TITLE: **Observation of the Consent Process**

PURPOSE: To observe the consent process

RESPONSIBILTIES: HSPP staff, IRB members, independent person hired by the IRB or any other person deemed appropriate by the IRB

PROCEDURES:

The process begins when the IRB determines that the consent process should be observed. This happens when:

- The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.
- There are Allegations or Findings of Non-Compliance.
- The nature of the research indicates that the consent process can be improved through observation.

The IRB will observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the legally authorized representative.

- If no, indicate that consent is not legally effective and the prospective subject may not be entered into the research.
- If yes, document in writing that the consent process was observed and that informed consent was freely given by the subject or legally authorized representative.

The process ends when the IRB determines that the consent process no longer should be observed.

MATERIALS:
None.

REFERENCES:

- 45 CFR §46.109(e), 45 CFR §46.116,
- 21 CFR §50.20, 21 CFR §50.25, 21 CFR §56.109(f)

REVIEW/REVISIONS: From 10/01/2010 version: Renumbered from P&P-012.