



SOP: Observation of the Research and Consent Process				
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1 PURPOSE

- 1.1 This procedure establishes the process to observe the consent process and the research.
- 1.2 The process begins when the IRB determines that the research and/or the consent process should be observed.
- 1.3 The process ends when the IRB determines that the research and/or the consent process should no longer be observed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 2.2 Added “and the research” to the items being observed by the IRB.

3 GUIDING PRINCIPLES

- 3.1 The IRB may consider observation of the research and/or the consent process when:
 - 3.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB 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.
- 3.2 The IRB, Institutional Official, or designee designates who conducts the observation. The IRB may have the observation conducted by:
 - 3.2.1 HSRO staff.
 - 3.2.2 IRB members.
 - 3.2.3 The Office for Research Compliance and Quality Assurance (RCQA)
 - 3.2.4 A person recommended by the investigator.
 - 3.2.5 An independent person hired by the IRB, but paid for by the investigator’s funds.

4 RESPONSIBILITIES

- 4.1 The person designated to conduct the observation of the research and/or the consent process and the research carries out these procedures.

5 PROCEDURE

Observe the research documents and procedures, as directed, to determine whether the research is being conducted in compliance with the protocol, applicable regulations, state law, standard operating procedures and IRB requirements;

- 5.1 Review the consent process and determine whether:
 - 5.1.1 The information in the consent document and any other written information was accurately explained to the subject or the subject’s legally authorized representative (LAR);
 - 5.1.2 The information provided to the subject or the subject’s LAR was correct and compliant with applicable regulations and standard operating procedures;
 - 5.1.3 The individual obtaining consent assessed whether the information in the information provided was understood by the subject or the subject’s LAR;
 - 5.1.4 The subject or the subject’s LAR apparently understood the information provided during the consent process;
 - 5.1.5 The informed consent was given by the subject or the subject’s LAR without apparent coercion or undue influence;
 - 5.1.6 If documentation of informed consent was required:
 - 5.1.6.1 The subject or the subject’s LAR received a copy of the signed and dated informed consent document.
 - 5.1.6.2 The person obtaining consent signed and dated the informed consent document.



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5.1.6.3 A copy of the signed and dated informed consent document was provided to the subject or the subject's LAR.

5.2 Determine whether any observation of non-compliance with applicable regulations, UM requirements and ethical principles were noted during the observations

5.2.1 If non-compliance with applicable regulations, UM requirements and/or ethical principles were noted during the observations, document in writing a description of the observation(s) and the issues identified.

5.2.1.1 If there is a concern that legally effective consent was not obtained or documented in compliance with applicable requirements, provide evidence that underlying federal regulations were violated/not followed, and the prospective subject may not be entered into the research.

5.2.2 If no non-compliance with applicable regulations, UM requirements and/or ethical principles were noted during the observations, document in writing a description of the observation(s) and include a statement that non-compliance was not observed.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None