All Things Considered– Part II
Waiver of Documentation of the Informed Consent Process at Continuation Review (CR)

If you have ever completed a continuation review application for a research study, you are familiar with attaching two clean copies of the consent/assent forms prepped and ready for the new IRB approval stamp and date range. But what if your study has a waiver of documentation of informed consent (you completed “Form F” and the IRB waived requirement to obtain a signed consent form)? For these studies, include with your CR submission, the approved documents used in the informed consent process. This may include a standard consent form excluding the signature lines, a survey cover letter, a phone script, etc. If you are making changes to these approved documents, include two copies with the changes underlined, and provide an explanation of how the changes differ from the currently approved documents. To help investigators keep up with and track the approved version of these documents, ORI is now providing an approval stamp with the valid approval date on the document — just like a consent form. Unlike the consent form, you are free to print a clean copy of the approved document prior to posting or mailing to a potential participant.

Protection through Destruction

Requirements for long-term maintenance of study documents vary according to applicable regulations and sponsor requirements. Once the retention period has been fulfilled and any sponsoring agency has provided written permission to destroy records, remember to consider methods that protect human subject’s confidential information. Paper records should be shredded or placed in a locked confidential recycling bin and film or tapes may be shredded or magnetized. For electronic or computer equipment, refer to the following policies for proper data destruction.

- [Guidelines for Managing Records: Records Destruction](#)
- [UK Business Procedures Manual Section E-12-4 & Appendix B](#)
  Data destruction prior to disposition, conveyance or transfer or equipment.
- [Hospital Policy HP01-06](#) Data overwriting for computing equipment.

ORI, IRB & IACUC will be closed Wednesday, December 24 through Thursday, January 1 and will reopen on Friday, January 2, 2009. If you anticipate a need for services during this time, please call 257-9428 before December 15.

Thanks and from all of us, we wish you a safe and happy holiday season!