The Department of Health and Human Services (DHHS) published an update in September 2016 to the requirements for registering clinical trials to ClinicalTrials.gov. The update was effective January 18, 2017 with a compliance deadline of April 18, 2017.

ClinicalTrials.gov has developed a checklist for determining if a clinical trial or study is an “Applicable Clinical Trial” (ACT) requiring registration.

The IRB staff will be hyperlinking the tool in the Project/Protocol Review Form and in the consent form template in IRBNNet for easy reference.

The ACT Checklist asks the following 4 questions:

1. Is the study interventional (a clinical trial)?
2. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)?
3. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study?
4. Do ANY of the following apply (is the answer “Yes” to at least one of the following sub-questions: 4a, 4b, OR 4c)?
   a. Is at least one study facility located in the United States or a U.S. territory?
   b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)?
   c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country?
If the answer to all four questions is “Yes”, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT and is required to be registered.

Additionally, consent forms for ACTs must still include the exact phrase "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The update requires that there be only ONE responsible party for each ACT for the purposes of submitting information about the ACT. The sponsor of an ACT will be the responsible party, unless the sponsor designates a principal investigator to serve in this role. In some instances, an investigator may be a sponsor-investigator by applying to the FDA for an IND/IDE (becoming the IND/IDE holder) or applying to the IRB with an investigator-initiated IND/IDE-exempt protocol. In these circumstances, the PI would be the responsible party charged with registering and submitting information about the ACT.

The update requires the “Responsible Party” to:

- Register no later than 21 days after enrollment of the first participant;
- Submit results no later than 12 months after primary completion date regardless of the approval status of the study product (i.e. FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA;
- Submit a copy of the full protocol and statistical analysis plan at the time of results information submission;
- Submit results information to include baseline information on race and ethnic background; and
- Submit more information on adverse events.

In order to maintain compliance with the update, UICOM-P investigators who act as a sponsor-investigators (as IND or IDE holders) or are applying to the IRB with an investigator-initiated IND/IDE-exempt protocol, will be subject to a Sponsor-Investigator/Investigator-Initiated Study Visit by the ClinicalTrial.gov Administrator for UICOM-P. The Administrator is responsible for creating the sponsor-investigator’s ClinicalTrials.gov user account and oversees the maintenance of UICOM-P’s records. The purpose of this visit is to introduce the sponsor-investigator to ClinicalTrials.gov and ensure the sponsor-investigator understands the ClinicalTrials.gov responsibilities.

New “Common Rule” for Research Afterall!

Following five years of input, the New Final Common Rule was published in the Federal Register on January 19, 2017. Former President Obama issued the rules late in his administration.

Although Congress could still nix the new 543-page rule, key changes are worth noting. The effective date for compliance with the New Rule, if implemented, is January 19, 2018.
BIOSPECIMENS

Extending the definition of human subject to biospecimens (regardless of whether the sample is identifiable or not), was NOT adopted in the Final Common Rule to the relief of many researchers. The new rule does speak to the option of “broad consent” for the “storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens”. Broad consent is described as an alternative to seeking study-specific consent or asking an IRB to waive the requirement to obtain informed consent later. If used for secondary research on identifiable data or biospecimens, the broad consent has 12 required elements that cannot be waived or altered:

- Risks
- Benefits
- Confidentiality of records
- Voluntary Participation
- Commercial profit
- Whole genome sequencing
- General description of research that may be conducted
- Description of data or biospecimens
- whether sharing will occur, and who might use it
- Period of time for storage/maintenance and for research use
- Notification of details for future research
- Return of clinically relevant results
- Contact information for questions

It is unclear if broad consent can be combined with a consent form for the MAIN study or if it must be its own document. Broad consent may also cause some nightmares because sites will need to create a mechanism for tracking subjects that refused broad consent. If a subject refuses broad consent, no waivers can be granted to use the identifiable data or biospecimens.

INFORMED CONSENT

The New Rule requires that key information be presented at the beginning of the consent form that aids a potential subject in making the decision to participate or not. There is little guidance on what is considered “key information;” only excluding lists of facts.

In addition to the already-required 8 elements of consent, one additional element has been added if the research involves the collection of identifiable private data or identifiable specimens: Statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent.

In addition to the already-optional 6 elements of informed consent, three additional elements have been added:

- commercial profit;
- return of clinically relevant results;
- whole genome sequencing of biospecimens.

