Audit findings by the UICOM-P Quality Improvement Program and the OSF Ministry Compliance Department have prompted the Office of Human Research Oversight (OHRO) to re-tool the Informed Consent Template.

Additional changes have been made since the first discussion of re-tooling the consent form template first appeared in the September 2016 HRPP Newsletter. The additional updates include:

- In the “Why am I being invited to volunteer?” shaded box area, the hyperlink to the applicable clinical trial evaluation checklist for determining whether a clinical trial or study is an “Applicable Clinical Trial” and requires registration on ClinicalTrials.gov. regarding clinical trial registration in ClinicalTrials.gov.

- In the “What happens if I am injured or hurt during the study?” section, directions were added stating the language for the section may vary by institution. The following template language was added that can be modified depending on the site of the research:

  “If you get ill or injured from being in the study, you should let the study doctor know right away. You should contact Dr. [   ] at telephone number [   ]. [For research involving greater than minimal risk, emergency contact information should be included here].

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the
research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial. Please ask about any added costs or insurance problems.

The University of Illinois College of Medicine at Peoria (UICOM-P) has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

• In the **Signature** section, please add a witness signature line and date line if your study does not specifically exclude the enrollment of subjects who are unable to read or write. Include the following paragraph under the witness and date lines: “If the subject is unable to read or write, an impartial witness is required to document that the participant understands the study and the consent process, and has consented to participate. A person who speaks and understands English, but does not read and write, can be enrolled in a study by ‘making their mark’ (fingerprint or X where legally accepted) on the consent document, as long as there is an impartial witness.”

**Previous Changes to the Consent Form Template are re-printed here for your easy reference:**

The main areas of change to the consent form template are:

• The **“Why am I being invited to volunteer?”** shaded box area regarding clinical trial registration in ClinicalTrials.gov.
• The addition of a **“What about confidentiality?”** (outside of the HIPAA sections of the form),
• The HIPAA Sections
  o 3. The personnel who may use or disclose your personal health information
  o 4. Who, outside of this institution, might receive your personal health information? and
  o 7. Changing your mind
• The addition of assent discussion documentation in the **Signature Section**.

**“Why am I being invited to volunteer?”**

The shaded box on the 1st page of the consent form template now offers a hyperlink to a helpful tool for determining if your study qualifies as an “applicable clinical trial” under the **Food and Drug Administration Amendments Act (FDAAA) Section 801** that requires clinical trial registration and results submission to ClinicalTrials.gov.

ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH).

If your study is not an “applicable clinical trial,” all references to ClinicalTrials.gov should be deleted from the consent form template in the shaded box and in the “Who can I call about my rights as a
research subject?” section.

“What about confidentiality?”

This section of the consent form template was added to cover how confidentiality of information that does not meet the definition of protected health information (PHI) (but could still identify the subject and are part of the research record) will be maintained. This section of the consent form template requires a description of how research records will be protected and where they will be stored. This section also requires the PI to indicate how the confidentiality of a subject’s identity will be maintained if the results of the study are published or presented at meetings.

**HIPAA Section #3, #4 and #7**

HIPAA Section #3 is for listing the individuals or institution that can use and disclose protected health information. Under HIPAA, “a use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.” A disclosure is defined as “the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information” 45 CFR 160.103 Definitions.

“Entity,” in both definitions, refers to the “covered entity.” Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

For our purposes, it is important to think about what “entity” maintains control over the electronically transmittable protected health information. In the case of a hospital, it is likely that the hospital maintains control of the records and is the covered entity. In the case of a private practice group, it is likely that the private practice group maintains control of the records and is the covered entity. Those individuals or institutions or organizations “within the entity” should be listed in HIPAA Section 3.

For HIPAA Section 4, all individuals, institutions or organizations “outside of the covered entity maintaining control of the records” should be listed here as “who” outside of the covered entity, may receive protected health information.

HIPAA #7 Section was updated to include the required HIPAA statements: “You have a right to refuse to sign this HIPAA Authorization,” and “You do not have to sign this form. If you do not, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits to which you are normally entitled.”

