1. PURPOSE

This procedure describes the requirements for waiver of some or all the elements of informed consent procedures and waiver of requirements for obtaining informed consent.

2. PROCEDURE

The IRB may approve an informed consent procedure that does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria. Note: exempt projects do not require a waiver.

3. SPECIFIC PROCEDURES

3.1 Non-FDA Regulated studies: IRB Waives One or More Requirements of Informed Consent

The IRB may approve an informed consent procedure that does not include, or which alters some or all of the elements of informed consent, or waives the requirement to obtain informed consent provided the IRB finds and documents that:

- 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:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; or
  - Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration, such as in prospective emergency research conducted under 21 CFR 50.24, when time may not permit informed consent.

Or that:

- The research involves no more than minimal risk to human subjects.
- The waiver or alteration will not adversely affect the rights and welfare of human subjects,
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, human subjects will be provided with additional pertinent information after participation.
- 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.

3.2 FDA Regulated Studies

The IRB is allowed to waive the requirement to document the informed consent process by determining that the regulatory criteria for waivers are met.

- When the IRB considers waiving the requirement to obtain written documentation of the informed consent process, the IRB reviews a written description of the information that may be provided to human subjects.

- When granting waivers of the requirement to obtain written documentation of the informed consent process, the IRB considers requiring the researcher to provide human subjects with a written statement regarding the research.

3.3 When Obtaining Informed Consent from a Parent is Not Reasonable

If the IRB determines that a research protocol is designed for conditions or for a human subject population for which parental or LAR permission is not a reasonable requirement to protect the human subject (e.g., abused or neglected children), it may waive the consent requirements provided that:

- The research was designed for conditions or for a human subject population for which parental or guardian permission was not a reasonable requirement to protect human subjects.
- An appropriate mechanism for protecting the children who would participate as human subjects in the research was substituted; and
- The research was not FDA-regulated.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the human subjects, and their age, maturity, status, and condition.

The IRB may waive parental permission by determining that:

- The research involves no more than minimal risk to human subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the human subjects;
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the human subjects or human subject's LAR will be provided with additional pertinent information after participation;
- The research is not FDA-regulated;
- 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 IRB may also consider an *alteration* of the informed consent process. This may occur in situations where human subjects are provided information about the study, but a consent discussion does not occur, such as on-line studies, surveys sent to human subjects via the mail, email or fax, and other types of research for which an informed consent process is not practical. Justification based on the above listed points must be provided to the IRB in the same manner as a request for waiver of informed consent.

3.4 An Emergency Situation Prior to IRB Review and Approval

For research which falls under the jurisdiction of the FDA, obtaining informed consent shall be deemed feasible except in certain emergency situations described under 21 CFR 50.23 and 21 CFR 50.24**.** In emergency situations where informed consent cannot be obtained prior to interaction or intervention with a human subject, the PI must submit to the IRB, within five (5) working days of the emergency, documentation of the necessary exception.

In review of the documentation, the IRB will ensure that the PI and a physician not otherwise participating in the investigation have adequately certified all of the following in writing:

a. the human subject was confronted by a life-threatening situation necessitating the use of the test article;
b. informed consent could not be obtained from the human subject because of an inability to communicate with, or obtain informed consent from the human subject;
c. time was not sufficient to obtain consent from the human subject or human subject's LAR; and
d. there was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the human subject.

4. RESPONSIBILITY

IRB staff and IRB members are responsible for determining whether informed consent waivers are applicable and appropriate, and determination should be documented appropriately.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24, 50.55(e)
21 CFR56.109(c), 56.109(d)
45 CFR 46.116(e), (f), and (g)

6. REFERENCED DOCUMENTS

Waiver or Alteration of Consent Process Checklist
Waiver of Written Documentation of Consent Checklist

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	6/29/2020	Avera Institutional Official	7/10/2020
• Added the additional reason the IRB may waive the informed consent requirement, as per regulation: 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. • IRB should document if the waiver is appropriate. • Updated regulations. • Other administrative edits.			
1.0	August 2016	Director HSRP / August 2016	