

Guidance on the New Informed Consent Requirement for a Concise and Focused Presentation of Key Information

Requirement

- 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.
- 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.

Guidance

Content

- In general, the beginning of an informed consent would include a concise and brief explanation of the following:
 - (1) the fact that consent is being sought for research and that participation is voluntary;
 - (2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
 - (3) Any reasonably foreseeable risks or discomforts to the prospective subject;
 - (4) Any benefits to the prospective subject or to others that may reasonably be expected from the research; and
 - (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
 - As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research.
- This section of the consent could, in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form.
- NOTE: this determination by the IRB is necessarily project and fact specific; the IRBs may require that somewhat different (or additional) information be presented at the beginning of an informed consent to satisfy the requirement for a concise and focused presentation of key information.

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Length and Format

- The initial presentation of the key pieces of information must be relatively short.
- While lists and charts may be used to facilitate comprehension and understanding, the informed consent 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.

Repetition of Information

- If information is included at the beginning of the informed consent, the information included at the beginning typically need not be repeated later in the body of the informed consent.

Relatively Simple Studies

- For some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief and still satisfy the informed consent requirements. The informed consent document could include the concise and focused presentation at the beginning of the informed consent document, followed by limited additional information.

Complicated Clinical Trials Studies

- For most complicated clinical trials involving cancer patients with long (e.g., 20- to 25-page) consent documents, the expectation is that the concise and focused presentation would be no more than a few pages, and would provide the key pieces of information about the trial in such a manner that facilitates a person's comprehension of why they might or might not want to participate in the research. In such cases, for example, we would not consider a 10-page description of elements such as potential risks, accompanied by lengthy and complex charts and graphs, to satisfy the "concise and focused" requirement.
- With regard to risks in the type of cancer trial mentioned above, for example, instead of needing to mention every reasonably foreseeable risk in the summary, this beginning section of the consent form should identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study.
- The most important reasonably foreseeable risks to subjects would be summarized at the beginning of the informed consent as part of the concise and focused presentation, but a more comprehensive and detailed description of reasonably foreseeable risks to subjects would be included later in the body of the informed consent.
- 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. Consider including a question after the summary that asks subjects if they have any questions or what are their concerns.