1. PURPOSE

This policy describes the requirements for documentation of informed consent and circumstances when the IRB may waive the requirement to document informed consent.

2. PROCEDURE

Unless specifically waived by the IRB, all human subjects, or their Legally Authorized Representative (LAR), must document that they are consenting to participate in any research project that is conducted at Avera.

3. SPECIFIC PROCEDURES

Each human subject or his/her LAR must sign and date a copy of the current IRB-approved informed consent form prior to enrollment or any participation in any phase of the study, and be given a copy of the signed document, unless the requirement is waived by the IRB. An electronic signature and date may also be accepted for more than minimal risk, non-FDA regulated studies, and FDA-regulated studies which must be compliant with applicable regulations (21 CFR Part 11), if approved by the IRB on an individual study-by-study basis. Electronic signatures may be permitted, but are not required, for non-FDA-regulated studies.

The IRB may approve procedures for documentation of informed consent that involve (a) a written informed consent form (including in an electronic format) signed by the subject, (b) a short form written informed consent form with oral presentation; or (c) in limited circumstances, a waiver of the requirement for a signed written informed consent form. Each of these options are described in detail below. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews.

In certain studies, use of electronic informed consent is an option. An electronic informed consent would still need to include all the required elements of a written informed consent. Instead of signing the human subject's name on paper with a pen, an electronic version of typing their name and date may be used instead. This version of the informed consent must be approved by the IRB prior to use. Another option would be for the human subject be informed that their consent is implied by submitting the informed consent and clicking on a button that states "I agree" or "I do not agree". The informed consent needs to be designed to allow the human subject to print a copy of the informed consent statement for their records, or have it emailed to them.

3.1 Waiver of Documentation

The IRB may waive the requirement for the PI to obtain a signed informed consent form for some or all human subjects if one of the following two sets of criteria are met:

FDA Regulated Research (as per 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(1)(ii))

- The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the worksheet: Criteria for Approval (HRP-314).
- The research presents no more than minimal risk of harm to human subjects

- The research involves no procedures for which written consent is normally required outside of the research context.
- The research does not involve newborn dried blood spots.

Non FDA Regulated Research (as per 45 CFR §46.117(c)(1)(i) – any of the following must be met)

- The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the worksheet: Criteria for Approval (HRP-314).
- That the only record linking the human subject and the research would be the informed consent document
- The principal risk would be potential harm resulting from breach of confidentiality,
- Each potential human subject that meets the inclusion criteria will be asked whether he/she wants documentation linking themselves with the research, and the human subject's wishes will govern
- The subject or LAR 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 subject 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 PI to provide human subjects with:
- A written statement regarding the research

The PI must provide the IRB with a completed written informed consent document containing all the elements of informed consent and study information that will be provided to the participant. The IRB must document determinations regarding waiver in the IRB minutes or IRB's protocol file.

3.2 Consent for Mail, Telephone Surveys, and Internet Surveys

If approved by the IRB on an individual study-by-study basis, the following may be considered:

- **Fax, Email or Mail:** The IRB may approve informed consent sent by mail or Email in one of two ways. (1) The PI or study team member mails, emails or faxes the consent document along with a letter requesting participation. The subject signs the informed consent and returns it. If the study is to be anonymous, the consent form is separated immediately upon opening the package.
  (2) The PI or study team member sends an informed consent statement to the subject which includes a statement that by returning the completed survey, the subject is providing and documenting his/her consent. This is known as implied consent and is acceptable if approved by the IRB.
- **Telephone:** The IRB may approve telephone informed consent. The PI or study team member must use an IRB-approved script when obtaining consent by telephone. The script must contain a comprehensive, succinct description of the study and include the relevant elements of informed consent in narrative form. (All possible efforts should be made to mail the informed consent document in advance to the subject.) The interviewer solicits any questions the potential human subject may have and answers them. The PI or study team member needs to document that the script was read, the individual was offered the opportunity to ask questions, and whether the subject agreed to or declined participation in the study. If a PI or study team member is taping

his/her phone conversations with the subject, the interviewer must immediately inform the subject that he/she is being taped.

- **For Anonymous Internet-Based Surveys:** It is sometimes appropriate to use an informed consent statement. Human subjects would still need to be presented with the informed consent information, but would be informed that their consent is implied by submitting the completed survey and/or clicking on an "I agree" or "I do not agree" button on the website. The website needs to be designed to allow the human subject to print a copy of the informed consent statement for their records.

4. RESPONSIBILITY

Chairs, IRB staff or IRB members are responsible for determining circumstances when the IRB may waive the requirement to document informed consent.

5. APPLICABLE REGULATIONS AND GUIDELINES

Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors – December 2016
21 CFR 50.23, 50.27, 56.109(c), 56.109(d)
21 CFR 11
45 CFR 46117

6. REFERENCED DOCUMENTS

Waiver of Written Documentation of Informed Consent Checklist

REVISION HISTORY

Revision Number	Version Date	Approved By, Date Approved
02	3/12/2019	Avera Institutional Official, 4/8/19
• Added that electronic signatures may be allowed in certain studies, with appropriate IRB approval. • Added in when a Waiver of Documentation of Informed Consent may be approved. • Added when informed consents may be emailed out. • Updated applicable regulations		
01	August 2016	Director HSRP / August 2016