Informed Consent Forms

January 2017

Background

One of the main ethical responsibilities of a Principal Investigator (PI) is to ensure that potential participants have been provided with all the information they might reasonably need to know. *Any research protocol utilizing human participants requires the informed consent of those participants.* Potential participants have the right to know what they are being asked to do prior to voluntary participation, no matter what the nature of the protocol and no matter how innocuous it may seem.

Investigators and/or approved study staff are responsible for obtaining and documenting the informed consent of research subjects or their legally authorized representatives (LAR) using an Institutional Review Board (IRB) approved consent form, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent. Investigators must give a copy of the informed consent document to each research subject (or the subject’s legally authorized representative), and keep the signed original or a copy for their records.

When the documentation requirement is waived, the IRB may require investigators to provide subjects with a written statement regarding the research, which is also an IRB approved document.

Q: What happens if the Informed Consent expires?

In certain circumstances, the IRB may provide a different approval period on the consent form which is shorter in duration then for the overall study. This is usually the case when the IRB is concerned about the risks to subjects and requires an interim report from the investigator after a designated number of subjects have been enrolled.

If the informed consent has expired, no new participants may be enrolled. The investigator must provide the interim report to the IRB for review. Upon review of the information provided, the IRB will issue a new stamped approved consent for a time period deemed appropriate for the monitoring of subject safety.

Q: Does it matter which version of the consent I use, as long as the date hasn’t expired?

Yes, it does matter which version of the informed consent document is used. After a revision or a continuing review has been IRB approved, and there is an updated stamped approved consent, this consent form is the most current version and replaces the previously IRB approved document (regardless of whether or not the date is still valid on the previous version).

Q: Where do I find the most current version of the consent form?

The most current IRB stamped approved document is found within myIRB on the study workspace under the ‘Stamped Docs’ tab. *Do not get the consent form from the upload consent smartform page; these are not the final stamped IRB approved versions.*
For the few studies existing in paper format until conversion to myIRB within the year, the IRB office will stamp the most current version of the consent and send it to the investigator along with the approval letter for the continuing review or revision. It will be the study team’s responsibility to make sure the most current version of the consent is distributed and used.

**Q: Who can obtain informed consent from subjects?**

IRB approved study staff with the function of “Obtains informed consent” within myIRB are the only people who can seek consent from subjects.

Per UF policy, volunteers may never obtain informed consent from subjects. On greater than minimal risk studies, Graduate Students, Doctoral Students, Residents and Post-Doc Fellows will be assessed on a case-by-case basis by the IRB to determine if they may be able to obtain consent from subjects.

**Q: Do I have to keep the hard copies of my signed informed consents?**

You may scan your consents on to a secure, backed up departmental server. The file should be encrypted or password protected. The entire informed consent must be scanned for each subject (i.e. not just the signature pages). Once the entire consent document has been scanned, you may destroy the hard copy.

**Q: What happens if signed informed consents are lost?**

If signed informed consents are lost, the IRB and Privacy Office should be notified immediately. Submission of a Reportable Event in the form of an Unanticipated Problem through myIRB within 5 business days of discovery is the way to notify the IRB. A detailed explanation of what happened, how it happened, what is being done to resolve the issue and a corrective action plan to avoid it happening again in the future is required as part of this reporting.

To notify the Privacy Office, call (352) 273-1212 or email: privacy@ufl.edu.

**Q: Is documentation of the informed consent process required?**

Documentation of the informed consent process is not required by the regulations; however it is good research practice and may serve as source documentation in the event that the signed informed consent gets lost. Documentation of the informed consent process is never a replacement for the signed consent document, but the IRB would take it under consideration when reviewing the Unanticipated Problem report to determine whether subjects and/or their data may be kept by the investigator.

**Q: How long do I have to keep signed informed consents?**

There are several different requirements that determine how long investigators have to keep signed informed consents and related study documents. Per Florida law and the regulations, the UF Records Retention office has different retention schedules based on children as subjects, pregnant women, fetuses and neonates as subjects, Investigational Drugs, and Investigational devices.
Here is the contact information for the UF Records Manager: tel: (352) 392-4180 or email: lib-recordmanagement@uflib.ufl.edu