GUIDANCE: Observation of the Consent Process

NUMBER	DATE	AUTHOR	APPROVED BY	AUDIENCE	USE	PAGE
HRP-012	10/01/2022	Center For Research	Director of Research	Investigators, Institutional Official, Designated Observer	Required: **X** Elective:	Page **1** of **1**

1 PURPOSE

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

1.2 This guidance begins when the Sharp HealthCare (SHC) Institutional Review Board (IRB) determines that the consent process should be observed.

1.3 This guidance ends when the SHC IRB determines that the consent process no longer should be observed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 The IRB may consider observation of 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 IRB staff.

3.2.2 IRB members.

3.2.3 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 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.

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

5.1.2 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.

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 45 CFR 46.109(e)

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