CONCISE SUMMARY

Description

The revised "common rule" (effective January 21, 2019) requires that the key information be included in the beginning of the informed consent in a concise and focused presentation. The University of Utah IRB refers to this as a "concise summary". Informed consent should begin with a concise summary of the key information. Key information is defined as the information that is most likely to facilitate understanding of the reasons why one may or may not want to participate in research.

The University of Utah IRB relies upon the limited federal guidance that has been provided. It is expected more information may be forthcoming and the UUIRB will update guidance at that time.

Applicability

Studies initiated before January 21, 2019 will be grandfathered and continue to be subject to the pre-2018 Common Rule. Studies initiated (approved) on or after January 21, 2019 are subject to the revised "common rule", also called the Final Rule. Investigators may choose to transition grandfathered studies to comply with the Final Rule. A concise summary will be required of studies subject to the Final Rule.

What should be in the concise summary?

In general, the beginning of an informed consent would include a concise explanation of the following:

1. The fact that consent is being sought for research, and participation is voluntary.
2. Purpose of the research, expected duration, and procedures.
3. Reasonably foreseeable risks.
4. Benefits that may be reasonably expected.
5. Appropriate alternative procedures or courses of treatment, if any.

The above five points constitute 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.

There may be additional information that should be provided in the concise summary depending on the nature of the specific research study. For example, if the study involves placebo, or if the study includes an investigational device or drug, that information would likely be considered key information.

The information presented in a concise summary is information that should already be provided in a consent process. There is no additional information beyond what is already required in the informed consent process.

How should the concise summary be presented in studies with no more than minimal risk?
Typically, studies with no more than minimal risk have a short consent process and consent document. For example, many main campus researchers use consent cover letters for questionnaires or interviews. A consent cover letter is typically one page. Therefore, the consent cover letter provides all the key information in a concise form.

For studies with limited risks or benefits, the entire informed consent may be relatively brief. Presenting the key information as described above at the beginning of the document will meet the concise summary requirement.

How should the concise summary be presented in studies with greater than minimal risk?
For studies with greater risks and more procedures, the key information to be presented in a concise and focused will differ greatly from those simple studies with limited risks. For example, a complicated clinical trial for cancer patients may have a consent document that is 20-25 pages. The concise summary for such a study would ideally be no more than a few pages. The most important foreseeable risks to participants could be summarized at the beginning of the informed consent, while the more comprehensive and detailed description of foreseeable risks would be presented later with the body of the informed consent.

The information included at the beginning need not be repeated later in the body of the consent. For example, if there is a statement about voluntary participation in the beginning of the consent as part of the concise summary, it would not need to be repeated later in the body of the document.

Suggestions for writing a concise summary

- There is not a required format for the concise summary. It may include bullets or be written in paragraphs.
- The concise summary should be at the beginning of the consent document.
- A concise summary should not be created by repeating information verbatim, or directly cutting and pasting sentences from the body of the consent document.
- Information provided in a concise summary does not need to be repeated later into the body of the document. For example, since the statement that consent is being sought for research is explained in the concise summary, it does not need to be repeated in the body of the document.
- If your consent document is no more than 2-3 pages, simply presenting the key information at the beginning before the rest of the information will satisfy the requirement for a concise summary.
- If the study's procedures and/or risks requires extensive explanation or description, a brief summary or overview of the procedures and/or risks should be given. It should then be explained that the more comprehensive and detailed description will be provided later in the consent document.

Examples
The University of Utah IRB has provided consent document models for which demonstrate different ways to write a concise summary. The consent document models can be found here: https://irb.utah.edu/informed-consent/consent-document-models.php

Example 1 (No greater than minimal risk)
The purpose of this research study is <<insert purpose of study>>. If you agree, you will participate in an audio-recorded interview about <<research topic>>. The interview should take about 60 minutes. Your participation is completely voluntary. You may choose not to answer a question or are free to withdraw consent and discontinue participation in the interview at any time for any reason without penalty or loss of benefits.

There are no known risks associated with participating in this study. There are no direct benefits for taking part in this study.

Example 2 (No greater than minimal risk)
You are invited to take part in a research study to. Participating in this study is voluntary and it is up to you to decide whether or not you want to participate.

The purpose of the study is to <<insert purpose of study>>. <<Insert the description of procedures. Because the description of procedures is relatively short, all the study procedures may be described here in a concise manner>>.

<<Insert the description of risks. Because the risks are limited for this minimal risk study, all the risks can be listed here in a concise manner.>> This study may not benefit you directly. The alternative is not to participate in the study.

Example 3 (Greater than minimal risk)
We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary.

We invite you to take part in a research study because you have mild or moderate sleep apnea. Sleep apnea is a common sleep disorder in which you have one or more pauses in breathing or shallow breaths while you sleep. It is your choice whether to be in the study.

The purpose of the study is to find out if treating sleep apnea will affect certain disorders that happen during pregnancy and other complications during pregnancy. The study will last throughout your pregnancy and will finish after delivery of your baby. Everyone in the study will answer questionnaires and have blood taken at study visits. You will either be assigned to a treatment group that uses a CPAP machine or another group that gets advice about getting good sleep. What group you will be in is decided by chance, like flipping a coin. We will be following-up with you by phone, text messages or e-mail in between study visits. After you deliver your baby, we'll ask to take a tissue sample from the placenta. The procedures will be described in more detail later in this document.

There are some risks and discomforts from the blood draw and if you use the CPAP machine. There is a risk of loss of confidentiality. All the risks will be described in more detail later in this document. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

You can get standard care for your pregnancy or sleep apnea even if you decide not to be in this study.

Example 4 (Greater than minimal risk)
You are being asked to take part in a research study. First, the most important points about this study are going to be summarized. Some of the information will be explained in greater detail after this summary.

Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study. You are being asked to take part in this study because you have been diagnosed with <<disease>>. In this study you will be given a combination of two drugs, Study Drug A and Study Drug B. The combination of the drugs used in the study is investigational. It has not been approved by the U.S. Food and Drug Administration (FDA).

<<Insert summary or overview of procedures>>. The study treatment will last for <<insert duration of study>>. A detailed description of the study procedures is explained later in this document.

There are side effects that may occur. The side effects range from very common to rare. The side effects vary in seriousness. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking the drug. A detailed list of possible side effects is provided later in this document.

There may not be any benefit to you from your being in the study. You do not have to be in this study to get medical care. The study doctor will talk to you about other things you can do for this disease, including the important risks and benefits. Some other things you might do are: <<insert description of alternative procedures>>.

References & Links

Consent Process Models https://irb.utah.edu/informed-consent/consent-process-models.php