Recent 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 two of the most widely used IRB forms, the Project/Protocol Review Form and the Informed Consent Template.

Changes to the Project/ Protocol Review Form

OHRO staff met recently with research coordinators for Project/Protocol Review Form user feedback and offered tips for successful form completion. During this time, some areas for improvement were identified; namely, Section 10 “Subject Populations” and Section 12 “HIPAA Compliance.”

In **Section 10**, the IRB’s expectation of the Principal Investigator (PI) for soliciting assent from minor subjects is delineated according to the age groups of newborn to 6, 7-13 and 14-17. The IRB expects the PI to request a waiver of assent for subjects ages newborn -6. A verbal assent process is expected by the IRB for subjects 7-13 in which the investigator explains the study in age-appropriate terms. If the minor verbally assents, the verbal agreement should be documented in the patient notes by the consenting individual.

For subjects ages 14-17, the IRB expects that written documentation of assent be solicited. The research should be explained to the minor in age-appropriate terms and the consent/assent form should be provided or read to the minor. If the minor assents, the agreement must be documented by written documentation on the consent/assent form. The consenting/assenting process should be documented in the patient notes by the consenting individual.
PLEASE NOTE: Investigators MUST seek the informed permission (consent) of parents or the court – appointed legal guardians before enrolling minors in research, unless the UICOM-P IRB has granted a waiver of parental permission requirements.

In Section 12, the difference between a partial waiver of HIPAA Authorization for screening purposes is explained as being necessary for identifying potential subjects for the recruitment phase of the study. The IRB is interested in knowing what variables/data will be ACCESSED through a query or review of records to determine the eligibility of subjects for a certain study (ex: looking at medical records or a database to identify potential subjects). Authorizations are eventually obtained when and if subjects enroll.

A partial waiver of HIPAA Authorization will cover:
- Review of database with PHI to identify potential subjects
- Review of medical charts to identify potential subjects
- Review of clinic schedules to identify potential subjects

A partial waiver of HIPAA Authorization will NOT cover:
- Cold calling
- Screening questionnaires with identifiers, where collected PHI is saved for research even if a person does not enroll
- Storage of data in database for research purposes (requires a whole waiver)

For a waiver of HIPAA Authorization for the MAIN study (following the recruitment phase), the IRB is interested in knowing what variables will be COLLECTED and MAINTAINED for the duration of the research project. A whole waiver allows for the use/disclosure in a research study without ever seeking HIPAA Authorization.

Although the justification for each kind of waiver is the same, the sections for justifying them have been separated into Section C2 and Section C3. The PI must analytically think about the difference between the two sets of data when answering the questions. The partial waiver should apply the inclusion/exclusion criteria such as date of birth and dates of services, to narrow a population.

Once you have narrowed your population to say, 50 eligible subjects, you now can dive into their individual records to collect the minimum necessary data to answer your research question. If you were granted ONLY a partial waiver, you will destroy/wipe out the identifying information that led you to that person as soon as you are done collecting the data necessary to answer your research question. You are severing all ties to the identity of the person.

If you were granted a partial waiver of HIPAA Authorization for screening purposes AND a whole waiver for the MAIN study, you can dive into the individual records to collect the minimum necessary data to answer your research question and the variables you are collecting CAN BE identifiable.

Changes to the Consent Form Template

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
  - 3. The personnel who may use or disclose your personal health information
  - 4. Who, outside of this institution, might receive your personal health information?
  - 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).

IRB Plans for Updating Old Consent Forms

As part of the initial review and Continuing Review of research studies (those open to enrollment ONLY), the IRB will review the consent for 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.”

Consent forms found to be missing these required statements will be contingently approved and the PI will be asked to amend the consent form by adding these two statements to the HIPAA Section #7 Section. Please remember: a contingent Continuing Review approval does not cause your study to lapse in its IRB approval. Approval will be back-dated to the date of the IRB meeting where it received a Continuing Review.

PLEASE NOTE: If you prefer to avoid a contingently approved Continuing Review based on these requests, you are welcome to amend your open and enrolling studies with consent forms at any time via Change in Research.

The new forms will be posted to the IRBNet Forms Library during the first week of October 2016.

In the Spotlight: Recognizing VA Research

The IRB was recently contacted regarding PIRB’s ability to review VA research. Our answer was “it depends.”

PIRB’s ability to review research involving Veterans hinges on whether 1) the study is funded by the Veteran’s Health Administration (VHA) of the U.S. Department of Veterans Affairs; 2) the PI has ANY VHA appointment; AND 3) VHA resources are being used. If the answer is YES to any of the criteria, PIRB cannot review the study. Only IRBs that have been designated by the VHA as a VA IRB through a Memorandum of Understanding can operate in this capacity.
If the answer to all three criteria is NO, PIRB can review the study without the need to apply the extra VHA requirements for IRB review. If any of the three situations change (funding, PI’s appointment or source of resources), a Change in Research must be submitted to the PIRB who will help to facilitate a transfer to an IRB designated as a VA IRB by the VHA.

