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New PIRB Services for Investigators

This fall the Peoria Institutional Review Board (PIRB) will launch three new services for our investigators:

Sponsor-Investigator IND Meeting – This meeting will go over the IND application, the 1571 & 1572 forms, submission to the IRB, sponsor-investigator responsibilities, reporting requirements for IND holders, and adverse events.

Sponsor-Investigator IDE Meeting – This meeting will go over the different types of IDE studies, submission to the FDA, submission to the IRB, sponsor-investigator responsibilities, reporting requirements for IDE holders, and unanticipated adverse device effects.

Start-Up Meeting – This meeting is designed to provide an overview of the PIRB review and approval process. An introduction to the PIRB Policies and Procedures as well as federal, state, and local laws and regulations will be provided. This meeting can be tailored to include specific
information that pertains to the type of study you are planning to conduct.

If you are anticipating conducting a study where you will be the IND/IDE holder, or are a new investigator, these meetings might be helpful to you. Meetings can be held with individuals or groups.

Call or email Heather Hermann, B.Sc., CIP in the OHRO to schedule your meeting. There is no charge for this service.

Phone: 309 680 8635
Email: heh@uicomp.uic.edu

How to Describe Your Research Data and Samples

When you submit your Project Protocol Review form to the IRB, Section 5 asks you to describe how your data is being stored. An important part of this description is letting the IRB know whether you are storing your data in identifiable, de-identified, or coded form or if the data is in fact anonymous. Additionally, the degree to which your subjects can be identified by the research team will determine the level of confidentiality measures you need to put in place to minimize risks to subjects.

The Project Protocol Review form asks you to describe these measures in your Research Summary in Section 7, item G. The terms identifiable, de-identified, coded and anonymous have very specific definitions and can determine the level of review your project needs. They are often confused. Please see the table below for the definitions the IRB uses.

<table>
<thead>
<tr>
<th>Identified</th>
<th>Your samples or data contain information (such as a name, social security number, address, medical record number, phone number) that would enable the investigator to readily link the data or sample with the identity of a specific individual.</th>
</tr>
</thead>
<tbody>
<tr>
<td>De-identified</td>
<td>A term used in the HIPAA Privacy Rule. Samples or data may not be linked to any of the 18 elements that can be used to identify an individual or their relatives, employer, or household members. The IRB generally interprets “de-identified” to mean that the investigator has no reasonable means by which to link data or samples to a specific individual, and for PHI, the IRB applies the HIPAA Privacy Rule’s definition of de-identified.</td>
</tr>
<tr>
<td>Coded</td>
<td>Identifying information for your samples or data has been replaced with a number, letter, symbol, or combination thereof. A separate list (key) exists. The key allows the investigator to match the code</td>
</tr>
</tbody>
</table>
assigned to the sample or data to the individual’s identity.

| Anonymous | At no point during the research does the investigator know the identities of the subjects. The samples and data have no identifiers of any kind and the investigator has no means by which to determine the identities of subjects. |

OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens
http://www.hhs.gov/ohrp/policy/cdebiol.html

De-identifying Protected Health Information Under the Privacy Rule
http://privacyruleandresearch.nih.gov/pr_08.asp

IRBNet Tech Tip by: Heidi Vermillion

Q – How do I share access of my study with my study team in IRBNet and what level of access should I grant?

A – Anyone currently listed on the study in IRBNet with full access can share access with another registered user in IRBNet. If the individual you want to share with isn’t registered as a user in IRBNet, please ask them to complete the “New User Registration” process located on the IRBNet website www.irbnet.org.

To Share Access:
Select your project from the “My Projects” tab and click on “Share this Project.” Click on “Share”, this will direct you to a page where you will select the organization the individual is registered with. If you need to search for the organization, you can use the “Search” box. For example, if you would like to see all organizations in the system located in Peoria, you can insert “Peoria” in the search box and select “search.” You can also search by entering a portion of the name of the organization. Next, you will search by their last name. Please note, if fewer than 20 users are registered with the organization you selected, all names will display on the screen and you will not have to search by last name. Once you have located the correct individual, you will have the option to grant them Full, Write or Read access. At this step, a description of each level of access is provided in IRBNet.

Full Access is required for those individuals that will be submitting packages in IRBNet. Individuals with Full Access will also receive auto-generated emails from IRBNet.
when activity occurs with the study.

Policy Reminder – Changing PI on an approved study by Deb Wolf

Summertime is one of our busier times for requests to change Principal Investigators on IRB approved studies. To make sure your PI change request can be processed efficiently, please follow these recommendations:

PI Change Packages in IRBNet must include:
Change in Research form indicating change in PI. Include whether the old PI is being removed or is becoming a sub-investigator.
Responsibilities of Investigator form that is either physically signed by the new PI or has the new PI's electronic signature on the package

Also Include if Applicable:
An updated Consent form with the new PI contact information
Conflict of Interest form if new PI was not previously on the study
Proof of Sponsor approval of PI change if study is sponsored (this may be an email or letter)

Once this package is submitted in IRBNet, reviewed and approved, the IRB Office Staff will unlock the package for the PI name to be updated in IRBNet on the Project Overview page. By clicking the yellow “Edit” next to “You have Full access to this project” you will then be able to enter the new PI’s name and then click “Lock – Revisions Complete” and IRB staff will post documentation.

Upcoming PIRB Meeting Dates

July: 12:30 PM Thurs. July 10, 2014
September: 12:30 PM Thurs. Sept. 11, 2014
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.

IRB 1 meets at 12:30 and IRB 2 meets immediately after.

Upcoming Presentations from your PIRB:

Please feel free to join us for

“Thinking about becoming a Sponsor-Investigator? Your IND application, 1571, and the IRB”

Tuesday July 29, 2014
12-1 PM
JUMP Trading Simulation & Education Center
Lecture Hall 162

Can’t make it? No Problem! You can watch the presentations later by visiting the UICOMP IRB LibGuide Page at:

http://researchguides.uic.edu/UICOMP-IRB

All Presentations given by the Education Program will be available to listen to and watch within a few days of the event.