WAIVER OF INFORMED CONSENT

Investigators wishing to do research involving access to or the use of identifiable private information or identifiable biospecimens will need to justify one more criterion, that the research could not practicably be carried out if not identifiable.
CONTINUING REVIEW OF RESEARCH

If the New Common Rule becomes effective, Continuing Reviews will not be required for studies that are eligible for expedited review (minimal risk) or have progressed to data analysis only and/or accessing follow-up clinical data from standard of care procedures (not being done because of the research) anymore.

IRB EXEMPTIONS

The New Rule creates an exempt category for research involving “benign behavioral interventions in adults” that are judged to be “brief in duration, painless, respectful and overall harmless.”

SINGLE IRB

The New Rule requires U.S. based institutions engaged in cooperative group research to use a single IRB for portions of the research taking place in the U.S., with some exceptions. Cooperative group research is defined as involving more than one institution and noting that each institution is responsible for safeguarding subject rights and welfare. NIH has a similar mandate. The mandate for the use of a single IRB is for federally funded research only.

LOCAL IMPACT

The New Rule will require changes to Peoria IRB forms, policies and procedures. The effective date for compliance with the New Rule, if implemented, is January 19, 2018. The compliance deadline for single IRB review is January 20, 2020. Informational sessions on the New Rule have stated that enacting any of the New Rule proposals prior to the compliance date will be viewed as noncompliance. Stay tuned!

For more information regarding the New Common Rule, please see:
http://blogs.harvard.edu/billofhealth/2017/01/18/final-common-rule-revisions-just-published/
https://www.statnews.com/2017/01/18/common-rule-human-experiments/

IRBNet Reminder: Creating a New Package for an Existing Study

Creating a new package in IRBNet is necessary when responding to a Request for Modifications, when submitting a Change in Research, a Continuing Review, Closure or any “Others” for IRB review. Steps to Follow for Creating a New Package for an Existing Study are:

1. Select project title from “My Projects”
2. Click on “Create a New Package” in left margin
3. Click on “Project History”
4. Click on the new package created: “Work in Progress (not submitted)”
5. Designer Page – download any needed forms from the library to complete and save to your computer
6. Designer Page – Upload the completed forms in IRBNet
7. “Sign this Package”
8. “Submit this Package”
*The newly created package will remain as a “work in progress” until the last step has been completed. You can keep your package open until you are ready to submit. Peoria IRB submission office will not be able to view and process your package until you have completed “Submit this Package.” Once the package has been submitted, the status will be changed to “Pending Review.”

**Special Message for those Approved as Authorized Research Personnel in NIH-Funded Clinical Trials**

Effective January 1, 2017, the National Institutes of Health (NIH) is requiring Good Clinical Practice (GCP) Training for all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials, consistent with principles of the International Conference on Harmonization (ICH).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

The UICOM-PIRB CITI GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) fulfills this requirement.

**How to Add GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) in CITI:**

1) Log into CITI at www.citiprogram.org using current username and password
2) Scroll down below your current courses to “My Learner Tools for University of Illinois College of Medicine at Peoria” and click the link that says “Add a Course”
3) Scroll down to Enrollment Question 4 and select “GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)”.
4) Click Submit to return to Main Menu and enter the “GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)” course. You will need to complete the “Assurance Statement” before you may access the first module of the course.

If you have questions regarding PIRB training requirements or adding a course, please contact any member of the OHRO staff at: 309-680-8630.
WIRB-Copernicus Group offers white papers on regulatory and ethical topics in clinical research. This white paper is one for EVERYONE entitled “Glossary of Commonly Used Terms in Human Subject Protection.” The purpose of the glossary is to provide clarification of the most commonly used terms related to human subjects research. Please request a copy of the white paper at: http://www.wcgclinical.com/glossary-commonly-terms-human-subject-protection/

****COMING SOON****
Introduction to the New IRB
Informed Consent Template
*
Presented by: Mindy Reeter

Upcoming PIRB Meeting Dates

Thursday, February 9, 2017 – 12:30 PM
Thursday, March 9, 2017 – 12:30 PM
Thursday, April 13, 2017 – 12:30 PM

Submission Deadlines are the end of business on the last Thursday of each month.

Meetings are held in Room A100-2 at the University of Illinois College of Medicine at Peoria.