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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 (LAR)*. 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 participants 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 prospective participant.
- 2.2. **Signature:** is a participant'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. The electronic signature is unique to the participant using it; is capable of verification; is under the sole contract of the participant 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* that is not FDA regulated. 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 participant or the participant's LAR, unless the IRB has approved a waiver of the requirement to document informed consent per 45 CFR 46.117(c). A written copy must 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 embodies the basic and required additional elements of informed consent (See CHECKLIST: Informed Consent Elements.) This form may be read by the participant, to the



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- participant or to the participant's LAR, but in any event, the investigator must give either the participant or the LAR adequate opportunity to read and ask questions about it before it is signed.
- 3.5. Alternatively, the investigator may provide an oral presentation of informed consent information in conjunction with a written short-form consent document stating that the required elements of informed consent have been presented orally to the participant or the participant's legally authorized representative.
 - 3.5.1. When this method is used, there must be a witness to the oral presentation.
 - 3.5.2. The IRB must approve a written summary of what is to be presented orally to the participant or the LAR. A short-form consent template is available at <https://research.uga.edu/documents/#hso>.
 - 3.5.3. The participant or the participant's LAR, the witness, and the person obtaining consent must sign and date the written short-form consent document and the summary.
 - 3.5.4. A copy of the signed and dated summary will be given to the person signing the document.
 - 3.6. Documents signed and dated 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 participants if it finds that **any** of the following conditions apply:
 - 3.7.1. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
 - 3.7.2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or
 - 3.7.3. The research presents no more than minimal risk of harm to participants, and participants and/or their LARS are members of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
 - 3.8. When student educational records are involved, the requirements of the Family Educational Rights and Privacy Act (FERPA) must be applied.
 - 3.9. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research that includes the required and appropriate additional elements of informed consent. See *CHECKLIST: Informed Consent Elements*.
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3.10. Obtaining a signature on a consent form does not necessarily complete the consent process. For example, investigators are required to provide participants with any new information that arises during the study that may affect the participant’s decision about whether to continue participation.

3.11. 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: Investigators

4.1. The investigators must ensure that research participants 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. 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 participant. 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 participant. Whenever possible, provide the consent form to the participant in advance of the consent discussion.

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

4.2.5. Read the consent document (or have an interpreter read the translated consent document) to the participant/LAR. Explain the details in such a way that the participant 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 written short-form consent document:

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



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to the participant.

- 4.3.2. Provide copies of the written short-form consent document and summary to the participant. Whenever possible provide these documents to the participant in advance of the consent discussion.
- 4.3.3. If the participant cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the participant. The interpreter may be a member of the research team, family member, or friend of the participant.
- 4.3.4. If the participant cannot speak English, obtain the services of an impartial witness who is fluent in both English and the language spoken by the participant to be present during the entire consent discussion to attest that the information in the written short-form consent document, summary, and any other information provided was accurately explained to, and apparently understood by, the participant, 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 participant.
- 4.3.6. Through the interpreter, explain the details in such a way that the participant understands 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 participant read the short consent form or have the interpreter read the short consent form to the participant.
- 4.4. The participant and the individual obtaining consent sign and date 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 criteria 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 IRB review.
 - 4.5.2. When printed copies of the consent materials will be presented to participants, 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. When 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.



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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 appropriate and sufficiently complete, and 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 printed format (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 his/her findings via the appropriate checklists. The documentation must explain 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 investigator.

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

Revision History:
09/19/2014: REV0 New Document
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