1 PURPOSE

1.1 This guidance establishes Sharp HealthCare (SHC) Institutional Review Board (IRB) authority to alter or waive the requirement to obtain informed consent and/or Health Insurance Portability and Accountability Act (HIPAA) authorization.

1.2 The guidance begins when an investigator submits a request for alteration or waiver of informed consent and/or of HIPAA authorization via *FORM: Initial IRB Review Application (HRP-211)*, *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)*, or *FORM: Update Recruitment Materials Request (HRP-222)*.

1.3 The guidance ends when the SHC IRB notifies the investigator of its determination(s) to alter or waive informed consent and/or HIPAA authorization.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENTS

3.1 The SHC IRB may approve an investigator's request to waive or alter the requirement to obtain informed consent for a specific research activity if the investigator demonstrates with specificity that the regulatory criteria for alterations or waivers for a particular research project are met.

3.1.1 **Waiver or Alteration of the Informed Consent Process for Public Demonstration Projects** – Under 45 CFR 46.116(e)(3), the SHC IRB may waive the requirement for the investigator to obtain informed consent for research if it finds and documents that the following criteria are met:

3.1.1.1 The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and the research or demonstration protocol is designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs.
- The research cannot practicably be carried out without the waiver or alteration.
- The research is not regulated by the U.S. Food and Drug Administration (FDA).

3.1.2 Waiver or Alteration of Informed Consent Process when Obtaining Informed Consent is Not Practicable

3.1.2.1 For research activities that are supported and/or regulated by DHHS - Under 45 CFR 46.116(f)(3) the SHC IRB may waive the requirement for the investigator to obtain informed consent for research if it finds and documents that the following criteria are met:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or their legally authorized representatives (LARs) will be provided with additional pertinent information after participation.

3.1.2.2 For certain FDA-regulated clinical investigations – Per FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects", the SHC IRB may approve an informed consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or may waive the requirements to obtain informed consent when it finds and documents that:

- The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The clinical investigation could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3.1.3 **Waiver or Alteration of the Informed Consent Process for Screening, Recruiting, or Determining Eligibility** - Under 45 CFR 46.116(g), the SHC IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's LAR, if it finds and documents that either of the following conditions are met:

3.1.3.1 The investigator will obtain information through oral or written communication with the prospective subject or LAR; or

3.1.3.2 The investigator will obtain identifiable private information by accessing records or stored identifiable biospecimens.

3.1.3.3 The research is not regulated by the FDA.

- Exception: The SHC IRB applies 45 CFR 46.116(g)(1-2) to approve research proposals in which an investigator will obtain information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's LAR, if it finds and documents that either of the following conditions are met:
  - The investigator will obtain information through oral or written communication with the prospective subject or LAR; or
  - The investigator will obtain identifiable private information by accessing records or stored identifiable biospecimens.

3.2 Research Involving Children: Waiver of Parental Permission/Guardian Consent

3.2.1 The SHC IRB may approve an investigator's request to waive the requirement to obtain parental permission if the investigator demonstrates with specificity that the criteria for waivers or alterations a particular research project are met.

3.2.2 Research regulated by the FDA is not eligible for waiver of parental permission, except for the use of an FDA test article meeting the emergency exception.

3.2.3 Research is ordinarily not suitable for a waiver of parental permission if it involves any of the following issues:

3.2.3.1 Parental political affiliations or beliefs

3.2.3.2 Mental or psychological problems

3.2.3.3 Sexual behavior or attitudes

3.2.3.4 Illegal, antisocial, or self-incriminating behavior

3.2.3.5 Appraisals of other individuals with whom the minor has a familial relationship

3.2.3.6 Relationships legally recognized as privileged (lawyers, doctors, clergy), and

3.2.3.7 Religious affiliations or beliefs.

3.3 As allowed by OHRP (45 CFR 46.117 (c)) and FDA regulations (21 CFR 56.109(c)), the SHC IRB may waive the requirement to obtain written documentation of informed consent. This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of the consent process itself. A waiver of documentation of consent does not mean that requirements of the consent process are removed.

3.3.1 **Waiver of Documentation of the Informed Consent Process to Protect Subjects' Confidentiality** – Under 45 CFR 46.117(c), the SHC IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds and documents any of the following:

3.3.1.1 That the only record linking the subject and the research would be the informed consent form.

3.3.1.2 The principal risk would be potential harm resulting from a breach of confidentiality.

3.3.1.3 Each subject or their LAR will be asked whether they want documentation linking them with the research, and the subject's or LAR's wishes will govern.

3.3.1.4 The SHC IRB has reviewed and determined that verbal or written information to be provided to subjects includes all required and appropriate additional elements of informed consent disclosure.

