
From: Biener, Steven L
Sent: Wednesday, December 21, 2011 3:55 PM
To: Schreiner, MARK S; Levy, Susan
Subject: Research involving phone interview and recording

Following up on my conversation with Dr. Schreiner, under the Recording or Filming of Patients policy, recording telephone call interviews is subject to IRB Approval. Language consistent with standard recording or filming language is to be incorporated in the ICF. (see D.1)

I understand the IRB has or will approve consenting the subjects over the phone, and not require a signed ICF. So long as the appropriate recording and filming language is included in the ICF and consented to by the subject consistent with the IRB approved procedure, I think that would be sufficient.

As you know, under PA's wiretap statute (a criminal statute), consent to recording the call must be secured before recording another person.

Once consent to recording is secured and the recording begins, will the entire conversation, including the discussion and consent of the ICF be recorded? If so, the recording would provide proof of consent of the subject. If the intent is not to record the ICF consenting process, then you may want to review the attached document regarding the procedures to be followed for getting telephone consents to treatment. It would be good to document your oral consenting process in a manner consistent with that process.

Let me know if you would like to discuss further.

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