid making similar errors in the future. In order to support improvement at an institutional level, the QA/QI manager shares aggregated data from reviews with the HRPP leadership and the Research Community to identify trends and target areas for education.

The program also makes self-evaluation tools available to investigators and study teams seeking to perform their own assessments.

For a full description of the HRPP QA/QI program, see HRP-142

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Upcoming Events

IRB Drop-in Sessions
2nd and 4th Thursday of each month
12:30-1:30 pm
UMMS Library

When SBER Involves Drugs and Devices: Cases to Clarify FDA Oversight
PRIM&R Broadcast
Thursday 9/20/18 from 1-2:30 pm
Amphitheater II (S4-102)

Clinical Research Professionals Group October Meeting
Wednesday, October 17, 2018
12:30-1:30 pm
or via Zoom (Login information available from CRPG listserv or by contacting hrpeducation@umassmed.edu)

Clinicaltrials.gov
Register online at events @ inside.umassmed.edu
Basics: Registration
Zoom: 9/25/18 3-4 PM
Intermediate: Registration
Zoom: 9/26/18 10-11 am
Basics: Record Maintenance and Results Reporting
TBD

Outside UMass:

PRIM&R
2018 Advancing Ethical Research (AER) Conference
November 15-17, 2018 San Diego, CA
https://www.primr.org/aer18/

AAHRPP @ UMMS

On August 13th and 14th, UMass Medical School hosted two site visitors from the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Over the course of the two days, the site visitors conducted interviews of nearly 50 individuals involved in human research protection at UMass Medical School (including Principal Investigators, Study team Members and key individuals in research and Medical School administration) and reviewed documents associated with our Human Research Protection Program.

We are pleased to report that the site visit went very well, and we look forward to hearing from AAHRPP regarding final accreditation determination in December.

Our thanks to all who participated or supported the site visit for contributing to its success!

UMCCTS Intake Portal, OCR Website Update

The UMass Center for Clinical and Translational Science has implemented an intake/service request portal.
Currently, the portal is being utilized by the Office of Clinical Research for intake of all agreements and amendments, OnCore updates/corrections and Certificates of Confidentiality. The portal can be accessed on their newly updated website at https://www.umassmed.edu/ocr/

Financial Conflict of Interest for Human Subjects Research

Accurate identification and management of conflicting financial interests is a key part of compliance and human research protection. The financial conflicts of interest (COI) process relies on the actions of UMMS researchers and study team members!

Who: Anyone involved in the design, conduct and reporting of research (including study team members!). Principal Investigators are responsible for ensuring that disclosures are accurate and complete for themselves and for study team members. Do not guess when completing forms for others!
What: Financial interests as outlined in the UMMS COI policy documents.
Where/How: There are three pathways to disclose financial interests:

1. Annually, via the central Conflict of Interest Disclosure system;
2. On the SFDI form for each project administered through Office of Sponsored Programs and
3. In eIRB on Initial and Continuing Review submissions.

When: Financial interests must updated within 30 days of any change, and must also be reviewed and confirmed for accuracy and completeness at least annually.

Have questions or need help? Contact Laurie Richard , Sr. COI Analyst for UMMS.

Focus on: Clinicaltrials.gov

Clinicaltrials.gov education is in full swing, and policies, procedures and resources are in development! Keep up to date by watching for announcements and posted sessions.

Investigational Drug Service

On August 21st, 2018, The UMCCTS and Investigational Drug Service leadership issued a joint reminder to the research community that all investigational agent use in human subjects research at UMMS must utilize the Investigational Drug Service. For more information, please see https://inside.umassmed.edu/ccts/human-research/ids-policies.