

## INFORMED CONSENT PROCESS AND THE ELEMENTS OF INFORMED CONSENT

### 1. Overview

Informed consent is an essential part of ethical human subjects research. Institutional Review Boards and investigators are responsible for ensuring that research subjects provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered (in non-exempt research) by the IRB.

This policy describes the requirements for valid informed consent processes, required and additional elements of consent disclosure, and the criteria for waiver or alteration of these requirements.

### 2. Definitions

**Informed Consent:** Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation. *Also: legally effective informed consent.*

**Legally Authorized Representative:** An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For purposes of OSU HRPP policy, the following are recognized in Ohio as legally authorized representatives:

- Persons appointed as health care agents under an Ohio Durable Power of Attorney for Health Care
- Court-appointed guardians
- Next of kin in the following order: spouse, adult child, parent, and adult sibling.

**Coercion:** Persuasion (i.e., of an unwilling person) to do or agree to something by using obvious or implied force or threats.

**Exculpatory Language:** As it applies to informed consent, any written or verbal communication through which a research participant (or his/her legally authorized representative) is asked to waive or appear to waive any of the participant's legal rights or to release (or appear to release) the investigator, sponsor, or institution or its agents from liability for negligence.

**Undue Influence:** Excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by their own free will or without adequate consideration of the consequences.

### 3. General Information

- A. Informed consent is an essential part of ethical human subjects research. The requirement to obtain the informed consent of individuals before involving them in research is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report. “Respect for persons” requires that individuals are treated as autonomous agents, the rights and welfare of persons with diminished autonomy are appropriately protected, and potential research participants are “given the opportunity to choose what shall or shall not happen to them.”
- B. The consent process involves more than a consent form. Informed consent has been described as an “interactive process that involves the researcher informing potential participants of the purposes and procedures of the research, the risks and benefits associated with the study, and how the data provided by the participant will be protected and stored” (AAA Statement on Ethnography and Institutional Review Boards). This discussion must be culturally and linguistically appropriate for the population under study.
- C. In addition to the language and content of the consent process, the nature and circumstances of the process are also important aspects of informed consent. Circumstances such as who will conduct the consent discussion, who will provide consent, and the timing of obtaining consent (including any waiting period between informing the participant and obtaining consent) are critical to facilitating the participant’s understanding of what has been disclosed and promoting the voluntariness of the participant’s decision about whether or not to participate in the research.
- D. Informed consent is an ongoing process. Even in the absence of new information or changes to research procedures, periodic review or confirmation of a participant’s consent is often desirable, e.g., in studies that take place over a long period of time, particularly complex studies, or longitudinal studies involving progressive disorders or aging populations. Participants must be in a position to freely decide whether to withdraw or to continue participating in the research.

### 4. Attributes of the Consent Process

To meet the federal requirements for informed consent, the consent process must have all of the following attributes:

- An investigator (or approved designee) will obtain the informed consent of the potential participant or the participant's legally authorized representative, unless the requirement for consent has been waived or altered by the IRB.

- The circumstances of the consent process will provide the participant or legally authorized representative sufficient opportunity to consider whether to participate.
- The circumstances of the consent process will minimize the possibility of coercion or undue influence.
- The information provided during the consent process will be presented in language understandable to the research participant or the participant's legally authorized representative.
- The information being communicated during the consent process is free of exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or to release (or appear to release) the investigator, sponsor, or OSU (or its agents) from liability for negligence.

## 5. Elements of Informed Consent

### A. Required Elements

The information provided during the consent process must be consistent with the federal requirements. Unless informed consent is waived or altered by the IRB (see "Waiver or Alteration of Informed Consent" below), the consent process must include the following basic elements:

- Statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental
- Description of any reasonably foreseeable risks or discomforts to the participant
- Description of any benefits to the participant or to others that may reasonably be expected from the research
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- Explanation of whom to contact for answers to pertinent questions about the research and research participant's rights and whom to contact in the event of a research-related injury to the participant
- Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
- For research involving greater than minimal risk, an explanation about whether:

- Medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained
- Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained.
- For research regulated by FDA, a statement that informs the participant of the possibility that FDA may inspect the records.

**B. Additional Elements**

One or more of the following elements will also be provided to potential participants during the consent process, when appropriate:

- Statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant’s consent
- Any additional costs to the participant that may result from participation in the research
- Consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant
- Statement that significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation will be provided
- Approximate number of participants involved in the study.

Additional information beyond the basic and additional elements of consent (above) may also be required when the IRB determines that this information would meaningfully add to the protection of research participants.

