UMMS Human Research Protection Program (HRPP) Newsletter

Volume 3 March 2016

Special points of interest:

- UMMS HRPP: Full AAHRPP Accreditation!
- Request a MiCard & TriNetX account
- REDCap reminders
- HRPP Quality Corner
- Helpful Hints from the IRB
- Ancillary Review Processes
- Upcoming educational opportunities

Contact Us:
IRB@umassmed.edu

HRPeducation@umassmed.edu

Visit us on the web:

http://www.umassmed.edu/ccts/human-research/

UMMS HRPP Receives Full AAHRPP Accreditation!

The UMMS Human Research Protection Program is thrilled to announce that we received *Full Accreditation* from AAHRPP! This initial accreditation is for 3 years. Thank you to everyone who contributed to this process and for your continued efforts to protect the human subjects who take part in research at UMMS!

Planning a study? Need access to de-identified data? MiCard and TriNetX can help!

To get access to these applications, visit the Clinical Data Portal at: umassmed.edu/it/cdp
Click on the "Get Access" tab at the top of the page and complete the "De-Identified Data Account Request Form" to request a user account.

Do you use REDCap for data management?
Visit the REDCap Security Best Practices page and learn about your responsibilities to ensure safety and security, including work-station security requirements. Includes:

- HIPAA's 18 Patient Identifiers
- How to set REDCap user rights and permissions

Not a REDCap user yet? You're missing out!
Get access to REDCap here. Click on the *REDCap Access Request Form,* complete and submit!

Join us for hands-on training!
Thursday, March 31 9:30–11:00 AM
Registration is required. Email HRPEducation@umassmed.edu

HRPP QUALITY CORNER: Spotlight on…

…record retention

Did you know…?

Per IRB guidance *Investigator Obligations: HRP-800*, you must retain research records for specified lengths of time. Institutional retention requirements can be found at http://inside.umassmed.edu/Policies/Policies-listing-page/UMass/Records-Management-Retention-and-Disposition-Policy/.

QA/QI audits have revealed that the practice for some research teams is to retain only the signature page of these important documents.

It is a requirement and best practice that you retain each and every page of all consent forms and HIPAA documents.

Office of Clinical Research
Human Research
Protection Program
ACC 7th Floor

Helpful Hints from the IRB

Preparing an IRB submission?

Please visit the IRB website to access the ***most current*** forms and templates. Recent updates include:

Investigator Study Plan Template with Instructions– *updated 12/8/2015*

Consent Form Template– *updated 2/3/2016*

Reminder: Ancillary Review Processes

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 ancillary reviews.

Institutional reviews may include:

- UMMS Radiation Safety Department http://inside.umassmed.edu/radiation/

⇒ Visit the *Clinical Trials* link on the left side of the page to access information and forms about the Subcommittee on Human Use (SHU) approval process.

- UMMS Institutional Biosafety Committee http://inside.umassmed.edu/Biosafety/

⇒ Visit the *Registration and Approvals* link on the left side of the page to access forms, learn about your responsibilities and the registration process.

⇒ Link to an excellent resource called "How to Register with UMMS IBC" under *Registration Process.*

⇒ Access a Questionnaire to Determine IBC Registration Requirement under *Forms.*

- Conflict of Interest (COI)

http://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/

⇒ Visit the *Forms*, and *Training tabs* on the left side of the page to access COI forms and instructions for COI training through CITI. Important procedural guidance can be found by reviewing the questions under the *FAQs* tab.

Additional departmental reviews may include:

- UMMS Department of Emergency Medicine
- UMass Memorial Acute Care Operations Committee (ACOC)
- UMass Memorial Cancer Research Office
- UMass Memorial Medical Center, Department of Clinical Engineering

⇒ If you are working with Investigational Devices, please contact the UMMMC Department of Clinical Engineering for review procedures.

Upcoming Education Opportunities

Clinical Research Professionals Group (CRPG) Meetings

Wednesday, April 13, 2016 from 2:30-1:30 PM in Lazare S1-607

Tuesday, May 9, 2016 from 2:00-3:00 PM in Hiatt S1-608

Research Coordinator Trainings

Basic Clinical Research Coordinator Course

Thursday, May 5, 2016

Intermediate Clinical Research Coordinator Course

Thursday, June 2, 2016

Registration will begin soon. Registration links will be distributed via CRPG email list, and posted on inside.umassmed.edu under *Events*.

Not part of CRPG email list? Email a request to be added to HRPeducation@umassmed.edu