# Informed Consent Guidance

## *What is Informed Consent?*

Informed consent for research is a process where researchers provide potential participants with all the necessary information about a study before they agree to take part. This ensures that participants understand what the research involves, including any risks, benefits, and their rights.

Legal and ethical foundations of informed consent in research are rooted in various national and international guidelines, such as the Belmont Report (1979), the Declaration of Helsinki (latest revision 2013), and the Common Rule (45 CFR 46) in the United States. Under the Department of Health and Human Services (HHS), the Common Rule specifies general requirements for informed consent, including the need for clear, understandable information and the prevention of coercion. These guidelines provide the basis for institutional review boards (IRBs) and ethics committees to evaluate research protocols and ensure proper informed consent procedures.

The informed consent process involves these key features:

a) Disclosure: Providing a detailed explanation of the study's purpose, procedures, risks, and benefits.
b) Comprehension: Ensuring participants fully understand the information provided about the study.
c) Voluntariness: Guaranteeing participation is voluntary, with the option to withdraw at any time.

The informed consent process should be an active process of sharing information between the investigator and the prospective subjects and can occur through a variety of formats (e.g. question-answer sessions, community meetings, videotape presentations). The prospective subjects should be in a position to freely decide whether to initially enroll in the research, or later, to withdraw or continue participating in the research. The informed consent process should ensure that all critical information about the research is shared, and that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed choices.

For most research, informed consent is documented using a written document that provides key information regarding the research. The consent form is intended, in part, to provide information about the study for the potential subject's current and future reference, and to document the interaction between the subject and the investigator.

**All aspects of the Informed Consent Process implemented by WP IRB are designed to comply with federal regulations (45 CFR 46).**

## *When must the Informed Consent be described and obtained from participants?*

Any research project that will utilize data collected from human participants requires the use of the Informed Consent process and must be reviewed by the WP IRB. Only research projects that fall under the category of Exempt Review do not require informed consent.

Federal regulations recognize eight categories of research that are exempt from IRB review. Below are the most commonly used exemption categories.

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| Category 1 | Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, including:<br>• Research on regular and special education instructional strategies.<br>• Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| Category 2 | Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:<br>i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or**<br>ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects |
| Category 3 | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:<br>The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or** |

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| | i. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**<br>ii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br>iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. |
| Category 4 | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:<br>i. The identifiable private information or identifiable biospecimens are publicly available; or<br>ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or<br>iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated HIPAA, for the purposes of health care operations, research, or public health activities and purposes as defined at 45 CFR 164; or<br>iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with federal regulations. |
| Category 5 | Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of |

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| | department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. |
| Category 6 | Taste and food quality evaluation and consumer acceptance studies:<br>i. If wholesome foods without additives are consumed, or<br>ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. |

Note: These exemption categories do not apply to research involving prisoners or involving children, except for category 1, and Category 2 in the following circumstances:

- For research involving children, exemption 2 (i) and 2 (ii) above may be applied only to research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.
- Exemption 2 may not be applied to survey procedures or interview procedures involving children as subjects.
- Exemption 2 (iii) above may not be applied to research involving children

Federal regulations permit the use of two additional categories of exempt review that apply only to research covered under a broad consent process. Adopting the use of broad consent procedures requires an infrastructure for the secure storage of Biospecimens that is not currently available university wide. In addition, the tracking requirements are burdensome for both the investigator and the IRB. Because of this, WPUNJ does not utilize the broad consent position at this time and therefore

Exempt Categories 7 and 8 are not included in the list of exempt categories. There are several other options for researchers using Biospecimens which these research protocols can be reviewed under.

## *What must be included in the Informed Consent Process?*

WP IRB's suggested informed consent template and assent templates comply with federal regulations (45 CRF 46 116 a (1-6) and 45 CRF 46 116 c). They include the elements listed below.

**General Requirements for Informed Consent (45 CFR 46.116 (a) (1-6))**

1. Before involving a human subject in research covered by the WP IRB, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. (i) Informed consent must begin with a concise and focused presentation 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

***A*dditional elements of informed consent (**45 CFR **46.116 (c)).**

Except when requesting a Waiver, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

1. 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;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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 to the subject;
6. The approximate number of subjects involved in the study;

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

## *What are the types of Informed Consent forms?*

WP IRB's suggested informed consent and assent templates include both the general requirements for Informed Consent (45 CFR 46.116 (a) (1-6)) and additional elements of informed consent (45 CFR 46.116 (c)).

A **written consent** document must include a description of how this process will be documented. The investigator should give either the subject or the representative adequate opportunity to read it before it is signed; however, this form may be read to the subject or the subject's legally authorized representative.

When the written consent is presented **orally** to the subject or the subject's legally authorized representative orally, two elements need to be included:

(1) a **short form written consent** document stating that the elements of informed consent have been presented orally.
(2) a **witness** to the oral presentation should be present.

The IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

## *When can the IRB approve a request to Waiver or Alter the Informed Consent Requirements?*

**Waivers of Informed Consent**

There are situations where obtaining informed consent may not be feasible or necessary. In such cases, researchers can request a waiver or alteration of informed consent from an Institutional Review Board (IRB).

A **waiver of informed consent** allows researchers to conduct human subjects research without obtaining informed consent from participants. This waiver can apply to an entire study or specific components of a study, and it may involve all participants or only some.

**Criteria for Waiving Informed Consent**

To approve a waiver of informed consent, the IRB must determine that the following criteria are met:

1. **Minimal Risk**: The research involves no more than minimal risk to the subjects.

2. **Practicality**: The research could not practicably be carried out without the waiver.
3. **Identifiable Information**: If the research involves identifiable private information or biospecimens, it could not be practicably carried out without using such information in an identifiable format.
4. **Rights and Welfare**: The waiver will not adversely affect the rights and welfare of the subjects.
5. **Additional Information**: Whenever appropriate, subjects will be provided with additional pertinent information after participation.

**Situations for Waiving Informed Consent**

Waivers of informed consent are typically approved in the following scenarios:

- **Secondary Data Analysis**: Secondary analyses of existing datasets or specimens.

**Alterations of Informed Consent**

In addition to waivers, researchers can request alterations to the informed consent process. This involves omitting or modifying certain elements of informed consent. Situations where alterations may be approved include:

- **Pre-Consent Activities**: Asking participants to perform specific research activities before providing full consent.
- **Eligibility Screening**: Retaining identifiable information from individuals who respond to eligibility screening questions but do not participate in the study.
- **Scientific Design**: Omitting or altering certain consent information for scientific design reasons, such as avoiding expectation bias.
- **To Maintain Anonymity**: In certain circumstances, a waiver of documentation of informed consent may be requested if the signaler on the informed consent form is the only identifier linking the participant the data collected as part of the study.

**Requesting a Waiver or Alteration**

To request a waiver or alteration of informed consent, researchers must submit an application or study protocol to the IRB. The application should specify whether the waiver or alteration is requested for the entire study or specific activities or participants. It should also describe how the research meets the criteria for a waiver or alteration.

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