UMMS Human Research Protection Program (HRPP) Newsletter

Volume 6 July 2017

This issue:

GCP Training Requirements

UMMS requires that all study investigators and staff who are involved in the conduct of Clinical Trials (as defined by NIH) complete GCP training. Training must be completed using one of the Collaborative Institutional Training Initiative (CITI) training modules. Training must be up-to-date to obtain approval for a new clinical trial or continuing review submission (with the exception of those studies in data analysis only or in long-term follow-up).

Effective January 2017, the National Institutes of Health instituted a policy that all NIH-funded investigators and staff involved in the conduct, oversight, or management of clinical trials should be trained in GCP. Of note, a clinical study is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo/control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

CITI offers 2 GCP training modules that will fulfill the UMMS and NIH requirement. The ICH Focus course further fulfills TransCelerate requirements for industry-sponsored research. The course selections are:

GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
or
NIH – Social & Behavioral Research Best Practices for Clinical Research

This training is valid for a three-year period, after which time a refresher course or additional training must be completed.

For more information, please visit the following site:

HRPP QUALITY CORNER: Spotlight on...

www.clinicaltrials.gov.....

Beginning June 19, 2017, ClinicalTrials.gov will undergo a series of changes focused on improving the ability to search, display, and review information about clinical research studies registered with the site. Changes will be introduced on ClinicalTrials.gov as they are ready, following testing and validation. It is anticipated that the most significant set of changes will be available on ClinicalTrials.gov in September 2017.

Some of the enhancements to ClinicalTrials.gov that are under development include:

- Searching for U.S. studies by ZIP code and radius in miles
- Redesigning the study record layout to make the most relevant information more prominent

Please access the link below to read about these changes:
https://www.nlm.nih.gov/pubs/techbull/mj17/mj17_clinicaltrials_improve_usability.html

Contact Us:
IRB@umassmed.edu

HRPeducation@umassmed.edu

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

Office of Clinical Research
Human Research Protection Program

Special Alert!

Training sessions for Epic, OnCore, and Epic/OnCore Research Conversion are all open for sign-up. Please check with your Department Administrator to determine your individual training requirements.

Come to the August CRPG meeting to hear about the latest developments!

The OnCore IT team can be reached at: ITCTMS@umassmed.edu

New UMMS Office
Office of Management

In May 2017, UMMS Senior Leadership named and expanded the operations and activities of the Office of Management (within Administration and Finance). This Office is directed by James G. Healy, J.D., Associate Vice Chancellor for Management and includes the Senior Privacy Officer (Gerry Campbell, JD), Senior Director of Compliance (Tracy Miller, JD), Legal Associate (Laura Harris, JD), Senior Conflict of Interest and Compliance Analyst (Laurie Richard), and Director of Property Services (Amy Forman). In addition, Commonwealth Medicine's former Office of Compliance and Review was restructured into the Office of Management. These Office of Management employees will remain in their offices at our South Street campus and will be overseen by Miller.

The Office of Management handles a wide variety of UMMS campus legal / risk exposure matters, including privacy, compliance, contracts, conflict of interest, and real property management. It also oversees campus-related litigation, and conducts policy and regulatory review. The Office of Management also oversees the newly-formed Enterprise Risk Management Committee (ERMC), whose members include Carol Bova, Gerry Campbell, Sonia Chimienti, Brendan Chisholm, Brian Coleman, Marcy Culverwell, John Finch, Deb Harnois and Patti Onorato. The ERMC meets quarterly to consider and assess campus risks and vulnerabilities. Please contact the Office at 508-856-6955 to assist with any of your inquiries, questions, and issues.

New FDA Guidance

IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects

Currently, FDA regulations governing the protection of human subjects allow exception from the general requirements for informed consent only in life-threatening situations when certain conditions are met (21 CFR 50.23) or when the requirements for emergency research are met (21 CFR 50.24). However, provisions in the 21st Century Cures Act (Cures Act), signed into law in December 2016, provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject.

A new FDA guidance, dated July 2017, allows an IRB to waive or alter informed consent requirements for certain minimal risk clinical investigations. FDA does not intend to object to an IRB waiving the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described above.

<u>All waivers or alterations of informed consent require prior IRB review and approval</u>. Waiver requests must be requested through the Consent Process section of the Investigator Study Plan either as a part of a new study or as a Modification to an existing study.

To review the FDA Guidance document, go to:
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf

Upcoming Events

- **Clinical Research Professionals Group (CRPG) Meeting:** Wednesday, August 16, 2017, 1PM-2PM , Lazare Amphitheater
- **Intermediate Clinical Research Coordinator Training:** October 24 - More details to follow!

Email HRPeducation@umassmed.edu for more information