- The SHC IRB will determine whether the investigator should provide subjects or their LARs with a written statement regarding the research.

3.3.1.5 The research is not regulated by the FDA.

3.3.2 Waiver of Documentation of the Informed Consent Process When Informed Consent is Normally Not Required Outside of the Research Context

3.3.2.1 For research activities that are supported and/or regulated by DHHS - Under 45 CFR 46.117(c), the SHC IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds and documents any of the following:

- The research presents no more than minimal risk of harm to subjects.
- The research involves no procedures for which written documentation of the informed consent process is normally required outside of the research context.
- The verbal or written information provided to subjects or their LARs includes all required and appropriate additional elements of informed consent disclosure.
- The SHC IRB will determine whether the investigator should provide subjects or their LARs with a written statement regarding the research.

3.3.2.2 For certain FDA-regulated clinical investigations - The SHC IRB may approve an informed consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or may waive the requirement for the investigator to obtain informed consent when it finds and documents that:

- The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to subjects;
- The research involves no procedures for which written documentation of the informed consent process is normally required outside of the research context.
- The SHC IRB has reviewed and determined that the verbal or written information to be provided to subjects or their LARs includes all required and appropriate additional elements of informed consent disclosure.
- The SHC IRB will determine whether the investigator should provide subjects or their LARs with a written statement regarding the research.

3.3.3 **Waiver of Documentation of the Informed Consent Process for Distinct Cultural Groups** - Under 45 CFR 46.117(c)(1)(iii), the SHC IRB may waive the requirement for

the investigator to obtain a signed informed consent form from some or all subjects if it finds and documents any of the following:

3.3.3.1 The research presents no more than minimal risk of harm to subjects.

3.3.3.2 The participants or legally authorized representatives are members of a distinct cultural group or community in which signing consent documents is not the norm.

3.3.3.3 There is an appropriate alternative mechanism for documenting that informed consent was obtained.

3.3.3.4 The verbal or written information provided to subjects includes all required and appropriate additional elements of consent disclosure.

3.3.3.5 The SHC IRB will determine whether the investigator should provide subjects or their LARs with a written statement regarding the research.

3.3.3.6 The research is not regulated by the FDA

3.4 **Waiver or Alteration of HIPAA Authorization Requirements** – Under 45 CFR 164.512(i)(2)(ii) and SHC *POLICY: Research and the HIPAA Privacy Rule (16508)*, the SHC IRB (which serves as SHC's Privacy Board) may approve a waiver or alteration of the Privacy Rule's Authorization requirements, in whole or in part, for the use and disclosure of PHI in connection with a particular research project. The investigator must demonstrate with specificity and the SHC IRB must find and document that the following criteria are met:

3.4.1 The use or disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals based on:

3.4.1.1 An adequate plan to protect the identifiers from improper use and disclosure;

3.4.1.2 An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and

3.4.1.3 Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;

3.4.2 The research could not be practically conducted without the waiver or alteration; and

3.4.3 The research could not be practically conducted without access to and use of the protected health information.

3.5 For each research project that includes requests for waiver or alteration of informed consent and/or HIPAA authorization, the SHC IRB will document its findings justifying the approval or disapproval of requests for waivers or alterations.

4 RESPONSIBILITIES

4.1 For each specific research activity, investigators and/or their designees are responsible for:

4.1.1 Requesting a waiver or alteration of the informed consent process and/or HIPAA authorization via *FORM: Initial IRB Review Application (HRP-211)* or *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)*

4.1.2 Complying with the SHC IRB's determination(s) relative to the request for waiver or alteration of informed consent and/or HIPAA authorization

4.2 For each specific research activity, the SHC IRB is responsible for:

4.2.1 Confirming that all regulatory criteria to approve a waiver or alteration of the informed consent process and/or HIPAA authorization are met

4.2.2 Documenting its justification for approval or disapproval of requests for waiver or alteration

4.2.3 Notifying investigators of their determination(s)

5 PROCEDURE

5.1 Waivers or Alterations to the Informed Consent Process

5.1.1 The investigator may request waivers or alterations to the informed consent process via:

5.1.1.1 *FORM: Initial IRB Review Application (HRP-211)*

5.1.1.2 *FORM: Update Recruitment Materials Request (HRP-222)*

5.1.1.3 *TEMPLATE: Research Protocol (HRP-500)*

5.1.1.4 *TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP)*

5.1.1.5 *TEMPLATE: Proposal for Nursing Research Studies (HRP-500NR)*

5.1.2 To approve a request for a waiver or alteration of the informed consent process, the SHC IRB must find and document that the criteria for waiver or alteration of informed consent are met via one or more of the following:

5.1.2.1 *CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)*

5.1.2.2 *CHECKLIST - Waiver of Written Documentation of the Consent Process (HRP-411)*

5.1.2.3 *TEMPLATE: Agenda / Minutes (HRP-501)*

5.1.2.4 *TEMPLATE: Notification of Non-Committee Reviews (HRP-501b)*

5.2 Special Considerations for Research Involving Deception

5.2.1 The investigator may, with protocol-specific justification, request an alteration of the consent process.

5.2.2 The investigator must describe in the research plan the procedures for the subject or their LAR to authorize the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that they will be unaware of or misled regarding the nature or purposes of the research.

