



U-MIC TRANSCRIPT

Key Information in Informed Consent Documents: The Revised Common Rule

Federal regulations at 45 CFR 46 subpart A—known as the Common Rule—define the basic responsibilities of both researchers and institutional review boards, including requirements regarding informed consent. Among numerous additions and modifications to informed consent requirements contained within the 2018 revised Common Rule, which is effective January 21, 2019, is the introduction of a “key information” section that must appear at the beginning of the informed consent document.

The revised Common Rule states:

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. [45 CFR 46.116(a)(5)(i)]

The regulation goes on to require that the informed consent document as a whole

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. [45 CFR 46(a)(5)(ii)]

Pending formal federal guidance to assist in complying with the key information requirement, researchers and IRBs are advised to employ a “reasonable person standard” in the development and evaluation of informed consent materials. The reasonable person standard involves consideration of a hypothetical average person on whom to base expectations about the concerns and behaviors of people in general. How a reasonable person may judge and experience a study depends on its particular nature, so the key information highlighted in the document should be selected and organized according to the likely concerns of the targeted subject population. Just as researchers are advised to use a reasonable personal standard in the development of their informed consent materials, IRBs should likewise apply this standard in their review.

Considerations for reviewing the Key Study Information section of an Informed Consent document

IRBMED has released a standard informed consent template structured to comply with all requirements presented in the revised Common Rule, including the key information requirement. The Department of Health and Human Services expects that in most instances the key information requirement may be satisfied by concisely addressing the following five elements of consent:

- that consent is being sought for *research* and that participation is *voluntary*

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- the *purposes* of the research, *duration* of participation, and study *procedures*
- foreseeable *risks* or discomforts
- potential *benefits* to subjects or others
- *alternatives* to participation

IRBMED's standard consent template's key information section begins with a statement that study participation is voluntary, followed by an explanation of research and how it differs from clinical care.

Researchers are then prompted to provide a concise summary of the purpose of their research; the template's blue help text boxes contain prepared language pertaining to common types of research—drug and device studies, behavioral interventions, and data or biospecimen collection—which researchers are instructed to complete with details specific to their research. The template's prepared language also includes definitions of common research concepts, such as randomization and washout periods. In its review, the IRB should confirm the accuracy and conciseness of the study purpose summary.

The template then prompts researchers to summarize foreseeable risks, offering sample language regarding types of risks that potential subjects may consider most relevant. To serve its purpose as key information, the statement of risks should be designed to orient potential subjects to the nature of the study and to highlight significant risks. Simply copying and pasting risk language from elsewhere in the document may not be adequate.

In its review, the IRB should evaluate the appropriateness of the risks addressed in the key information section. For example, reviewers should consider whether the most common or serious should appear, or whether a general statement about study risk would be more valuable to potential subjects than a list of risks. A statement such as "Participation in this study involves serious risks, some of which could be painful, require hospitalization, or be life threatening" may be sufficient.

The key information section of IRBMED's standard template next prompts researchers to summarize potential study-related benefits. As with risks, a general statement may be more useful to subjects than an itemized list. In its review, the IRB should confirm that the key information section's characterization of potential benefit, including whether benefit is direct or indirect, is consistent with the information in the benefits section of the document.

The key information section of the standard template closes with brief statements regarding duration of study participation and alternatives to taking part. The IRB should once again ensure that these statements align with the information presented elsewhere in the document.

As with all aspects of the informed consent document, the summaries within the key information section alone do not replace a full consent process, which must allow the prospective subject sufficient

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opportunity to discuss the study with the researcher and to make an informed decision whether or not to participate. Likewise, the key information presented at the beginning of the consent document should not be construed to satisfy all informed consent requirements enumerated in the Common Rule.

Contact the IRB for more information about the revised Common Rule's key information requirement in informed consent documents.

Posted: January 17, 2019