UMMS Human Research Protection Program (HRPP) Newsletter

Volume 5 April 2017

Special points of interest:

- Common Rule Update
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- Electronic Informed Consent Update
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Common Rule Update

In January of this year, the U.S. Department of Health and Human Services published historic revisions to the Federal Policy for the Protection of Human Subjects (referred to as the Common Rule). The Common Rule was first published in 1974 and has not been changed since 2005. The compliance date is January 19, 2018.

In brief, the changes are:

- The informed consent must include, at the beginning of the document, a clear and concise description of the study, its risks and benefits, and appropriate alternative treatment.
- A broad consent can be used for the storage, maintenance, and secondary research use of identifiable biospecimens.
- New, exempt research categories (i.e. limited IRB review) have been established based on their risk profile.
- U.S. based institutions engaged in federally funded cooperative research must use a single IRB. This requirement becomes effective in 2020.
- New studies that are approved under the 2018 regulations will not require continuing review if they undergo expedited review or have reached long-term follow-up.

For now, continue to submit to the IRB as you normally would. Stay tuned for updates as the IRB begins to revise templates and eIRB. Training classes will be offered.

HRPP QUALITY CORNER: Spotlight on...

Record retention:
Did you know that study teams are required to maintain study documentation for a minimum of three years after completion of the research? Missing informed consent pages continue to account for a portion of deviations related to informed consent forms as determined by routine QA/QI audits.

Also, did you know signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations must be retained for at least six years after completion of the research?

All pages of the signed and dated informed consent and HIPAA documents must be retained, not just the signature pages.

Please refer to the **Investigator Guidance HRP - 800**, **Section 2.22** for additional information regarding retention of records for drug studies conducted under an IND.

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

Office of Clinical Research
Human Research Protection Program

Special Alert!

- The implementation of OnCore is progressing across all clinical research departments.
- Research Information Technology is working hard to address any issues that have been raised by these current users.

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

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

Electronic Informed Consent Update

Electronic informed consent (eIC) is thought to be the next big technological innovation in clinical trials. There is an increasing interest in the research community to use electronic media to supplement or replace the paper informed consent process. A recent survey of the top 50 pharmaceutical companies indicates that 66% of them are engaged in or are planning an eIC initiative.

An eIC has the ability to fulfill all of the requirements of the informed consent process, e.g., it: 1) provides adequate information about the research that allows the potential subject to make a voluntary decision to participate; 2) evaluates the subject's understanding of the information being presented; 3) provides an opportunity for asking questions; 4) documents the subject's consent; and 5) notifies subjects of any amendments that may influence informed consent.

Specifically, eIC refers to the use of electronic systems and processes that may employ multiple media tools including: text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, callout boxes, knowledge review, dictionary/glossary, and content flags to convey information related to the study and to obtain and document informed consent. In addition, the procedure for eIC may include an electronic method to capture the subject's signature provided the system meets the relevant requirements contained in 21 CFR part 11. Of note, the UMMS Clinical Research Volunteer Registry is currently using electronic consenting.

It is important to remember that the eIC is not meant to replace the discussion between the subject and the study staff, but rather support it. The investigator must ensure that subjects have the opportunity to ask questions.

For additional information about electronic informed consent:

- FDA Guidance for Institutional Review Boards, Investigators, and Sponsors: Use of Electronic Informed Consent: Questions and Answers, December 2016.
- Grady, Christine, The Changing Face of Informed Consent, N Engl J Med 2017; 376:856-861.

FDA Q and A

Q: Is there anything in the regulations that prohibit the use of a manual date stamper?

A: The regulations do not prohibit the use of date stamps by clinical investigators. However, per 21 CFR 50.27(a), the regulations require the informed consent form to be both signed AND dated by the subject or the subject's legally authorized representatives. ICH E-6 Good Clinical Practice: Consolidated Guidance (Section 4.8.8) recommends that the informed consent form be signed AND dated by the subject or the subject's legally authorized representative AND by the person who conducted the informed consent discussion.

Source: www.fda.gov – Replies to Inquiries to FDA on Good Clinical Practice

Upcoming Education Opportunities

- **Clinical Research Professionals Group (CRPG) Meeting:** Tuesday, April 25, 2017 from 12N-1PM in Belmont Hill Room ACC 7th floor
- **Basic Clinical Research Coordinator Training:** Thursday, May 18, 2017 from 9AM-12:30PM in Belmont Hill Room ACC 7th floor

Email HRPeducation@umassmed.edu for more information