

Consent process observations are conducted by IRB Managers or other HRPP staff (the “Observer” in procedures below) to determine adherence to HRPP Policies.

Summary

As part of the IRB oversight options, the IRB may require that a staff member observe the consenting of research participants to determine:

- Whether the informed consent process has been appropriately completed and documented;
- Whether the participant has had sufficient time to consider study participation, that no coercion has been used by the consenting staff; and
- That the information presented to the participant reflects the content of the consent form and is conveyed in understandable language.

Procedures

1. Protocol Selection

Periodically at the request of RCO Management, Continuous Quality Improvement (CQI) staff provides a selection of suggested protocols for routine consent observation. The IRB also may require that one or more informed consent process situations be observed for selected protocols. IRB considerations on choosing such protocols include the criteria listed in [HRPP Chapter 12.7](#), as well as protocols that enroll at an extremely high rate.

2. Observer procedures

- i. Contact the study coordinator and the PD about the need for consent observation when a participant is scheduled to come in for consenting.
- ii. A mutually agreeable date and time is set up.
- iii. At the consent observation meeting, the observer:
 1. Introduces herself /himself to the potential participant;
 2. Explains the reason for her/his presence; and
 3. Obtains the participant’s verbal permission for observing consent.
- iv. Document the observations on the [Consent Observation Checklist](#) [CHK-C15].
- v. If possible, discuss initial observations privately with POC after consenting is completed.
- vi. Forward the completed Consent Observation Checklist to the Senior IRB Manager, who will forward to the Senior Compliance Analyst.

3. Senior Compliance Analyst procedures

- i. Monitors the review process; receives the Observer’s report; tracks the forms and results.
- ii. Assists in determining if additional education is required or if a second consent observation should be scheduled for the study.
- iii. Prepares a summary report which is sent to RCO Senior Management as instructed.
- iv. RCO Senior management may request that a copy be sent to other parties e.g., POC, Protocol Director (PD), IRB Chair.

Resources	
Guidance, Forms	<ul style="list-style-type: none"> • CHK-C15 Consent Observation Checklist • TEM-29 Consent Observation email template
HRPP Policy Manual	<ul style="list-style-type: none"> • Chapter 12.7