**6. Consent Language**

**A. Exculpatory Language**

The informed consent process 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. The following are examples of unacceptable (i.e., exculpatory) and acceptable language:

<b>Exculpatory Language</b>	<b>Acceptable Language</b>
Your signature on the consent form indicates that the study has been fully explained to you.	Your signature indicates that you are satisfied with the explanations provided during the consent process.

<p>You are freely donating all blood, urine, and tissue samples to the University and voluntarily giving up all rights, claim, and interest to these specimens.</p>	<p>By consenting to participate, you authorize the use of your biological fluids and tissue samples for the research described above.</p>
<p>By consenting to participate in this research, you should understand that you are giving up any property rights you may have in the biological fluids and tissue samples obtained in the course of the research.</p>	<p>Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.</p>
<p>By signing the consent form, you are agreeing that you will not hold the University responsible for compensation for any injuries that you may receive as a result of participation in this research.</p>	<p>The University makes no commitment to provide free medical care or payment for treatment of any injuries should you be injured as a result of participating in this research. Medical services will be offered at the usual charge.</p>

**B. Complex Language**

The information provided during the consent discussion must be presented in language understandable to the participant or the participant’s legally authorized representative. The consent discussion should not include complex, technical, or highly specialized language or medical jargon that would not be understandable to potential participants.

**7. Special Considerations in Informed Consent**

The circumstances of the consent process must provide potential participants or their legally authorized representatives sufficient opportunity to consider whether to participate and minimize the possibility of coercion or undue influence. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as pregnant women, prisoners, children, students, employees, or adults unable to consent, additional safeguards are required to protect the rights and welfare of these participants.

Additional requirements for obtaining informed consent (or assent) in specific populations are described in the following OSU HRPP policies:

- Pregnant women, fetuses, or neonates [Research Involving Pregnant Women, Human Fetuses, or Neonates]
- Prisoners [Research Involving Prisoners]
- Children [Research Involving Children] and [Assent and Parental Permission]
- Students or employees [Vulnerable Populations: OSU Students, OSU Employees, and Adults Unable to Consent]

- Adults unable to consent [Vulnerable Populations: OSU Students, OSU Employees, and Adults Unable to Consent]
- Non-English speaking individuals [Short Form Informed Consent].

## **8. Observation of the Consent Process**

According to the federal regulations, the IRB has the authority to observe or have a third party observe the consent process. Observation of the consent process can provide additional protections to research participants, e.g., in studies involving adults with diminished decision-making capacity or studies with complex interventions. Observation can be performed by members of the IRB, ORRP staff, or by other individuals designated by the IRB, investigator, or sponsor.

## **9. Waiver or Alteration of Informed Consent**

In the limited circumstances described below, the IRBs can approve a consent process that does not include, or alters, some or all of the elements of informed consent.

### **A. Research on Public Benefit or Service Programs**

The IRB can waive or alter the requirements for informed consent for non-exempt research examining state or local public benefit or service programs or certain features of those programs if all of the following criteria are met:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs
- The research could not practicably be carried out without the waiver or alteration
- The research is not FDA-regulated.

Note: Similar research conducted under federal authority or research conducted by (or subject to the approval of) a private entity would not qualify.

### **B. Minimal Risk Research**

The IRB can waive or alter the requirements for informed consent for non-exempt research that meets all of the following criteria:

- The research involves no more than minimal risk to subjects
- The waiver or alteration will not adversely affect the rights and welfare of subjects

- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, subjects will be provided with additional pertinent information after participation
- The research is not FDA-regulated.

#### C. Research Designed to Study Conditions in Children

The IRB can waive or alter the requirements for parental or guardian permission for certain non-exempt research involving children. For more information see OSU HRPP policy [Assent and Parental Permission].

#### D. Planned Emergency Research

The IRB can approve a waiver of the requirements for informed consent for non-exempt research in life-threatening situations in which it is not possible to obtain informed consent from subjects or their legally authorized representatives. For more information see OSU HRPP policy [Planned Emergency Research].

### 10. Applicable Regulations/Guidance

21 CFR 50.20, 21 CFR 50.25, 21 CFR 56.109, 21 CFR 56.111, 45 CFR 46.111, 45 CFR 46.116, American Anthropological Association Statement on Ethnography and Institutional Review Boards (Adopted by AAA Executive Board 06/04/04) <http://www.aaanet.org/stmts/irb.htm>, APA Ethical Principles of Psychologists and Code of Conduct (Section 8.02), Code of Ethics of the American Anthropological Association (Approved 06/98), FDA Information Sheets: “A Guide to Informed Consent” and Frequently Asked Questions “Informed Consent Process,” 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 – 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)