Policy Reminder: 3.3 Required Training in Human Subjects Protections

It is the policy of the UICOM-P IRB that all individuals engaged in research using human subjects be familiar with UICOM-P IRB policies, procedures and related federal regulations.

UICOM-P IRB requires CITI training of all investigators. All investigators and authorized study personnel must complete either the Biomedical or the Social & Behavioral Basic Human Subjects Course depending on the type of research they intend to perform. Additionally, all investigators must complete the Conflict of Interest minicourse. Certificates of Training are collected by the OHRO staff. While all investigators need education in the basics of human subjects research, some may require additional education if their work involves especially difficult topics or special populations. It is the responsibility of the (PI) to ensure all authorized study personnel are adequately trained to carry out their responsibilities.

The PI and any authorized study personnel engaged in research involving protected health information (PHI) must successfully complete training involving the HIPAA privacy rule and protected health information. This module is located within the required CITI Basic Human Subjects courses. New research protocols will not be accepted from PIs who have not completed the initial education requirement. A new protocol may be reviewed and approved if the PI holds a current certification of training. However no investigator or authorized study personnel listed on the application may participate in any human subject research until they have completed the initial education requirements. This means the individual may not have any contact with research subjects or their private identifiable information. Upon completion of the initial education requirements, a Change in Research Form may be submitted and approved to add individuals as authorized study personnel on the study.

All investigators and authorized study personnel must meet the UICOM-P continuing education requirement every three (3) years after certification of initial education for as long as they are involved in human subject research. There is no exception to this requirement. The CITI Refresher Course in the Protection of Human Research Subjects is required.

Investigators must submit evidence of refresher training prior to the expiration of their initial training certification. New research protocols and applications for continuing review from PIs who have not submitted satisfactory evidence of continuing education will require re-assignment of the PI to an appropriate coinvestigator or other authorized study personnel that have completed his/her continuing education. The PI will be removed from the study until refresher training is completed and a Change in Research Form requesting that the PI be added back to the study is submitted and
Other authorized study personnel who have not submitted evidence of refresher training after their initial training has expired will be administratively removed from studies at the time of continuing review. All contact or interactions with subjects or their identifiable private information by the research team member must cease. Once refresher training is completed, a Change in Research Form requesting that the individual be added back to the study must be submitted and approved before the individual may participate in the study.

UICOM-P faculty received an e-mail message via Faculty Listserv from the Vice Chancellor for Research regarding OPRS Live. The e-mail announces a new, web-based Institutional Review Board (IRB) submission system, is now available to all faculty, staff and students across the UIC campus. UICOM-P faculty performing research reviewed by the Peoria IRB should continue to use IRBNet, PIRB’s electronic submission system at https://www.irbnet.org.

Some members of the UICOM-P IRB team were very busy this summer serving others.

John Hafner, MD, (IRB I Co-Chair) traveled to Haiti with the Friends of the Children of Haiti July 10th-16th 2016.
Deb Wolf (IRBNet Expert) traveled to Guatemala with Bethel Ministries International July 24th-31st, 2016. Deb wrote the following when asked about her motivation and feelings about her summer experience:

“Several years ago, I was in a group that was asked to write down our “Bucket List.” One of the items I included was a mission trip. I had no idea that Guatemala would be the destination. But in July of 2016, I was able to travel with 14 of what I would now consider “my closest friends” to Coban, Guatemala. Our team had the privilege of building two homes made of sheet metal and concrete floors for families previously living with nothing but a dirt floor and whatever boards or heavy plastic they could gather to provide themselves shelter. Our team assisted 85 adults and children in being fitted with a wheelchair as well as distributing eyeglasses, clothes, shoes required for children to be able to attend school, and food.

This trip provided me a glimpse into the lives of people less fortunate than even the poorest of poor in our country and served as a reminder of how grateful I am to live in the USA.”

Quorum Review’s Knowledge Center featured an article on September 26, 2016 regarding Apple’s new requirements for using its ResearchKit to create study apps. Through an interview format, Jim Gearhart, the author, has Q&A with Jeremy Block, a nationally recognized expert in the research regulatory side of healthcare for digital health and mobile health, as well as pharma/biotech/devices. Apple’s requirements are familiar to those of us working in human subjects protections: 1) the requirement for review and approval by an independent ethics committee, and 2) informed consent. To access this article, click HERE.
****COMING SOON****

Introduction to the New IRB Forms:
Project/Protocol Review Form & Informed Consent Template
Presented by: Mindy Reeter

PRIM&R’s 2016 Advancing Ethical Research Conference
November 13-16, 2016
Anaheim, CA
http://www.primr.org/aer16/

**Upcoming PIRB Meeting Dates**

Thursday, October 13, 2016 – 12:30 PM

Thursday, November 10, 2016 – 12:30 PM

Thursday, December 8, 2016 – 12:30 PM *(Submission deadline moved to 11/18/16 due to Thanksgiving holiday)*

Submission Deadlines are the end of business on the last Thursday of each month *(please see one exception above).*

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

University of Illinois College of Medicine at Peoria Institutional Review Board
One Illini Drive, Box 1649
Peoria, IL 61656-1649
Phone: (309) 680-8630  Fax: (309) 671-3406
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