New Guidance for Data Management

The IRB has just completed guidance to assist researchers in developing data management plans for human research data. The guidance presents relevant definitions and key concepts concerning human research data, describes the roles and responsibilities for data management, outlines the elements of a research data management plan, and provides guidance for maintaining and using human research information once projects are completed.

The protection of privacy and the confidentiality of information about research subjects is a special concern for IRBs in their review of research data management. Research subjects must have a reasonable expectation that personal information will be disclosed only with their permission or in ways that are consistent with the consent process, and in compliance with the laws and regulations. Violations of confidentiality could have serious consequences for research subjects, including potential discrimination, misuse of genetic information, loss of insurance, or loss of privacy. Even with all the appropriate state and federal laws, University and hospital policies, and requirements of IRBs all aimed at protecting the confidentiality of a research subject’s individually identifiable private information, violations of privacy can and do occur. Such violations may be inadvertent (accidental) or due to carelessness, deliberate or compelled by regulation or law.

Clearly defined and faithfully followed procedures to protect the confidentiality of human subjects can significantly reduce the possibility of violations to the confidentiality of human research data and should be part of every study design.

The guidance is located in our Research Manual as Appendix O (attached separately). During the development of this guidance, the IRB found that we were not obtaining enough information to clearly understand the plans for the data. To this end, many of our forms have been revised to now include questions that will help us in our review. Some of the questions will require a little more thought and may even require that investigators contact IT staff at the applicable institution. Those contacts are embedded within the guidance and listed below.

RPO staff will immediately begin to review new projects and continuing projects keeping this guidance in mind.

| UVM IT Information Security Questions |
| iso@uvm.edu |

| COM IT Information Security Questions |
| infosecurity@med.uvm.edu |
Consent forms will no longer include expiration dates. RPO staff have determined that approximately 30% of consent deviations are due to the use of an expired consent form. Though the content of the consent is identical to the previous version, the newly approved consent released at time of continuing review was not used.

**Current Process**

As all consenting designees are aware, currently an IRB-approved consent form is identified by the IRB approval stamp on the signature page of the document. The stamp includes a unique IRB-assigned identification number (CHRMS or CHRBSS) as well as an expiration date.

The expiration date corresponds to the overall protocol approval expiration date. If a protocol is approved for one year, so is the consent form. Each year when the protocol is reapproved, RPO staff has been updating the consent form expiration to match the protocol expiration date.

If changes to the consent occurred over the course of the year, via an amendment, RPO staff has been applying a new version letter such as “A” or “B” to the stamp. This helps us to identify what version of the consent form corresponds to a specific amendment. A new version letter was added to the stamp, while the expiration date did not change.

**Future Process**

In an effort to reduce burden and increase compliance the Medical and Behavioral Committees have agreed to change our current procedure for stamping the consent forms. The consents will no longer have expiration dates. Once a consent is approved, it is valid until it is officially changed by an amendment.

The new stamp includes a unique IRB assigned identification number (CHRMS or CHRBSS) as well as an Approved on Date. There will no longer be an expiration date included in the stamp.

At time of initial approval the consent forms will be stamped and given an approval date. Any time an amendment requires a change to the consent form, the form will be re-stamped and given a new approval date. No more letter versions will be used.

**Advantages**

At time of continuing review, consent forms will no longer need to be submitted for re-approval as it will remain valid until an amendment revises the content of the consent form.

We anticipate this change will benefit PI’s by reducing minor noncompliance deviations. Often times the content in the consent has not changed but the form has expired.

The consent and HIPAA forms will now have the same “Approved On” IRB stamp on the subject signature page.

**Transition Plan**

- **New Protocol Approvals**
  The new IRB approval stamp will be used on all new protocol approvals after July 1, 2015.

- **Continuing Approvals**
  Over the course of the next year, if the consent has not been previously amended with the new IRB approval stamp, RPO staff will issue a new “Approved On” stamp to the consent form at time of continuing review.

- **Amendments Affecting the Approved Consent Form**
  If an amendment requires a change to the consent form and the consent currently has the old IRB stamp, the new IRB stamp will be affixed to that consent form once the amendment is approved. A new approval date will be applied. **PLEASE DO NOT SUBMIT AN AMENDMENT just to obtain the new IRB approval stamp as this would cause delays in processing.**

**THERE IS NO ABSOLUTE DEADLINE TO INCLUDE THIS NEW STAMP NOR ANY OF THE OTHER RECENT CONSENT CHANGES (SEE OVERVIEW OF RECENT CONSENT CHANGES) IF THE ITEMS HAVE NOT BEEN ADDRESSED BY THE NEXT CONTINUING REVIEW, IT WILL BE REQUESTED BY RPO STAFF AT THAT TIME.**