

Procedure for Observation of the Consenting Process

- 1) When the IRB determines that a protocol can be approved, but needs observation of the consenting process, its rationale for that decision is described in the minutes of the convened meeting. (e.g. risk of study). The IRB will also decide the number of observations to be done, ranging from observing the first (*'specified number'*) participants, to including the entire sample, based on their judgment of risk.
- 2) The IRB Manager will contact the study coordinator and the study Principal Investigator (PI) about the need for observing consenting of study participants. They will work out mutually agreeable dates and times for the observer to observe consenting.
- 3) Just prior to observing consenting, the observer will:
 - i. Introduce himself/herself to the potential study subject,
 - ii. Explain the reason for the observer's presence, and
 - iii. Obtain the participant's verbal permission for observing consent.
- 4) The observer will document her observations on the Consent Observation Checklist. During consenting, should any issues or questions arise that the consenter is unable to address and that the observer is qualified to discuss or answer, the observer may offer appropriate explanations or information.
- 5) After consenting has been completed, the observer may meet with the person who administered consent to discuss the findings about the consenting that has just taken place. Often, the consenter does not have an opportunity to sit down with the observer immediately after a participant has been consented because the staff member must stay with the participant to initiate study screening.
- 6) In all cases, the observer prepares a written report which is conveyed to the consenter. If either the observer or the consenter wishes to discuss the findings face-to-face, they will arrange an informal meeting. Occasionally, the observer may schedule a second consent observation with the study staff member, to determine if some observed "deficiencies" have been corrected.
- 7) Because the informed consent observations are done for both educational and monitoring purposes, the written reports are first shared with the consenter who is being evaluated. Then, with that person's response in mind, (and possible corrective actions planned), the observer would share the findings with the Protocol Director, the IRB Chair and IRB Manager. Should repeated serious deficiencies be noted by the observer, they would follow the STANFORD policy on non-compliance (See Chapter 3.)

See: Consent Observation Checklist (Document C.4.f.iv.)