1 PURPOSE

1.1 This guidance establishes the process for review of research plans to ensure there are adequate measures for 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 SHC IRB oversight of the research activity is complete.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENT

3.1 It is the policy of the SHC IRB, in accordance with *POLICY: Confidentiality of Information (01950.99)* and *POLICY: Research and the HIPAA Privacy Rule (16508),* to review research protocols and investigator plans to confirm that the study design and methods adequately consider the privacy rights and expectations of subjects and offer an adequate plan for maintaining the confidentiality of sensitive information related to the study subjects.

4 RESPONSIBILITIES

4.1 To approve research, SHC IRB must find and document 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 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), TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP), TEMPLATE: Proposal for Nursing Research (HRP-500NR), 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 The investigator or designee will include detailed information *FORM: Initial IRB Review Application (HRP-211)* or *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)* regarding how the investigator will ensure the protection of written and paper documents and other physical media (e.g., USBs, 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)* or *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)* 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 individually identifiable, coded, and/or de-identified data sets 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 foreseen, describe the rationale, 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 Certificates of Confidentiality (CoC) - Investigators obtain a CoC when appropriate or required to protect the disclosure of data.

5.1.4.1 Research is automatically covered by a CoC whenever a research activity is funded in whole or in part by the National Institutes of Health (NIH) and involves identifiable, sensitive information. See *GUIDANCE: Definitions (HRP-001)*. Examples of research automatically covered by a CoC include:

- Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a

manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

- The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
- The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained.
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

5.1.4.2 Not all federal agencies issue a CoC automatically upon the award of the funding. Many agencies still offer a process through which a CoC may be obtained through an application. To apply for a CoC through these agencies the investigator or their designee must contact the funding agency's designated CoC coordinator for further guidance on the process and requirements for obtaining a CoC from the agency. For guidance on how to apply for a CoC from select agencies:

- FDA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality
- Health Resources & Services Administration (HRSA) (proof of IRB approval required*): https://www.hrsa.gov/sites/default/files/hrsa/about/organization/bureaus/opae/coc-policy-update.pdf
- Substance Abuse and Mental Health Services Administration (SAMHSA) (proof of IRB approval required*): https://www.samhsa.gov/grants/gpra-measurement-tools/certificate-confidentiality
- *Select agencies will require that your application for a CoC includes documentation of IRB approval. The SHC IRB can grant approval while the CoC application is pending but a revised protocol and *FORM: Modification Request (HRP-213)* is required to document that the CoC has been issued.

5.1.4.3 If your study is not federally funded or is funded by an agency that does not have a specific CoC process, you may still seek a CoC through the NIH online CoC system.

5.1.4.4 When research is covered by a CoC, researchers:

- May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about

such an individual and that was created or compiled for purposes of the research.

- May disclose information only when:
  - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
  - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
  - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
  - Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
- Must inform subjects (for example, in the consent document) of the protections and limitations of certificates of confidentiality.
  - For studies that were previously issued a Certificate, and notified subjects of the protections provided by that Certificate, NIH does not expect subjects to be notified that the protections afforded by the Certificate have changed, although the SHC IRB may determine whether it is appropriate to inform subjects.
  - If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect subjects consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that subjects who were previously consented to be re- contacted to be informed of the Certificate, although the SHC IRB may determine whether it is appropriate to inform subjects.
- Must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

5.2 The convened SHC IRB or designated 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. For research that is subject to 21 CFR 56 and/or 45 CFR 46 requirements, the SHC IRB will document its findings relative to privacy and confidentiality via *WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)*, which will be maintained in the submission item file.

6 MATERIALS

6.1 POLICY: Confidentiality of Information (01950.99)
6.2 POLICY: Research and the HIPAA Privacy Rule (16508)
6.3 GUIDANCE: Definitions (HRP-001)
6.4 MANUAL: Investigator Guidance (HRP-101)
6.5 FORM: Initial IRB Review Application (HRP-211)
6.6 FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)
6.7 FORM: Modification Request (HRP-213)
6.8 WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)
6.9 TEMPLATE: Protocol (HRP-500)
6.10 TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP)

6.11 TEMPLATE: Proposal for Nursing Research (HRP-500NR)
6.12 TEMPLATE: Informed Consent Document with California Bill of Rights and PHI Authorization (HRP-502)

7 REFERENCES

7.1 21 CFR 11; 21 CFR 56.111(a)(7)
7.2 45 CFR 46.111(a)(7)
7.3 ICH-GCP E6(R2) 2.11
7.4 https://humansubjects.nih.gov/coc/index

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