

## **DOCUMENTATION OF THE INFORMED CONSENT PROCESS**

### **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 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. 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 OSU 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 OSU HRPP policy [Informed Consent Process and the Elements of Informed Consent].

### **3. 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 OSU consent template language 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.

#### **B. Additional Elements**

- 1. The following additional elements of informed consent are included in OSU consent templates for biomedical and cancer research because this information is often relevant in medical research:
  - Statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided

- Approximate number of participants involved in the study
- Any additional costs to the participant that may result from participation in the research.

However, addition or deletion of any of these elements from consent forms (medical or non-medical) can be approved by the IRBs, based on the nature of the research.

2. The following additional elements will also be considered for inclusion:
  - Statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable (e.g., in studies involving investigational drugs or devices)
  - Statement that the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable, if the participant is or may become pregnant (e.g., in studies involving drugs or devices used in pregnant women or women of childbearing potential for which the safety profile in pregnancy is unknown)
  - Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent (Note: Circumstances must be specific and may not include "If you do not follow study procedures," as participants are not in a position to know all of the study procedures)
  - Consequences of a participant's decision to withdraw from the research (e.g., in studies involving interventions for which stopping the intervention would have adverse consequences if not monitored or replaced by another treatment)
  - Procedures for orderly termination of participation (e.g., when in best interest of participants and specified in study procedures).

#### C. Exculpatory Language

Consent forms may not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights or release (or appear to release) the investigator, sponsor, or OSU (or its agents) from liability for negligence. For examples of unacceptable and acceptable language see OSU HRPP policy [Informed Consent Process and the Elements of Informed Consent].

#### 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 6<sup>th</sup> to 8<sup>th</sup> grade reading level. However, characteristics of the potential participant

population should be considered when determining appropriate consent form language.

#### **4. Short Form Consent Documents**

Use of short form consent documents at OSU 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 OSU HRPP policy [Short Form Informed Consent].

#### **5. 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. OSU 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) is an acceptable method of documenting informed consent. When a signed consent form has been faxed, the original signed document need not also be provided.
- C. Electronic signatures may be used to document consent, in compliance with 21 CFR 11 and applicable FDA Guidance (<http://www.fda.gov/cder/guidance/5667fnl.pdf>). Electronic versions of consent forms (when used to meet documentation requirements) must also be available in hard copy for review and retention by potential participants.
- D. 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 OSU HRPP policy [IRB Recordkeeping].

#### **6. 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.

## **7. 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 participants. Minor changes to previously approved consent forms can be reviewed by expedited procedures as described in OSU HRPP policy [Expedited Review Procedures].

## **8. 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 participant and the research would be the consent document
- 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
- 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 participants
- The research involves no procedures for which written consent is normally required outside of the research context.

### C. 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 OSU 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. Applicable Regulations/Guidance

21 CFR 50.20, 21 CFR 50.25, 21 CFR 50.27, 21 CFR 56.109, 21 CFR 56.111, 45 CFR 46.111, 45 CFR 46.116, 45 CFR 46.117, 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 Frequently Asked Questions” (revised 07/14/08), OHRP Guidance “‘Exculpatory Language’ in Informed Consent” (OPRR Cooperative Oncology Group Chairpersons’ Meeting 11/15/96), 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), OSU Policy and Procedure Manuals for University Hospitals and James Cancer Hospital and Solove Research Institute (# 03-27, revised 08/10/07)