



INFORMED CONSENT PROCESS AND THE ELEMENTS OF INFORMED CONSENT

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

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 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 his/her own free will or without adequate consideration of the consequences.

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.** 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.
- E.** Projects involving deception or incomplete disclosure of material aspects of the research must meet the criteria for a waiver or alteration of informed consent. When appropriate, participants should be given additional pertinent information (debriefed) after they have participated in such a study. Debriefing procedures and materials must be submitted for IRB review. If investigators believe debriefing is not an appropriate procedure for the



proposed study, or that the debriefing could cause more harm than the deception/incomplete disclosure itself, appropriate justification must be provided to the IRB. The IRB will make a final determination about whether debriefing is necessary and whether the proposed process is sufficient.

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 subject or the subject'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 subject 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 subject or the subject's legally authorized representative.
- The information being communicated during the consent process is free of exculpatory language through which the subject or legally authorized representative is made to waive or appear to waive any of the subject's legal rights or to release (or appear to release) the investigator, sponsor, or the university (or its agents) from liability for negligence.

5. Informed Consent Components

A. Concise Summary

Lengthy and/or complex consent documents must begin with a concise and focused summary of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research, and to encourage discussion about the pros and cons of research participation. The following items may be addressed in this summary: the purpose of the research, the expected duration, and the research procedures to be followed; the most important risks or discomforts (i.e., highest frequency or greatest severity); the reasonably expected benefits; and appropriate alternative procedures or courses of treatment. Other additional information may be needed based on the study design and the intended subject population. Information listed in the concise summary need not be repeated later in the consent form unless that information is necessary to help ensure the consent remains understandable to the subject.

B. 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:



- A 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
 - A description of any reasonably foreseeable risks or discomforts to the subject
 - A description of any benefits to the subject 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 subject
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
 - Explanation of whom to contact for answers to pertinent questions about the research and the subject's rights and whom to contact in the event of a research-related injury to the subject
 - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable bio-specimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - A statement that the subject's information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- 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 subject of the possibility that FDA may inspect the records
 - For applicable clinical trials, the following statement notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

**C. Additional Elements**

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

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
 - Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's consent
 - Any additional costs to the subject that may result from participation in the research
 - Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
 - A 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 subjects involved in the study
- A statement that the subject's bio-specimens (even if identifiers are removed) may be used for commercial profit and whether or not the subject will share in this commercial profit
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
 - For research involving bio-specimens, whether the research will (if known) or might include whole genome sequencing.

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 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.

B. Complex Language

The information provided during the consent discussion must be presented in language understandable to the subject or the subject'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, prisoners, children, students, employees, or individuals with impaired decision-making capacity, 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 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: Students, Employees, and Adults Unable to Provide Consent](#)]
- Adults unable to provide consent [[Vulnerable Populations: Students, Employees, and Adults Unable to Provide 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 for this waiver.

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 requested waiver or alteration
- If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format
- Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participation.

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 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 HRPP policy [[Planned Emergency Research](#)].

10. Exception to the Informed Consent Requirement

Information or bio-specimens can be obtained for the purposes of screening, recruiting, or determining eligibility of prospective subjects without informed consent (and without the need for the IRB to waive informed consent) if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- The investigator will obtain identifiable private information or identifiable bio-specimens by accessing records or stored (existing) identifiable bio-specimens.

**11. 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.

12. Applicable Regulations/Guidance

21 CFR 50.20, 21 CFR 50.25, 21 CFR 56.109, 21 CFR 56.111, pre-2018 and Final Rule (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), APA Ethical Principles of Psychologists and Code of Conduct (Section 8.02), Code of Ethics of the American Anthropological Association (Approved 02/09), FDA "Questions and Answers on Informed Consent Elements, 21 CFR 50.25(c)" (02/12), 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 "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), FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects" (07/17)

13. History

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