1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.

1.2 The process begins when the TAMU IRB determines that the consent process should be observed.

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

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 SOP Statement

3.1 The IRB has the authority to observe, or have a third party observe, the consent process.

3.2 The IRB may consider observation of the consent process when:

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

3.3 The IRB, Organizational Official (IO/OO),, HRPP Administration or designee designates who conducts the observation. The IRB may have the observation conducted by:

- 3.3.1 IRB staff.
- 3.3.2 IRB members.
- 3.3.3 HRPP staff
- 3.3.4 A person recommended by the investigator and approved by the IRB
- 3.3.5 An independent person hired by the IRB but paid for by the investigator's funds.
- 3.3.6

4 RESPONSIBILITIES

4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

5.1 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 If the consent process was inadequate, indicate that consent does not appear to be legally effective and the prospective participant may not be entered into the research.

5.3 If the consent process was adequate, document in writing that the consent process was observed and that informed consent was freely given by the subject or legally authorized representative.

5.4 The observer will document their findings. Documentation of the observation will be provided to the IRB. Use REVIEW TOOL WORKSHEET: Consent Process (HRP-336) or equivalent.

6 MATERIALS

6.1 Review HRP-336 - WORKSHEET: Consent Process

7 REFERENCES

7.1 45 CFR §46.109(g)

7.2 21 CFR §56.109(f)