Guidelines to Informed Consent

In 2019, revisions to the Federal Policy for the Protection of Human Subjects, or Common Rule, were published to enhance the subject's understanding of a research study. Researchers are expected to consider and understand the revised regulations outlined in the Common Rule. Although the regulations apply to federally funded studies, most researchers and IRBs are complying with the new regulations to ensure safety and understanding. As researchers, we carry the responsibility to promote participants' autonomy, including their right to make informed decisions before volunteering to participate in a research study (LeCompte & Young, 2020).

eCFR :: 45 CFR Part 46 Subpart A -- Basic HHS Policy for Protection of Human Research Subjects

Code of Federal Regulations/Elements of Informed Consent

Eight Basic Elements of Informed Consent:

1.	Explanation of the purpose (s) of the research and role of the participant, including information about the expected duration, description of procedures, and identification of any procedures which are experimental.
2.	Description of reasonably foreseeable risks or discomforts
3.	Description of any reasonably expected benefits for the participant or others.
4.	Disclosure of appropriate alternative procedures or courses of treatment that may be advantageous to the subject (this element may be omitted for studies that do not include a procedure or treatment).
5.	Description of the extent to which confidentiality of records identifying the subject will be maintained.
6.	Explanation as to whether any compensation and/or treatments are available for research-related injuries or health problems and where further information may be obtained (this element applies to studies that involve more than minimal risk).
7.	Identification of person to contact for answers to pertinent questions or concerns about the research (usually the primary investigator), about the participant's rights (usually the IRB), and about whom to contact in the event of a research-related injury.*
8.	Statement that participation is voluntary, that refusing to participate or discontinuing participation will involve no penalty or loss of benefits to which the participant is otherwise entitled.
	New Requirements: When Applicable
9.	• A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens, after removal, may be used for future research or distributed to other researchers without additional consent. OR • A statement that the private information or biospecimens collected will NOT be used for future research even if identifiers are removed.

***** *If possible, review the informed consent document with the subject before consent to ensure all questions have been answered to the subject's satisfaction and to secure the subject's full understanding of the study, including any benefits and risks.*

Additional Elements of Informed Consent:

When appropriate, one of more of the following shall also be provided to each participant.

1.	**A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant)**
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, which may be related to the subject's willingness to continue participation, will be provided to the subject.
6.	The approximate number of subjects involved in the study.
	Three Additional Elements if Relevant to Research
7.	A statement about the biospecimens and if they will be used for commercial profit and whether or not the subject will share in the profit
8.	A statement regarding whether the research results, including individual results, will be disclosed to the subjects and under what conditions. *
9.	A statement about whether the research will or will not or might include whole genome sequencing

**Applies to all research studies, not only those with biospecimens*

Additional Guidelines:

- Contact the IRB chair if you are planning research that involves the collection and use of biospecimens.
- Use the template provided to enhance informed consent.
- The black font remains as part of the form and complies with federal regulations.
- Utilize the sample language or examples in red font and italics as a guide to include information as it pertains to your research study.
- The reading level for the informed consent document should reflect simple lay language at an 8th grade level. The flow of the information should resemble a conversation between you and the prospective participant.
- Upon completion of your informed consent document, please be sure to remove the explanatory text. Proofread for spelling and grammar errors. Ensure the page format includes Times New Roman or Calibri, font size 12, font color black, and 1" margins.

References

LeCompte, L. L., & Young, S. J. (2020). Revised Common Rule changes to the consent process and consent form. *The Ochsner Journal*, *20*(1), 62–75. https://doi.org/10.31486/toj.19.0055

National Archives and Records Administration. (2023, February 1). Code of Federal Regulations. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A#p-46.116(a)