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 as per Under OHRP 45 CFR 46.116(c), (d), and (e).

1.2 The guidance begins when an investigator submits an IRB application for review.

1.3 The guidance ends when IRB determination is made to alter or waive consent and/or HIPAA authorization and the investigator is notified of the decision.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENT(S)

3.1 The IRB may approve an investigator's request to waive or alter the requirement to obtain informed consent if the investigator demonstrates with specificity that the criteria under 45 CFR 46.116(c) or 46.116(d) are met.

3.2 As allowed by OHRP (45 CFR 46.117 (c)) and FDA regulations (21 CFR 56.109(c)), the 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 The IRB may approve an investigator's request to waive or alter the requirement to obtain informed consent if the investigator demonstrates with specificity that the criteria under 45 CFR 46.116(c) or 46.116(d) are met.

4 RESPONSIBILITIES

4.1 To request a waiver or alteration of the informed consent process, the investigator must demonstrate that each of the criteria under Section 46.116(c) or (d) is met for the given protocol. (*FORM: Initial IRB Review Application [HRP-211]*)

4.2 To approve a waiver or alteration of the informed consent process, the IRB must find and document that all regulatory criteria under 45 CFR 46.116(d) are met and that the research is not subject to FDA regulations.

5 PROCEDURE

5.1 To approve such a request for a waiver or alteration of the informed consent process under 46.116(d), the IRB must find and document the following:

5.1.1 The research involves no more than minimal risk to the subjects;

5.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

5.1.3 The research could not practicably be carried out without the waiver or alteration; and

5.1.4 Whenever appropriate, subjects will be provided with additional pertinent information after participation. (*FORM: Initial IRB Review Application [HRP-211]*)

5.2 Special Considerations for Research Involving Deception

5.2.1 In research involving deception, the investigator may, with protocol-specific justification, request an alteration of the consent process. The 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 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 The IRB may waive parental permission by determining that the criteria for waivers or alterations are met. However, research is ordinarily not suitable for a waiver of parental permission if it involves any of the following issues:

5.3.1.1 Parental political affiliations or beliefs

5.3.1.2 Mental or psychological problems

5.3.1.3 Sexual behavior or attitudes
5.3.1.4 Illegal, antisocial, or self-incriminating behavior
5.3.1.5 Appraisals of other individuals with whom the minor has a familial relationship
5.3.1.6 Relationships legally recognized as privileged (lawyers, doctors, clergy), and
5.3.1.7 Religious affiliations or beliefs.

5.3.2 If the 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 Consent ("waiver of signature").

5.4.1 To approve a waiver of documentation, the IRB must find that the protocol-specific justification for waiving documentation satisfies regulatory criteria. Specifically, the IRB must determine the regulatory basis for the waiver as one of the following (note that (a) does not apply for FDA-regulated research). Under OHRP (45 CFR 46.117(c)(1) the IRB must find and document either:

5.4.1.1 The only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes will govern; or

5.4.1.2 The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or

5.4.1.3 For research subject to OHRP and FDA regulations, the IRB must find and document that the research involves no more than minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context. (45 CFR 46.117(c)(2), 21 CFR 56.109(c)(1)).

5.5 Waiver or Alteration of HIPAA Authorization

5.5.1 In order to waive or alter an authorization, the investigator must provide sufficient information on which the IRB may make the following three findings specified by the Privacy Rule (45 CFR 164.512(i)(2)(ii) and SHC *POLICY: Research and the HIPAA Privacy Rule (16508)*.

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

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

5.5.1.1.2 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

5.5.1.1.3 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;

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

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

6 MATERIALS

6.1 POLICY: Research and the HIPAA Privacy Rule (16508)
6.2 FORM: Initial IRB Review Application (HRP-211)

7 REFERENCES

7.1 OHRP 45 CFR 164.512(i)(2)(ii)
7.2 OHRP 45 CFR 46.117(c)(1)
7.3 OHRP 45 CFR 46.116(c) (d), and (e),
7.4 FDA regulations (21 CFR 56.109(c))

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