THE OHIO STATE UNIVERSITY

DOCUMENTATION OF THE INFORMED CONSENT PROCESS

LANGUAGE IN GRAY BOXES IS ONLY APPLICABLE TO STUDIES APPROVED ON/AFTER JANUARY 21, 2019

1. Overview

Federal regulations require that in most circumstances informed consent is documented by use of a written consent form approved by the IRB and signed by the research participant or the participant's legally authorized representative. Consent forms must include the required (and any applicable additional) elements of informed consent, unless the IRB approves either an alteration of consent, use of a short form stating that the elements of consent have been presented, or a waiver of the requirement for written documentation of the consent process.

2. Definition

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3. General Information

A. The informed consent document provides key information regarding research participation and serves as a reference for participants or their legally authorized representatives. Although a signed consent form is usually required, alone it does not constitute an adequate informed consent process. For more information on the informed consent process, see HRPP policy [Informed Consent Process and the Elements of Informed Consent].

B. Unless waived or altered by the IRB, consent forms must include the basic elements of informed consent, and when appropriate, any additional elements as described below and by HRPP policy [Informed Consent Process and the Elements of Informed Consent].

4. Informed Consent Documents

A. Required Elements

Consent form templates containing the basic elements of informed consent are available on the ORRP website. To streamline IRB review and assure that regulatory requirements are met, use of the applicable consent template is generally required. The IRBs can also approve consent forms on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting informed consent. The federally required consent elements are described in HRPP policy [Informed Consent Process and the Elements of Informed Consent].

B. Additional Elements

One or more additional elements of informed consent will also be provide to potential participants during the consent process, when appropriate, or as required when the IRB determines that the information would meaningfully add to the protection of research participants. The additional elements are described in HRPP policy [Informed Consent Process and the Elements of Informed Consent].

C. Exculpatory Language

Consent forms may not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights or release (or appear to release) the investigator, sponsor, or the university (or its agents) from liability for negligence.

D. Complex Language

Consent forms must be written in language understandable to the participant or the participant's legally authorized representative. Complex, technical, or highly specialized language or medical jargon should be explained in terms that potential participants are likely to understand. Generally, consent forms should be written at a 6th to 8th grade reading level. However, characteristics of the potential participant population should be considered when determining appropriate consent form language. Consent template language for specific topics (e.g., Certificate of Confidentiality) is available on the ORRP website (see Consent Template Language by Topic).

5. Short Form Consent Documents

Use of short form consent documents in Ohio State research is limited to situations involving a potential research participant or his/her legally authorized representative who does not speak/understand English, and enrollment of participants speaking the specific language was not anticipated (i.e., a translated consent form in the participant's language has not been approved by the IRB). For more information on use of the short form consent, including witness, signature, and follow-up translation requirements, see HRPP policy [Short Form Informed Consent].

6. Signature and Recordkeeping Requirements

A. FDA regulations require that a participant or his/her legally authorized representative date the consent form at the time it is signed. Although not required by DHHS regulations, OHRP recommends that consent forms are dated to document that a participant's informed consent was obtained prior to beginning research interventions or interactions. Ohio State consent form templates include a line for adding the date and time the consent form is signed. A copy of the consent document is to be given to the person signing the form.

B. A signed consent form that is sent to an investigator by facsimile (fax) or email is an acceptable method of documenting informed consent. When a signed consent form has been faxed, or scanned and returned through a secure email account, the original signed document need not also be provided.

C. Electronic signatures may be used to document consent, in compliance with 45 CFR 46, 21 CFR 11 and applicable FDA Guidance. A written copy (electronic or hard copy) must be given to the individual signing the consent form. Electronic versions of consent forms (when used to meet documentation requirements) must be available for review and retention by potential participants.

Complete signed consent forms should be stored confidentially in a secure location for at least three years after completion (or cancellation) of the research, unless a longer retention period is required by other applicable university policy or contractual agreement. For more information on record retention see HRPP policy [IRB Recordkeeping].