**Signature Section**

The age of the subject is requested and the answer will drive the individual obtaining consent to complete signatures boxes A) for Adult Subjects, B) for the individual obtaining consent, C) for parents/court-appointed guardians or an Authorized Subject Representative in the case of an adult subjects unable to consent for him/herself (as applicable), and D) Assent Documentation (as applicable).
As you may be aware, the New Rule was published in the Federal Register on January 19, 2017. New regulations promulgated near the end of a Presidential term are subject to a repeal process that involves Congress and the new President. Under current law, this repeal process can be undertaken through the first several months of a new Presidential Administration. Unless definitive action is taken soon, the fate of the revised Common Rule may continue to be uncertain until late May or June 2017. Stay tuned!

It is the policy of the UICOM-P IRB that all IRB submissions via IRBNet require the electronic signature of the PI, or designee. All UICOM-P new study submissions require the electronic signature of the Clinical and/or Research Supervisor prior to submission to OHRO. Studies performed by residents require the electronic signature of his/her Program Director (PD).

**Exception to the Rule**: If the required signatory is not a registered user of IRBNet and does not wish to register, a scanned physical signature is acceptable when uploaded into IRBNet.

The person signing as “Clinical and/or Research Supervisor/Program Director (PD for residents only)” should be the individual who has the necessary professional credentials to act as the principal investigator’s supervisor and hold him/her accountable for job performance. The person signing on the line above attests to the following:

1) As the employer or supervisor of the principal investigator, I will hold him/her accountable for compliance with human subjects protection policy and procedures;

2) The resources and environment required for satisfactory completion of this project are available to the investigator; and

3) This project has been reviewed for scientific merit and meets the expectations of our discipline.
Important Information for all IRBNet Submitters: Hospital Sign-Off Change

In addition to the signatures discussed above, OSF and UnityPoint Health – Methodist/Proctor require Institutional Review of ALL projects. This is accomplished by sharing with Stephanie Madrigal (OSF Saint Francis Medical Center Research); Paul Pedersen, MD and Linda Zimmerman (OSF St. Joseph Medical Center for signature by Paul Pedersen, MD) or Vaughn Hanna, MD (UnityPoint Health – Methodist/Proctor Research) and Natalie Dilts. For research at OSF, you will also need to complete the applicable OSF document (separate forms for OSF Saint Francis Medical Center and OSF St. Joseph Medical Center) and e-mail the completed form to the address indicated. The OSF forms are located in the IRBNet Forms Library for you easy reference.

Important Message for UICOM-P Researchers

When the U.S. Department of Health and Human Services issued a final rule (42 CFR 11) about ClinicalTrials.gov in September 2016, UICOM-P appointed Institutional PRS Administrators ["Administrator(s)"] to serve in an oversight capacity. Your UICOM-P Administrators are Mindy Reeter (mreeter@uic.edu) and Dennis Driscoll (dennisd@uic.edu). The Administrators assist UICOM-P researchers with:

a. establishing user accounts and temporary passwords;
b. resetting a password when the original is lost or forgotten;
c. working with PRS to change ownership of a study; or
d. transferring a study to another institution.

To help you determine if your research project requires registration on ClinicalTrials.gov, please use this checklist-based tool for studies initiated on or after 1/18/17 by clicking here.

Hot off the Presses...

Quorum Review’s Knowledge Center featured an article on 19 April 2017 entitled “Giving Healthcare Research a Ride.” If you find that transportation challenges are an obstacle to patients, read this article that tested whether easy transportation improved preventative healthcare.
Educational Opportunities

OSF Healthcare
Annual Research Symposium
May 17, 2017
JUMP SIMULATION CENTER
Get more information at:
https://www.jumpsimulation.org/events/all-events-courses#

UICOM-P Family Medicine Research Day
May 18, 2017
UICOM-P Lecture Hall
Get more information at:
http://illinois.edu/calendar/detail/5492?eventId=33267812

Traveling this summer??

OHRP’s Research Community Forum
“Navigating a River of Change: Bringing Research Up to Par”
July 18-19, 2017
Augusta, GA
Register at:
http://www.augusta.edu/research/dhhs/

Upcoming PIRB Meeting Dates

Thursday, May 11, 2017 – 12:30 PM
Thursday, June 8, 2017 – 12:30 PM
Thursday, July 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.