



Investigator Guidance: Elements of Consent

Obtaining informed consent from a prospective research participant is essential. Unless waived by the IRB, a consent form is an integral part of the consent process through which researchers seek volunteers to participate in human research studies or clinical trials. As such, great attention must be given to the creation of these documents to ensure a prospective research participant understands and comprehends the information disclosed in consent forms so that they are able to make an informed decision about whether to participate in human research studies.

To meet federal requirements, consent forms should be written in language understandable to the participant (or authorized representative). Every effort should be made to ensure that technical and scientific terms are adequately explained or that common terms are substituted.

Standard IRB Consent Format

The HSRO/IRB has developed standard language as well as a standard format to be used in portions of all consent documents. These documents are available on the HSRO website. Each investigator should determine the IRB's requirements before submitting a study for initial review. Where changes are needed from the standard paragraphs or format, the investigator can save time by anticipating the local IRB's concerns and explaining in the submission to the IRB why the changes are necessary.

Sponsor-prepared sample consent documents

For some funded studies, sample or draft consent documents may be provided by a sponsor or cooperative study group. However, the UM IRB that reviews the study is the final authority on the content of the consent documents that is approved for use in obtaining consent from prospective study participants.

For studies that are subject to the requirements of the FDA regulations, Investigational New Drug Applications (IND) submitted to FDA are not required to contain a copy of the consent document. If the sponsor submits a copy, or if FDA requests a copy, the Agency will review the document and may comment on the document's adequacy.

For significant risk medical devices, the consent document is considered to be a part of the investigational plan in the Application for an Investigational Device Exemption (IDE). FDA always reviews these consent documents. The Agency's review is generally limited to ensuring the presence of the required elements of informed consent and the absence of exculpatory language. Any substantive changes to the document made by the UM IRB must be submitted to FDA (by the sponsor) for review and approval.

Elements of Consent

Informed consent documents for studies that are subject to the DHHS regulations must meet requirements specified in 45 CFR 46.116. Informed consent documents for studies that are subject to the FDA regulations must meet the requirements of 21 CFR 50.25. Both sets of regulations require the same* eight (8) basic elements of consent and six (6) additional elements of consent that applies based on the study to be conducted. The IRBs have the final authority for ensuring the adequacy of the information in the informed consent document(s). All consent forms should meet the minimum requirements of the respective regulations with the expectation that a well-written document will exceed those requirements.

Required Elements of Consent

- A statement that:
 - the study involves research
 - explains the purposes of the research
 - explains the expected duration of the subject's participation
 - explains the procedures to be followed
 - identifies any procedures which are experimental
- A description of reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or others, which may reasonably be expected from the research
- A description 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*
- As statement that:
 - participation is voluntary
 - refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
 - the subject may discontinue participation at any time without loss of benefits to which the subject is otherwise entitled

Required for More than Minimal Risk Research

- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained
- Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

Additional Elements

- A statement that:
 - the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable
 - if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable
- Anticipated circumstances under which the subject's 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
- The 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, which may relate to the subjects willingness to continue participation will be provided to the subject.
- Approximate number of subjects involved in the study.

Required for FDA-Regulated Research

- The possibility that the Food and Drug Administration may inspect the records.
- For controlled drug/biologic/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Recommended for Clinical Trials

- The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed
- The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care
- The approval of the IRB
- The probability for random assignment to each treatment
- The subject's responsibilities
- When there is no intended clinical benefit to the subject, a statement to this effect
- The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access
- If the results of the trial are published, the subject's identity will remain confidential
- Amount and schedule of all payments
- How to contact the research team for questions, concerns, or complaints about the research
- How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input
- Whom to contact in the event of a research-related injury to the subject

UM-Specific Requirements

- UChart language
- IRS template language for compensation of \$600 or more per calendar year
- Category B devices – “You will not be billed for a device, a price greater than that charged to the University which should not exceed an amount necessary to recover the costs of manufacture, research development, and handling of the device”
- 24-hour contact number

References:

1. 45 CFR 46.116
2. OHRP Informed Consent Checklist – Basic and Additional Elements
3. 21 CFR 50.20
4. FDA: A Guide To Informed Consent - Information Sheet
5. UM Informed Consent Boilerplate Language

*Basic element a(5) of the DHHS regulations differ from that of the FDA regulations insofar as the FDA has an added requirement to disclose the possibility that the FDA may inspect the records.