1 PURPOSE
1.1 This procedure establishes the process to observe the consent process.
1.2 The process begins when the HRRC determines that the consent process should be observed.
1.3 The process ends when the HRRC determines that the consenting process no longer should be observed.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None
2.2 Correction of spelling and grammatical errors throughout SOP.
2.3 Replaced all references to “IRB” with “HRRC.”
2.4 Section 1.3 Clarification of when observation of consent process ends.
2.5 Section 3.1.1 Clarification of who may request verifications of the consent process.
2.6 Section 5.2.3 Clarification of who may request that the results of the observation be reviewed at a convened meeting

3 POLICY
3.1 The HRRC may consider observation of the consent process when:
3.1.1 The HRRC requests verification from sources other than the investigator that no material changes have taken place since prior HRRC review.
3.1.2 There are Allegations or Findings of Non-Compliance.
3.1.3 The nature of the research indicates that the consent process can be improved through observation.
3.1.4 At the discretion of the HRRC chair, a convened HRRC, or by other qualified Human Research Protections Office (HRPO) staff members, as part of routine compliance inspections/ audits or quality improvement monitoring.

3.2 The HRRC may have the observation conducted by:
3.2.1 HRRC members.
3.2.2 HRPO staff.

4 RESPONSIBILITIES
4.1 The person designated to conduct the observation (designated observer) of the consent process carries out these procedures.

5 PROCEDURE
5.1 The designated observer will inform the Principal Investigator (PI) of the consent observation request and the reason for the request.
5.2 The designated observer 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.

5.2.1 If no, indicate that consent is not legally effective and the prospective
subject may not be entered into the research.

5.2.2 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.

5.2.3 The HRRC or HRRC chair may request that the results of the observation
be reviewed at a convened meeting of the HRRC or by qualified HRPO
staff. Further actions may be determined at the time of review.

5.2.4 The results of the observation and any further determinations will be
communicated to the PI and maintained in the study record.

6 MATERIALS
6.1 None

7 REFERENCES
7.1