

<b>Waiver of Documentation of Informed Consent</b>	Effective	
	Revised	1.21.2019

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to outline the requirements to obtain a waiver for the documentation of informed consent.
- 2.0 Persons Affected:**
- 2.1 Principal investigators (PI) and research team members
  - 2.2 University and Medical Center Institutional Review Board (UMCIRB) members
  - 2.3 UMCIRB office staff
- 3.0 SOP:** The IRB can allow the use of a consent process which does not include obtaining the signature of the potential participant before they actually participate. Justification for this request and consideration for what information will be provided to potential participants must be made by the investigator and approved by the IRB.
- 4.0 Definitions:**
- 4.1 Waiver of written consent:** the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all research participants if it finds any of the following:
- 4.1.1 That 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 (not applicable to FDA regulated human research); or
  - 4.1.2 That 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
  - 4.1.3 If the subjects or LARs 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 harms to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained
- \*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.
- 5.0 Responsibilities:**
- 5.1 UMCIRB office staff will
    - 5.1.1 Perform a pre-review of the consent information and waiver request provided by the investigator.
    - 5.1.2 Communicate with the PI or appropriate research personnel on any changes that might be needed with regard to the request for waiver of documentation of consent.
  - 5.2 Investigators have the responsibility to
    - 5.2.1 Provide complete and robust justification for a waiver of documentation of the consent process.
    - 5.2.2 Provide the consent language that will be provided to the potential participants.
      - 5.2.2.1 Although the signature of the potential participant to consent to research may be waived, the language that is provided to this individual should still be

provided to the IRB for approval prior to beginning the research.

**5.2.3** In situations where the investigator is initiating planned emergency medicine research, waiver of consent is allowed in the Food and Drug Administration (FDA) regulations. For further information on the informed consent responsibilities associated with such research, see SOP entitled, “Planned Emergency Research” Sections 4.2. and 5.1.

**5.3** UMCIRB/UMCIRB Chairperson (or designee)

**5.3.1** Reviews each waiver request to determine whether sufficient justification is provided in order to grant approval.

**5.3.2** Reviews consent language that will be provided to potential participants.

## **6.0 Procedures:**

**6.1** When requesting a waiver of documentation of informed consent:

**6.1.1** There should be a justifiable rationale why a waiver of documentation of consent is being requested.

**6.1.2** The PI should still provide the potential participant with the same type of information as required in a formal consent in order for the individual to make an informed decision on participating.

## **Revision History:**

<b>Date</b>	<b>Change</b>	<b>Reference Section(s)</b>
1.22.2015	Updated to stand-alone document.	All
1.27.2016	Addition of reference to Planned Emergency Medicine SOP	Section 5.2.3
1.21.2019	Updated definitions secondary to revised regulations.	Section 4.0

## **References:**

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50> and

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>