Background

In accordance with its charge, the IRB has procedures for observation of the informed consent process in ongoing research, when appropriate. As part of IRB oversight, the IRB may require that a staff member or an outside third party observe the consenting of research participants to determine whether:

- The informed consent process has been appropriately completed and documented;
- The participant has had sufficient time to consider study participation;
- No coercion has been used by the consenting staff; and
- The information presented to the participant reflects the content of the consent form and is conveyed in understandable language. (HRPP Chapter 12.7)

These observations are conducted by CQI staff, IRB Managers, or other RCO staff members ("Observer").

(A) CQI procedures - CQI:

1. Periodically at the request of Management selects protocols for routine consent observation, using the criteria listed in HRPP Chapter 12.7.
2. Monitors the review process; receives the Observer's written report; tracks the forms and results. *See (B) Observer Procedures*
3. Assists in determining if additional education is required or if a second consent observation should be scheduled for the study.
4. Prepares a summary report which is sent to the POC, the Protocol Director (PD), and if appropriate, to the IRB Chair.
5. Forwards review results to the Director of Compliance Office.

(B) Observer procedures – Observer:

1. Contacts the study coordinator and the PD about the need for consent observation when a participant is scheduled to come in for consenting. A mutually agreeable date and time is set up.
2. At the consent observation meeting, the observer will:
    i. Introduce herself /himself to the potential participant;
    ii. Explain the reason for her/his presence; and
    iii. Obtain the participant's verbal permission for observing consent.
3. Documents the observations on the Consent Observation Checklist (CHK-C15).
4. May discuss any initial observations privately with the POC after consenting is completed.
5. Prepares a written report which is forwarded to the CQI Associate Director and the Senior Compliance Analyst.