IRB Update
Institutional Review Board
The University of Texas at Austin

September 2014
Volume 4, Issue 9

Do you have questions or concerns about the material here or about your submission?

Contact your IRB Program Coordinator in the Office of Research Support.

Sandra Borucki
Program Coordinator
sborucki@austin.utexas.edu
512-471-8653

Meghan Hammock
Program Coordinator
mhammock@austin.utexas.edu
512-232-2625

Veronica Inchauste
Program Coordinator
veronica.inchauste@austin.utexas.edu
512-232-2625

Eunjung Lee-Furman
Program Coordinator
eunjunglf@austin.utexas.edu
512-471-6386

Jennifer Maraj
Program Coordinator
jmaraj@austin.utexas.edu
512-471-6577

Chan Kean
Sr. Program Coordinator,
QA & Education
cekan@austin.utexas.edu
512-471-6733

Holly Tieu
Sr. Program Coordinator,
IRB and COI
htieu@austin.utexas.edu
coi@austin.utexas.edu
512-232-2044

Federalwide Assurance
00002030
AAHRPP Accredited Since
March 17, 2006

Obtaining a Waiver of Documentation of Informed Consent

Investigators 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 the IRBaccess application form. Remember to also indicate in the proposal document that you are “requesting a waiver of documentation of informed consent” and to modify any consent documents accordingly (i.e., remove signature lines).

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

When is a Subject Signature Not Required?

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

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

Please contact the Office of Research Support with any questions, comments, or concerns.

voice: 512.471.8871 | web: http://www.utexas.edu/irb | email: orsc@uts.cc.utexas.edu