What Are Waivers and When Do I Need Them?

By Renée Collins, IRB HIPAA Coordinator

There are waivers for consent and waivers for authorization. There are two main types of waivers of consent, a full waiver of consent, and a waiver of documentation. The IRB asks about modifications of consent in the same section, but modifications are requested when you are changing the consent process but still plan on obtaining full consent (ex. within 12hrs after doing the study procedure). HIPAA waivers of authorization are needed to enroll in a study if PHI is being accessed, used, and/or kept and written authorization is not being obtained or “to identify” if PHI is being shared outside the covered entity.

Full Waiver of Consent:

- Typically used for retrospective record reviews;
- Subject never knows their information was used for research;
- Consent will never be obtained from the participant;
- The data will need to be de-identified at the earliest feasible time point;
- There must be a justification for requesting a full waiver such as no access to accurate contact information, people having left the practice, or they may be deceased.

Waiver of Documentation of Consent:

- Typically used in survey studies, prospective record reviews, or phone screens when PHI is collected;
- Information is provided to the potential subject, but a signature is not required. This can be in writing or read to the potential subject;
- Use when the only link to the participant would be the signed consent form and the principal risk is disclosure OR;
- There are no study procedures or risks for which consent is typically required outside of research;
- Template sample can be found on the IRB-01 website under Standardized Text.

HIPAA Waiver of Authorization:

- “To Enroll” - typically used in record review studies when identifiers are being collected or a link maintained for a period of time;
- “To Enroll” - also needed if phone screen collects PHI prior to informed consent being signed;
- “To Identify” - typically needed if PHI is being obtained in the screening process and the information is being shared outside the covered entity (e.g., screening log to sponsor).

myIRB...Help!

The IRB office has received a few phone calls recently where study staff members have been unable to correctly print informed consent forms from myIRB that show both the stamped watermark and expiration dates. We’ve discovered that the print screen needs to have a radio button for “shrink oversized pages” selected. Otherwise, the date stamp is too high on the page and only the watermark logo will print. The printers in the IRB office default to this setting but others do not.

Attached with this newsletter is a pdf of a screen shot where you can see what the print screen might look like. Please keep in mind that each print screen may look different.
When an Investigator Leaves UF/Shands/VA

If an investigator’s employment with the University, Shands or VA is discontinued, he or she must do one of the following with each approved/active study prior to leaving the university: (1) assign the study to a new principal investigator or (2) close the project. These changes must be reported to the IRB by submitting either a formal revision or a Study Closure report. This notification must be submitted in advance (prior to the termination of employment).

In the event the PI fails to do either, all active studies become the PI’s supervisor’s (Department Chair, Dean, etc.) responsibility. The supervisor will then be responsible for the conduct of all studies and must either name a new PI and renew or close each study.

The Office of Research has also implemented a “Notification of Departing PI” form. This is a short form that College representatives (e.g. Research Dean, Department Chair, or Departmental Contact) can submit to inform all research units (Division of Research Programs, Contracts & Grants, IRB, RAC, IACUC, etc.) that a PI is leaving the University. This is a web-based form that tells us who the PI is that is leaving, his/her date of departure, reason for leaving, and who we should contact if we have questions. Once filled out, the College representative clicks a submit button and all research units will receive an email containing the results of the form.

The form can be accessed directly at: http://research.ufl.edu/depart.html.

Or at the Office of Research Forms page at: http://research.ufl.edu/faculty-and-staff/forms.html.

Advertisements for Subject Recruitment

All flyers; newspaper, radio, and television advertisements; and electronic or web-based notices designed to recruit participants for research must be reviewed and approved by the IRB before they can be implemented. Federal regulations (21 CFR 56.107(a) and 56.111) require that all communication between an investigator and a potential subject must be reviewed and approved by the IRB. This includes advertising because it begins the process of informed consent.

The UF IRB’s position is that advertisements, generally, should be limited to the information that the prospective subjects need in order to determine their possible eligibility and interest. An ad may include, but does not require, all of the following items:

- Contact information of the PI and/or research staff to contact for further information;
- The condition under study/or purpose of the research;
- A summary of eligibility criteria;
- A brief list of participation benefits and risks, if any;
- The time or other commitment required of the subjects;
- The location of the research.

The IRB will review the content of any advertisement and its mode of communication for appropriateness. IRB-approved print advertisements will have an IRB stamp and date of approval. The final/most recent IRB-approved stamped version should be posted. Please refer to the IRB opinion paper (ADVERTISING to Recruit Subjects) for more information.

IRB Full Board Meeting Deadlines

~ Spring 2015 ~

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IRB Education Opportunities

~ March Brown Bag Series ~

Broad Building, Room 104
Noon - 1:30 PM
March 11, 2015

“Using Social Media in Clinical Research”

By Lauren Solberg JD, MTS
Assistant Professor
Program in Bioethics, Law and Medical Professionalism
Department of Community Health & Family Medicine
University of Florida, College of Medicine

RSVP: Tiffany Danielle Pineda
tiffany.danielle@ufl.edu
To ensure that myIRB stamped documents print both the study expiration dates and the UF watermark – ensure that the button below is checked: