1. PURPOSE

1.1. Federal regulations for human research generally require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the research participant or the participant’s legally authorized representative. This policy describes the process to document the informed consent and the conditions and considerations under which the investigators may seek a waiver from the requirement to document informed consent.

2. DEFINITIONS

2.1. Documentation of informed consent: means providing subjects with a written version of the required elements of consent and obtaining their signature (or other mark) on a written document as verification of their decision to participate in the research. Documentation of informed consent generally occurs during the consent process after the elements of informed consent have been presented to the prospective participant and the investigator has responded to any questions or concerns from the individual.

2.2. Signature: is a subject’s name written by him or her in a characteristic way as a form of identification or authentication.

2.3. Electronic signature: means an electronic or digital method executed or adopted by a party with the intent to be bound by or to authenticate a record, which is unique to the subject using it, is capable of verification, is under the sole control of the subject using it, and is linked to data in such a manner that if the data are changed, the electronic signature is invalidated.

3. POLICY

3.1. This policy applies only to non-exempt human research. See Policy and Procedure: Exempt Review.

3.2. Federal regulations require the documentation of informed consent by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative, unless the IRB has approved a waiver of the requirement to document informed consent (per 45 CFR 46.117(c) for DHHS and 21 CFR 56.109(c)(1) for FDA). A copy of the signed and dated consent form shall be given to the person signing the form.

3.3. For the purposes of this policy, both written signatures and electronic signatures are acceptable.

3.4. Where informed consent is documented in accordance with 46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. See CHECKLIST: Informed Consent Elements. This form may be read to the subject or the subject’s legally authorized representative, but in
any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. Subjects who do not speak English should be presented with a consent document written in a language understandable to them.

3.5. Alternatively, if a subject does not speak in English or in a language where there is a translated version of the full consent form, or if the subject is illiterate, 45 CFR 46.117(b)(2) permits an oral presentation of informed consent information in conjunction with a short form written consent document (stating that the required elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be an impartial witness to the oral presentation. Also, the IRB shall approve a written summary of what is presented orally to the subject or the representative. A short form consent template is available at [https://research.uga.edu/documents/#hso](https://research.uga.edu/documents/#hso).

3.5.1. The subject or the subject’s legally authorized representative, the witness, and the person obtaining consent sign and date the short form consent document and the summary.

3.5.2. A copy of the signed and dated summary will be given to the person signing the document.

3.6. Documents signed and returned to the investigator by mail, fax, or as attachments to e-mail are considered to be in compliance with the requirements for documentation.

3.7. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

3.7.1. 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; or

3.7.2. 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.

3.8. For FDA-regulated studies, regulations allow the waiver of a signed consent form if the IRB determines 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 the research context.

3.9. When participants are children and the information is sensitive, Protection of Pupil Rights Amendment (PPRA) must be applied, regardless of whether there is funding or not.

3.10. When student educational records are involved, the requirements of the Family Educational Rights and Privacy Act (FERPA) must be applied.

3.11. 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 that includes the required and appropriate additional elements of informed consent. See CHECKLIST: Informed Consent Elements.
3.12. Obtaining a signature on a consent form does not necessarily complete the consent process. For example, researchers are required to provide subjects with any new information that arises during the study that may affect the subject’s decision about whether to continue participation.

3.13. Consent forms must be retained for a period of three years after the study is complete. For some disciplines, the forms and data must be kept longer. For example, the American Psychological Association requires forms and data be kept for six years.

4. PROCEDURES: Researchers

4.1. The researchers must ensure that research subjects provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered. See Policy and Procedures: Informed Consent Process for Research.

4.2. If the consent process will be documented in writing with the long form of consent documentation:

4.2.1. Use the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject. This version will be date-stamped by the IRB with the current approval period for the study.

4.2.2. Provide a copy of the consent form to the subject. Whenever possible, provide the consent form to the subject in advance of the consent discussion.

4.2.3. For subjects who cannot read, and whenever required by the IRB or the sponsor, obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

4.2.4. If the subject cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject. The interpreter may be a member of the research team, a family member, or friend of the subject.

4.2.5. Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Explain the details in such a way that the subject understands what it would be like to take part in the research study.

4.3. If the consent process will be documented in writing with the short form of consent documentation:

4.3.1. Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in language understandable to the subject.

4.3.2. Provide copies to the subject. Whenever possible provide the short consent form and
Documentation of Informed Consent

summary to the subject in advance of the consent discussion.

4.3.3. Obtain the services of an interpreter fluent in both English and the language understood by
the subject. The interpreter may be a member of the research team, family member, or friend of the subject.

4.3.4. Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given. The witness and the interpreter may be the same person. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

4.3.5. Have the interpreter translate the summary (not the short consent form) to the subject.

4.3.6. Through the interpreter, explain the details in such a way that the subject understand what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

4.3.7. Have the subject read the short consent form or have the interpreter read the short consent form to the subject.

4.4. The subject and the individual obtaining consent signs and dates the consent document unless the requirement for written documentation of the consent process has been waived by the IRB.

4.5. If a waiver of the requirement for written documentation of consent is requested, the criterion for the waiver must be selected by the investigator and a justification that documents how the study meets the criteria must be provided and supported with study-specific findings.

4.5.1. Materials used to present the required and appropriate additional elements of informed consent must be submitted for review.

4.5.2. Where hard-copy of the consent materials will be presented to subjects, use the most current IRB-approved version. This version will be date-stamped by the IRB with the current approval period for the study.

4.5.3. Where consent materials will be presented only in electronic format (e.g., for online surveys/questionnaires), use the most current IRB-approved version. This version will not be date-stamped by the IRB with the current approval period for the study.

4.6. For FDA-regulated studies where the IRB waives the requirement for written documentation of informed consent, the IRB may require the researchers to:

4.6.1. review the elements of informed consent verbally with the subject or the subject’s legally authorized representative

4.6.2. provide subjects with a written statement regarding the clinical investigation
4.6.3. In studies where there is minimal risk of harm, use the written statement to guide the consent process/discussion, and document the consent process/discussion including the participant’s consent, date, and the name of the researcher conducting the consent in the study records.

5. PROCEDURES: Institutional Review Board

5.1. The IRB Reviewer will ensure that the required and appropriate additional elements of disclosure have been included in the information that will be presented to the potential participants. The elements must be sufficiently complete and appropriate; the use of templates and suggested verbatim language or by investigator-created language equal in meaning to the verbatim template language is highly recommended.

5.2. Upon approval, finalize any consent document that will be provided to participants in hard-copy (affix a mark that contains the study ID number and the beginning and end date of the approval period).

5.3. If a waiver of the requirement to document informed consent has been requested by the investigator, the IRB Reviewer will determine if the justification is adequate to grant the waiver, and will document its findings via the appropriate checklists (the justification/findings must document why the IRB judged that each criterion was met for the specific protocol and may reference other parts of the submission to supplement the justification provided by the researcher.)

6. MATERIALS

6.1. TEMPLATES: Consent Documents, https://research.uga.edu/documents/#hso
6.2. CHECKLIST: Informed Consent Elements
6.3. CHECKLIST: Waiver or Alteration of the Consent Process
6.4. CHECKLIST: Waiver of Written Documentation of Informed Consent
6.5. WORKSHEET: Short Form of Consent Documentation

7. REFERENCES

7.1. 21 CFR §50.20, 50.25
7.2. 45 CFR §46.116 and 45 CFR §46.117
7.3. Policy and Procedure: Exempt Review
7.4. Policy and Procedures: Informed Consent Process for Research