Did You Know That Physical Signatures Are Not Always Required?

The following are typical examples in which an investigator may obtain consent from subject(s) without requiring a written signature.

- Research on sensitive topics or incriminating behavior.
- Interviews that are not conducted face-to-face, e.g., Skype, instant messaging, email, etc.
- Interviews in contexts and cultures in which signing documents is considered inappropriate.
- Research in populations with low literacy.
- Anonymous surveys.
- Surveys distributed online, therefore obtaining a physical signature is impractical.

Contact your IRB Program Coordinator to determine if a waiver of documented consent is appropriate for your study.

Spanish-Language Consent Templates Have Been Updated

The IRB Spanish-Language Consent Templates have been updated and are available on the “Forms” page of the IRB website.

Upcoming Educational Workshop

The Office of Research Support hosts frequent educational sessions and workshops to assist you with working with the IRB. The next session is:

Date: February 9, 2012
Topic: Step-by-Step: How to Write & Submit an IRB Proposal & Application

For more information and registration, visit http://www.utexas.edu/research/rsc/news/

Obtaining a Waiver of Documentation of Informed Consent

PIs may apply for a waiver of documentation of informed consent if the research meets one of the two following conditions according to 45 CFR 46.117 & 21 CFR 56.109(c)(1):

Condition 1 (both must be true):
- The research presents no more than minimal risk.
- The research involves procedures that do not require written consent when performed outside of a research setting.

Condition 2 (all must be true):
- The principal risks are those associated with a breach of confidentiality concerning the subject’s participation in the research.
- The consent document is the only record linking the subject with the research.
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern.
- The study is not FDA regulated.

If your study meets either of the above conditions, you can apply for a waiver of documentation of informed consent:

- In your IRBaccess application: Step 4, Question 12, Item B.
- In your IRB Proposal: Part VI (Human Subject Interactions), Section C (Procedure for Obtaining Informed Consent).

Remember to indicate in the proposal document that you are “requesting a waiver of documentation of informed consent.” Contact your IRB Program Coordinator for assistance.

The next IRB Full Board meeting is February 27, 2012
The deadline to submit paper copies is February 10, 2012.