Electronic Signatures

Overview:

A growing number of researchers are either conducting research at a distance (e.g., by telephone; over the internet) or are moving to an entirely computer-based where all data and correspondence are collected and stored electronically. In response to many queries, the University of Pittsburgh has prepared this guidance to clarify the various approaches available to obtain and document consent to participate in a research study and HIPAA authorization for research access and use of medical records from a covered entity.

Description:

Minimal Risk Research:

According to the federal regulations [45 CFR 46.117(c)(2)], the IRB may waive the requirement for the investigator to obtain a signed consent if it finds that the research presents no more than minimal risk of harm AND involves no procedures for which written consent is normally required outside of the research context. Signed consent cannot be waived if the study involves procedures like a blood draw or which requires a HIPAA authorization. Otherwise, investigators conducting minimal risk research may always request from the IRB a waiver of the requirement for signed consent (complete section 4.6 in OSIRIS), but must describe how they will (a) inform subjects about the study and (b) document their agreement to participate. Ordinarily, a consent script or form that includes all required elements of consent (see 45 CFR 46.116; IRB Consent Guidance) must be attached to the OSIRIS application, and best practice would hold that subjects receive a copy of the script or an information sheet that describes the study and their rights as a research subject.

In this situation, an 'electronic signature' is not required but investigators using an interactive computer-based system may want to document the person's agreement by having them click a button ("I agree**").** Note that this mechanism is NOT applicable to HIPAA authorization requests.

Greater Than Minimal Risk Research and/or HIPAA Authorizations:

Electronic signatures may be used for documenting consent and for HIPAA authorizations, but they must meet the following standards, according to Pennsylvania's adoption of the Uniform Electronic transactions Act (UETA):

> An "electronic signature" is an electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record (73 PS 2260.103). This should be:
>
> - Unique to the signer
> - Capable of being verified
> - Under the signer's sole control

- Linked to the record in a way that it can be determined if anything in the document was changed after the signature was applied
- Created by a reliable method for the purpose in which the signature was used

The University of Pittsburgh IRB, working with the University Office of General Counsel and with the Information Security Office, has developed the following requirements for an electronic signature. In lieu of a traditional written signature (e.g., on paper, or with a stylus on an electronic touch pad), researchers may design a consent form that collects the following information which taken together, constitute an electronic signature:

- Subject's full name
- Subject's birthdate
- Subject's answer to one of the following verifiable questions (note: either all three may be available as in a drop-down list, or only a single question need be presented)
    - Mother's maiden name
    - Subject's place of birth
    - Name of subject's high school

Although not required, it is recommended that a tick-box or button be included to denote "I agree". Subjects should be informed that they will receive (or may access) a copy of this consent form. There is no requirement that the document be signed. If this process is being used to obtain the person's HIPAA authorization, appropriate language to that effect needs to be included (see example, below).

This electronic signature consent should be described in the 'consent process' section of the OSIRIS application. Subjects must be afforded an opportunity to discuss the research with a member of the research team (by phone, via email, texting, or other interactive procedures) prior to providing their electronic consent.

Note: investigators must also describe in their OSIRIS application how this information will be encrypted and stored. Storage must meet all Pitt (and if applicable, UPMC) data security requirements for research data.

Example of the format for consent to research and HIPAA Authorization:

The above information has been explained to me and all of my current questions have been answered. To indicate my agreement to participate in this research study, and to allow the use and disclosure of my medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box and by completing the fields below.

Click ***here*** to print a copy of the consent form to keep for your records.

I agree

Full Name: _____ ___ _____(first, middle initial, last name)
Birthdate: ____ / _____ / _____ (mm/dd/year)

Answer to ONE of 3 questions from drop-down box:

What is your mother's maiden name?

In what city were you born?

What high school did you attend?

Additional Information:

Pennsylvania Statutes:

- TITLE 73. TRADE AND COMMERCE CHAPTER 41. REGULATORY ELECTRONIC TRANSACTIONS5.1 – Inspection Information

Title 45 Part 46 Protection of Human Subjects

- General Requirements for informed consent 45 CFR 46.116
- Documentation of informed consent 45 CFR 46.117