5.2.3 The SHC IRB may approve the research, including the request to alter the requirement for informed consent, if the investigator demonstrates that deception or incomplete disclosure is necessary and addresses concerns relating to participant protection (e.g., debriefing).

5.3 Research Involving Children: Waiver of Parental Permission/Guardian Consent

5.3.1 The investigator may request a waiver of the requirement to obtain parental permission via:

5.3.1.1 *FORM: Initial IRB Review Application (HRP-211)*

5.3.1.2 *FORM: Update Recruitment Materials Request (HRP-222)*

5.3.1.3 *TEMPLATE: Research Protocol (HRP-500)*

5.3.2 The SHC IRB may approve the waiver of parental permission if it finds and documents that the criteria for waivers or alterations are met via:

5.3.2.1 *CHECKLIST: Research Involving Children (HRP-416)*

5.3.2.2 *TEMPLATE: Agenda / Minutes (HRP-501)*

5.3.2.3 *TEMPLATE: Notification of Non-Committee Reviews (HRP-501b)*

5.3.3 If the SHC IRB waives the requirement for parental permission, it may require an alternative mechanism to protect the child participants (e.g., appoint a qualified child advocate).

5.4 Waiver of Documentation of Informed Consent ("Waiver of Signature")

5.4.1 The investigator may request a waiver of documentation of (signed) informed consent via:

5.4.1.1 *FORM: Initial IRB Review Application (HRP-211)*

5.4.1.2 *TEMPLATE: Research Protocol (HRP-500)*

5.4.1.3 *TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP)*

5.4.1.4 *TEMPLATE: Proposal for Nursing Research Studies (HRP-500NR)*

5.4.2 To approve a waiver of documentation of informed consent, the SHC IRB must find and document via *CHECKLIST: Waiver of Written Documentation of the Consent Process*

(HRP-411) that the protocol-specific justification for waiving documentation are satisfied.

5.5 Waiver or Alteration of HIPAA Authorization

5.5.1 The investigator may request a waiver or alteration of the Privacy Rule's HIPAA authorization requirements, in whole or in part, via:

5.5.1.1 *FORM: Initial IRB Review Application (HRP-211)*

5.5.1.2 *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)*

5.5.1.3 *FORM: Update Recruitment Materials Request (HRP-222)*

5.5.1.4 *TEMPLATE: Research Protocol (HRP-500)*

5.5.1.5 *TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP)*

5.5.1.6 *TEMPLATE: Proposal for Nursing Research Studies (HRP-500NR)*

5.5.2 To approve a request for waiver or alteration of the Privacy Rule's HIPAA authorization requirements, the SHC IRB must find and document via *CHECKLIST: HIPAA Waiver of Authorization (HRP-441)* that the protocol-specific justification for waiving or altering HIPAA authorization are satisfied.

6 MATERIALS

6.1 POLICY: Research and the HIPAA Privacy Rule (16508)
6.2 FORM: Initial IRB Review Application (HRP-211)
6.3 FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)
6.4 FORM: Update Recruitment Materials Request (HRP-222)
6.5 WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314)
6.6 CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)
6.7 CHECKLIST: Waiver of Written Documentation of the Consent Process (HRP-411)
6.8 CHECKLIST: Research Involving Children (HRP-416)
6.9 CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
6.10 TEMPLATE: Research Protocol (HRP-500)
6.11 TEMPLATE: Proposal for Evidence-Based Practice (EBP) Project (HRP-500EBP)
6.12 TEMPLATE: Proposal for Nursing Research Studies (HRP-500NR)

7 REFERENCES

7.1 FDA: 21 CFR 56.109(c); 21 CFR 56.109(d); Guidance - IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects
7.2 DHHS: 45 CFR 46.116(e); 45 CFR 46.116(f); 45 CFR 46.116(g); 45 CFR 46.117(c)(1); Informed Consent FAQs
7.3 HIPAA: 45 CFR 164.512(i)(2)(ii)

This document is available on www.sharp.com/research, IRBANA or by contacting research@sharp.com.