Guidance on Observation of the Consenting Process

1) When the IRB determines that a protocol requires observation of the consenting process, its rationale for that decision is described in the minutes of the convened meeting (e.g. risk of study) and reported to the PI in the approval letter which is also forwarded to the Office of Regulatory Affairs & Compliance (ORAC) and/or Office of Clinical Research (OCR). The IRB will determine the number of observations necessary (ranging from observing solely the first participant, to observing a specified number of participants up to and including the entire sample, depending on the risk).

2) The ORAC or OCR and the PI/Coordinator will work out mutually agreeable dates and times for the observer to observe consenting.

3) Observers will be required, just prior to observing consenting, to:
   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 his/her observations. During consenting, should any issues or questions arise concerning the reason for the observation, the observer may contribute to the discussion (under the supervision of the consenter), attempt to mitigate the risk (e.g., explain the potential for undue influence, explain the voluntary nature of the decision, reflect on the alternatives, etc.), or they may suggest the subject refrain from making a decision until a different consenter is available to answer their questions.

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. This may be deferred if no substantive issues arise or it may be scheduled at a later time if the consenter does not have an opportunity to meet with the observer immediately after a participant has been consented (e.g., 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 a meeting. Occasionally, the observer may schedule a second consent observation with the study staff member, to determine if observed “issues/deficiencies” have been addressed.

7) Because the informed consent observations are performed for both educational and monitoring purposes, the written reports are first shared with the consenter who is being evaluated. Then, incorporating that person’s response (written or verbal (possibly with corrective actions already conceived), the observer shares the findings with the IRB Director, the IRB Chair and PI. Should deficiencies be noted by the observer as serious or continuing non-compliance the IRB policy on non-compliance would be initiated.