

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-012-0	12/11/2015	HSO	IRB	Page 1 of 2

1. PURPOSE

- 1.1. The purpose of this **policy** is to establish the University of Georgia Institutional Review Board (UGA IRB) process for observing the consent process.

2. POLICY

- 2.1. The IRB has the authority to observe, or have a third party observe, the **consent process**.
- 2.2. An observation may be conducted when:
 - 2.2.1. the IRB wants verification from sources other than the investigator that no material changes have taken place since the last IRB-approved submission;
 - 2.2.2. there are investigations of a complaint, a **suspension or termination of IRB approval, unanticipated problems involving risks to participants or others**, or allegations or findings of non-compliance;
 - 2.2.3. the consent process is being observed as part of an investigator quality improvement assessment (see *Policy and Procedure: Quarterly Evaluations of the HRPP*);
 - 2.2.4. the nature of the research indicates that the consent process can be improved through observation; or,
 - 2.2.5. any other situation the IRB deems appropriate in order to provide additional protections to the **research participants**.
- 2.3. The convened IRB or IRB Chair designates who conducts the observation. The observation may be conducted by one or more of the following:
 - 2.3.1. IRB staff;
 - 2.3.2. IRB members; and/or
 - 2.3.3. An independent person hired by the IRB, but paid for by the investigator's funds.

3. PROCEDURES: Institutional Review Board

- 3.1. 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 using the *Checklist: Observation of the Consent Process*.
 - 3.1.1. 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.
 - 3.1.2. If no, interrupt the process, privately inform the researcher and provide education; determine then if a **legally effective informed consent** process can be continued.

- 3.2. If the observer determines that consent is not legally effective, the prospective subject may not be entered into the research.
- 3.3. Provide appropriate education if the observation identifies items in the checklist that needs improvement.

4. MATERIALS

- 4.1. Checklist: Observation of the Consent Process
- 4.2. Policy and Procedure: Quarterly Evaluations of the HRPP

5. REFERENCES

- 5.1. 45 CFR 46.109(e)
- 5.2. 21 CFR 56.109(f)