

Procedures for Monitoring the Consent Process

When the IRB determines that a protocol can be approved, but 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).

The IRB will also identify whether an IRB member, selected trained OHRS staff member or a qualified member of the DF/HCC auditing committee will conduct the consent observations. All consent monitors will receive training from OHRS.

Consent Monitoring Procedures:

1. Once the consent monitor has been identified, the OHRS Senior Director or staff member will provide this information to the principal investigator.
2. Prior to the consent session, the principal investigator or designated study team member will provide the monitor with a copy of the approved informed consent document.
 - The consent monitor will utilize a copy of the approved consent document during the consent process to assure that all elements of the consent document are addressed by the investigator.
3. Prior to initiating the consent process, the person obtaining consent will:
 - Introduce the consent monitor to the potential study subject;
 - Explain the reason for the monitor's presence; and
 - Obtain the subject's verbal permission for observing consent.
4. The consent monitor has five principal duties:
 - **Listen.** The consent monitor should listen to the consent process and exchange between the investigator and the subject and the subject's family.
 - **Observe.** The consent monitor should closely observe the communication between the investigator and the subject. The monitor should use her/his knowledge of the consent document and be prepared to ask questions of the investigator or the subject if it appears that things are not clear.
 - **Ask Questions.** At any time during the consent session, the consent monitor may request that the investigator review or clarify information for the potential subject and/or seek clarification of comprehension from the potential subject.

The consent monitor should be prepared to ask questions in order to facilitate comprehension on the part of the subject. In order to understand whether the subject fully comprehends the research and is making a knowledgeable decision about participation, questions should elicit a response from the subject that requires some deliberation and thought about the research rather than yes/no questions.

- **Document.** The consent monitor should document the interactions, questions, answers, and the decision-making process.
 - **Decide.** The consent monitor should decide with the investigator and the subject whether the subject should be enrolled in the research, be provided additional time to consider participation in the research, or not be enrolled. The consent monitor may determine that a subject does not understand the consent process or the research and request that the investigator re-review the materials with the subject. If the monitor does not think the subject understands the research or all items of the consent document, then the subject should not be enrolled in the research.
5. At the end of the consent session, the consent monitor will prepare a written report summarizing his/her observations. The consent monitor will forward the report to OHRs for IRB review.