John Carroll UNIVERSITY | INSTITUTIONAL REVIEW BOARD

The Required Elements of Informed Consent

From 45 CFR 46, §46.116(b)

In human subject research, the informed consent process must include the following required elements, where applicable:

1. **A statement that the study involves research**, an explanation of the purposes of the research, the expected duration of the subject's participation, and a description of procedures to be followed.
2. A description of any **reasonably foreseeable risks or discomforts** to the subject. (Examples: you may become upset; you may recall disturbing memories, etc.)
3. **A description of any benefits** to the subject or to others that may reasonably be expected from the research;
4. **A disclosure of appropriate alternative procedures** or courses of treatment, if applicable, that might be advantageous to the subject. (In minimal risk social/behavioral research, this is often not applicable.)
5. A statement describing **the extent to which confidentiality of records identifying the subject will be maintained**.
6. An explanation of **any compensation**, if applicable (Examples: SONA credit, extra credit from the instructor, entry into a drawing for a gift card, receive pizza and soda, etc.), and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained (Example: referral to Counseling Center or other mental health support)
7. An explanation of **whom to contact for answers to pertinent questions about the research and research subjects' rights**, and whom to contact in the event of a research-related injury to the subject (i.e. the researchers' contact information AND the IRB Office contact information)
8. **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 the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
9. **One of the following statements** about the collection of identifiable private information or identifiable biospecimens:
    a. A statement that identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject, if this might be a possibility; **or**
    b. A statement that the subject's information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

10. **Requirement that participants be 18 years of age or older.** Only a legal adult can give informed consent for themselves. Minors would require an additional Parental Consent from a parent or legal guardian. (See the IRB website for guidelines for doing research with minors)

The following are **Additional Elements of Informed Consent** that must be used, but only when appropriate. (These are less common in the typical social, behavioral, and educational research done at JCU and are more commonly used in clinical trials.)

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 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
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

The requirement for a written and signed consent form may be waived if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. See the IRB Administrator for more information about defining minimal risk and informed consent format requirements.

See http://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html for a helpful informed consent checklist and more information about documentation of consent. Also visit the JCU IRB website: https://jcu.edu/research/irb