1 PURPOSE

1.1 This guidance establishes the process for review, of research plans to for adequate protection of subjects' privacy and confidentiality.

1.2 The guidance begins when a study protocol is developed and submitted to the Sharp HealthCare (SHC) Institutional Review Board (IRB).

1.3 The guidance ends when IRB supervision of the study activities is complete.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENT

3.1 It is the policy of the SHC IRB to review research protocols and investigator plans for evidence that the study design adequately considers the privacy rights and expectations of subjects, and offers an adequate plan for maintaining the confidentiality of sensitive information related to the study subjects.

4 RESPONSIBILITIES

4.1 To approve research, SHC IRB reviewers must determine that, where appropriate, there are adequate provisions to protect the privacy interests of potential or current subjects, and that there are adequate provisions for protecting the confidentiality of subject data.

4.2 SHC IRB reviewers will also examine each study to assess the amount and types of subject data involved, how subjects will be identified and approached, what information will be collected, how it will be collected, and plans for its use, storage and disclosure.

5 PROCEDURE

5.1 Investigators develop research protocols using *TEMPLATE: Protocol (HRP-500)* or ensure sponsor-provided templates include a description of the procedures the investigators will use to protect the privacy of potential and current subjects and the confidentiality of sensitive subject data.

5.1.1 *FORM: Initial IRB Review Application (HRP-211)* is to include detailed information on how the investigator will address the protection of written and paper documents and other physical media (e.g. CDs, tapes) including electronic data, and how that data will be used, maintained, stored, and transmitted.

5.1.2 *FORM: Initial IRB Review Application (HRP-211)* will also include detailed information on how subjects will be identified and approached, how contact information for subjects will be stored, and with whom this and any other subject-identifiable data set will be shared. As applicable, discussion shall include such information as where, when, and how potential subjects will be approached and consented. Researchers may also address whether future contact with the subjects is fore seen, and describe why this is so and how future contacts will be managed.

5.1.3 Research regulated by the FDA must comply with the information security requirements of 21 CFR Part 11.

5.1.4 Investigators obtain Certificates of Confidentiality when appropriate or required to protect the disclosure of data. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. See *GUIDANCE: Definitions (HRP-001)*.

5.2 The convened SHC IRB or reviewers using the expedited procedure reviews and approves the information security plan according to regulations [45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7)] and SHC policies.

6 MATERIALS

6.1 FORM: Initial IRB Review Application (HRP-211)

6.2 TEMPLATE: Protocol (HRP-500)

7 REFERENCES

- https://humansubjects.nih.gov/coc/index

This document is available in IRBANA or by contacting research@sharp.com.