Guidance on Informed Consent Summary (Key Information)

Overview:

On 19 January 2017, the U.S. Department of Health and Human Services (HHS) issued a final rule to update the current regulations at 45 CFR 46, Subpart A - "Federal Policy for the Protection of human Subjects" (the Common Rule). The revised regulations include important changes to the requirements for informed consent intended to “better protect human subjects involved in research, facilitate research, remove ambiguity, and reduce regulatory burden.” The revised regulations specify that subjects must be provided with the information that a “reasonable person” would want to have in order to make an informed decision, and the informed consent process must begin with a concise and focused presentation of the “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. Revisions to informed consent are effective 19 January, 2018.

Description:

General Requirements for Informed Consent, new subsection 46.116(a)(5)(i)

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, and **provide sufficient information that a “reasonable person” would want to have**. 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.

Investigators remain responsible for providing more information to subjects when it is requested, making sure that subjects have sufficient time and opportunity to discuss the research, and to answer any questions subjects may have.

Currently there is no federal guidance defining exactly what “key information” is required in the concise and focused introduction. This is due in part to the fact that the application of this new requirement will depend upon the nature of the specific research study. The “key information” that a subject will need to decide whether to enroll in a Phase II Clinical Trial will be different from the “key information” needed to decide whether or not to enroll in a longitudinal or observational research study involving not greater than minimal risk.

The new rule does provide a brief description of five “factors” or “elements” that may encompass the “key information” that should appear at the beginning of an informed consent process and consent form.

1. A statement that the project is research and that participation is voluntary	*EXAMPLE: "You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision."*
2. A summary of the research, including...	• *Purpose of the research* • *Duration, number of study visits* • *Overview of study procedures* • *Other study specific information*
3. Reasonable, foreseeable risks or discomforts	*EXAMPLE: "Risks and side effects related to the [procedures, drugs, interventions, devices] include those which are:* *Likely: _____*

	Less Likely: _____ *Rare but serious: _____*
4. Reasonable, expected benefits	*EXAMPLE: "There will be no direct benefit to you from participating in the study. However, this study will help doctors learn more about X disease and it is hoped that this information will help in the treatment of future patients with conditions like yours."*
5. Alternative procedures to course of treatment, if any	*EXAMPLE: "If you decide not to participate in this research, your other choices may include:* • *Getting treatment or care for [disease] without being in a study* • *Taking part in another study* • *Getting no treatment"*

The concise and focused introduction is meant to be brief, but the amount of information that should be included will depend on the nature of the research. For some minimal risk studies, the concise introduction may require only four or five paragraphs. For more complex research trials, up to two pages may be required. In general, the introduction should not be more than two pages. To facilitate brevity, information may be provided in bulleted lists or in the form of an outline.

It is important to note that the concise and focused introduction should include a summary of why an individual may want to participate, but should also include information about why an individual may not want to participate in the research, such as the fact that participation involves significant time commitments or risks. While the introductory section should not list every foreseeable risk of participation, it should describe those risks that occur with significant frequency or are of significant severity. Information provided in the concise summary should not be repeated in the main body of the consent document.