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 Office of Protocol Support and Management (OPSM) 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 PI 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.

v. If possible, discuss initial observations privately with Person Obtaining Consent (POC) after consenting is completed.

vi. Forward the completed Consent Observation Checklist to the IRB Manager, who will forward to the Quality Assurance Specialist.

3. Quality Assurance Specialist 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 OHSP Director and IRB Manager, who in turn will provide to OPSM as instructed.

iv. OHSP Director may request that a copy be sent to other parties e.g., POC, Principal Investigator (PI), IRB Chair.

Consent process observations are conducted by IRB Manager or other OHSP staff (the “Observer” in procedures below) to determine adherence to OHSP Policies.
## Consent Process Observation

### Resources

| Guidance, Forms | • Consent Observation Checklist |
| HRPP Policy Manual | • Chapter 12.7 |
This form is to be completed by the person observing consent.

Protocol #:  
Date:  

1) Name and Title of the observer:  

2) Study name:  

3) Name and Title of the Person Obtaining Consent (POC):  

4) Description of Participant, e.g., does participant fit the age/gender profile per the protocol?  

5) The observer considers the following key elements when observing consenting of a potential study participant (other issues may also be considered by the observer):  

   Is the consent form the most recent IRB-approved version? Yes □ No □  

   Does the POC mention that the study involves “research?” Yes □ No □  

   Does the POC describe the study procedures (following the consent descriptions)? Yes □ No □  

   If study involves an unapproved agent (i.e., not FDA approved), does POC explain this? Yes □ No □  

   Does the POC solicit and sufficiently answer questions? Yes □ No □  

6) Does the POC avoid using medical terms and scientific jargon that the participant clearly does not understand, and does the POC communicate using understandable language? Yes □ No □  

7) If participant agrees to enroll, are the consent form and HIPAA Authorization properly signed and dated? N/A □ Yes □ No □  

8) Is a copy of the signed consent form with HIPAA Authorization given to the participant? N/A □ Yes □ No □
Consent Observation Checklist

9) Is the consenting “environment” suitable (e.g., private, reasonably comfortable)? **Yes** □ **No** □

10) Did the POC spend sufficient time obtaining informed consent? ................................. **Yes** □ **No** □

Other:

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