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## 1. POLICY:

There are instances in which it may be appropriate to waive or alter the requirement to obtain informed consent or documented (signed) informed consent from subjects. All requests for such waivers or alterations must meet federal regulatory requirements and must be approved by the Institutional Review Board (IRB).

These procedures apply to all non-exempt research protocols.

## 2. DEFINITIONS

- 2.1** *Assent.* An Individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- 2.2** *Enroll.* To enter into a research study by means of signing an informed consent document.
- 2.3** *Information Sheet.* A document conveying information typically required in an informed consent document absent signature lines for subjects.
- 2.4** *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.5** *Informed Consent Document.* A document that certifies a person's informed consent.
- 2.6** *Informed Consent Process.* The process of informing a potential subject or a potential subject's Legally Authorized Representative (LAR) which includes, but is not limited to, explanation of the protocol, review of the consent document, and answering questions.
- 2.7** *Minimal Risk.* Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.
- 2.8** *Not Practicable.* Incapable of being put into practice or of being done or accomplished. The term "not practicable" means more than simple inconvenience, it means the research could not be otherwise conducted.
- 2.9** *Risk.* The possibility of harm to a subject in a research study.
- 2.10** *Test Article.* Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or

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any other article subject to regulation under the Federal Food, Drug and Cosmetic Act or under §351 or 354-360F of the Public Health Service Act.

### **3. PROCEDURES**

#### **3.1 Waiver or Alteration of Informed Consent**

- 3.1.1 To obtain a waiver or alternation of informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process.
- 3.1.2 The request for waiver or alteration will be reviewed by the convened IRB (see SOP 302: Initial Review) or by the IRB Chair or designated expedited reviewer (see SOP 303: Expedited Review).
- 3.1.3 The IRB reviewer may approval the waiver or alteration of informed consent pursuant to 45 CFR 46.116(e) (Public Benefit and Service Programs), if the IRB reviewer determines and documents that:
  - (a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - (i) Public benefit or service programs;
    - (ii) Procedures for obtaining benefits or services under those programs;
    - (iii) Possible changes in or alternatives to those programs or procedures; or
    - (iv) Possible changes in methods or levels of payment for benefits or services under those programs; and
  - (b) The research could not practicably be carried out without the waiver or alteration.
- 3.1.1 The IRB reviewer may approval the waiver or alteration of informed consent pursuant to 45 CFR 46.116(f) (General Research), if the IRB reviewer determines and documents that:
  - (a) The research involves no more than minimal risk to the subjects;
  - (b) The research could not practicably be carried out without the requested waiver or alteration;

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- (c) 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;
- (d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

3.1.2 The IRB reviewer will document the findings for Waiver or Alteration of Informed Consent.

3.1.3 An alteration to informed consent may apply when conducting a study where there is deception or an incomplete disclosure. Examples of such research would be certain types of ethnographic research, and studies that require deception because the study would be compromised if participants were told the true purpose.

### **3.2 Screening, recruiting, or determining eligibility.**

An 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 either of the following conditions are met:

3.2.1 The Investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

3.2.2 The Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

### **3.3 Subject Refusal to Grant Broad Consent**

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with SOP 320: Informed Consent Requirements, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

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### **3.4 Waiver of Signed Consent Form**

- 3.4.1 A waiver of a signed informed consent form may be appropriate for some research studies. Examples of such studies are survey or interview studies that contain highly sensitive questions (e.g., health status, sexual practices, criminal behavior, etc.), or surveys containing non-sensitive information.
- 3.4.2 To obtain a waiver of documented (signed) informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process.
- 3.4.3 The request for waiver or alteration will be reviewed by the convened IRB (see SOP 302: Initial Review) or by the IRB Chair or designated expedited reviewer (see SOP 303: Expedited Review).
- 3.4.4 The IRB reviewer will consider the Investigator's request and review the request to determine either:
  - (a) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
  - (b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
  - (c) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- 3.4.5 The IRB reviewer will document the findings for Waiver or Alteration of Informed Consent.
- 3.4.6 In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research, such as an information sheet, in lieu of an informed consent document.

### **3.5 Waiver or Alternation of Informed Consent in FDA Research**

- 3.5.1 When research is subject to the Food and Drug Administration (FDA) regulations, a waiver or alteration of informed consent will be allowed

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only in certain emergency situations that meet the criteria in 21 CFR 50.23 or 21 CFR 50.24.

- 3.5.2 In most FDA research, the obtaining of informed consent will be deemed feasible, unless both the Investigator and a physician who is not otherwise participating in the research certify in writing all of the following:
- (a) The human subject is confronted by a life-threatening situation necessitating the use of the test article.
  - (b) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
  - (c) Time is not sufficient to obtain consent from the subject's legal representative.
  - (d) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
- 3.5.3 If immediate use of the test article is, in the Investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in Section 3.4.2 in advance of using the test article, the determinations of the Investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the research.
- 3.5.4 The documentation required in Section 3.5.2 or 3.5.3 shall be submitted to the IRB within five (5) working days after the use of the test article.

#### **4. RESPONSIBILITY**

##### **4.1 Investigator Responsibilities**

- 4.1.1 The Investigator request waiver or alternation of informed consent as part of the protocol submission process.
- 4.1.2 The Investigator must conduct the informed consent process in accordance with the IRB approved protocol.
- 4.1.3 The Investigator must use the IRB approved consent form unless that requirement has been waived.
- 4.1.4 If a waiver of signed informed consent is granted in accordance with Section 3.4 above, the Investigator must ask the subject whether the

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subject wants documentation linking the subject with the research, and the subject's wishes will govern.

## **4.2 IRB Responsibilities**

- 4.2.1 HRPP Protocol Analysts are responsible for conducting administrative review of requests for waiver or alteration of informed consent and signed informed consent, informed consent forms and debriefing informed consent forms, information sheets and communicating requests for clarification and required changes to investigators.
- 4.2.2 The IRB Administrator is responsible for advising Investigators on appropriate procedures and requirements. Additionally, s/he is responsible for assisting the Protocol Analysts with administrative reviews.
- 4.2.3 IRB Members are responsible for reviewing informed consent procedures and documents, requests for waivers and alterations and making findings and determinations for full review protocols.
- 4.2.4 IRB Chair or his/her designee is responsible for reviewing informed consent procedures and documents, requests for waivers and alterations and making findings and determinations.
- 4.2.5 IRB Reviewer is responsible for documenting findings for granted waivers and alterations on the Review Form for Waiver or Alteration of Informed Consent.

## **5. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.116; 45 CFR 46.117

21 CFR 50.23; 21 CFR 50.24

[OHRP Guidance on Informed Consent](#)

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**6. REFERENCES TO OTHER APPLICABLE SOPs**

302 Initial Review

303 Expedited Review

320 Informed Consent Requirements