7. Research Participants Unable to Sign a Consent Document

A. A person who speaks and understands English but does not read and write can be enrolled in a study by "making his/her mark" on the consent document. An adult who is not involved in the research will witness the informed consent process and sign the consent document.

B. A person who understands English but is physically unable to talk or write can be enrolled in a study if he/she is competent and able to indicate approval or disapproval by other means. The method used to communicate with the potential participant and the specific way in which the individual communicated agreement to participate in the study is to be documented on the consent form. An adult who is not involved in the research will witness the entire consent process and sign the consent document.

8. Consent Form Revisions

Consent forms should be revised when new information about reasonably foreseeable risks, potential benefits, or other information becomes available that will improve the consent process. Amendments to consent documents must be reviewed and approved by an IRB prior to the revised consent form being utilized, except when necessary to eliminate apparent immediate hazards to subjects. Minor changes to previously approved consent forms can be reviewed by expedited procedures as described in HRPP policy [Expedited Review Procedures].

9. Waiver of Documentation of Informed Consent

In limited circumstances, the IRB can waive the requirement for the investigator to obtain a signed consent form for some or all research participants.

A. Risk of Breach of Confidentiality

The IRB can waive the requirement for written documentation of informed consent for non-exempt research if all of the following criteria are met:

- The only record linking the subject and the research would be the consent document
- 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
- The research is not FDA-regulated.

B. Minimal Risk Research

The IRB can waive the requirement for written documentation of informed consent for non-exempt research if both of the following criteria are met:

- The research presents no more than minimal risk of harm to subjects
- The research involves no procedures for which written consent is normally required outside of the research context.

C. Distinct Cultural Groups or Communities

The IRB may waive the requirement for a signed informed consent form if the subjects are members of a distinct cultural group or community in which signing forms is not the norm for non-exempt research if both of the following criteria are met:

- The research involves no more than minimal risk
- There is an alternative method for documenting that consent was obtained.

D. Additional Requirements

1. When the requirement for written documentation of consent is waived, the IRB must review a written description of the information (i.e., a "script") that will be provided to participants (e.g., when consent is obtained by telephone or online). This information must include the basic elements of informed consent and any applicable additional elements as described above and in HRPP policy [Informed Consent Process and the Elements of Informed Consent**],** unless an alteration of consent has also been approved by the IRB.

2. When the requirement for written documentation of consent is waived, the IRB may also require that an investigator provide participants with a written statement regarding the research. Examples include approved consent forms (without signature lines), cards containing researcher and/or third party contact information, and information sheets outlining study procedures.

9. Posting of Clinical Trial Consent Forms

For clinical trials conducted or supported by a federal department or agency, the Final Rule requires that a copy of an unsigned, IRB-approved consent form be posted on a publicly available federal website (e.g., ClinicalTrials.gov). The funding awardee or federal department/agency is responsible for posting the form after recruitment is complete, but no later than 60 days after the last study visit. Proprietary or institutionally sensitive information may be redacted. Only one consent form per study must be posted regardless of the number of subject classes or study sites.

10. Applicable Regulations/Guidance

21 CFR 50.20, 21 CFR 50.25, 21 CFR 50.27, 21 CFR 56.109, 21 CFR 56.111, pre-2018 and Final Rule (45 CFR 46.111, 45 CFR 46.116, 45 CFR 46.117), FDA "Questions and

Answers on Informed Consent Elements, 21 CFR 50.25(c)" (02/12), FDA Information Sheets: "A Guide to Informed Consent," FDA Information Sheets: Frequently Asked Questions "Informed Consent Process" and "Informed Consent Document Content," OHRP "Informed Consent FAQs", OHRP Guidance "Informed Consent Checklist" (09/30/98), OHRP Guidance "Informed Consent – Legally Effective and Prospectively Obtained" (OPRR Reports 93-03, 08/12/93), OHRP Guidance "Tips on Informed Consent" (OPRR, revised 03/16/93), The Ohio State University Policy and Procedure Manuals for University Hospitals and James Cancer Hospital and Solove Research Institute (# 03-27)

11. History

Issued: 09/08/2008
Revised: 05/14/2012, 07/13/2016, 12/17/2018