Consent Summary of Key Information: Guidance and Alternative Formats

Institutional Review Board and Human Subjects Office

Summary

The revised Common Rule requires consent information to "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" (45 CFR 46.116(a)(5)(i)). FDA's proposed regulations would add identical language to 21 CFR 50.20. Draft guidance from the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP), issued in 2024, outlined the elements of key information that should precede the presentation of the full informed consent document.
The UI IRB **Consent Summary of Key Information** template in HawkIRB contains specific instructions and template language to help UI researchers comply with this regulatory guidance.

This educational tool is provided to offer guidance about different approaches to the consent process, including ways to present key information to potential subjects, and document formatting examples.

Facilitating comprehension in the consent process might include:

- Utilizing plain language.
- Reading the consent language aloud while the participant follows along and can ask questions.
- Asking the participant follow up questions about the information in the consent document.
- Offering a video or PowerPoint presentation about the study that the participant can watch and listen to.

Plain Language

The guidance recommends following plain language principles for key information section and the entire consent form. (See https://www.plainlanguage.gov/.)

Plain language principles generally involve a combination of text-based and visual approaches (e.g., pictures and diagrams), including

- organizing information with the most important points first,
- breaking complex information into understandable groups,
- using simple language, and
- defining technical terms.

Note: The guidance suggests using these formatting options (e.g., bulleted lists, two-column format, white space), could be appropriate for the **entire** consent form, not just the key information section.

Follow Up Questions

One way that research team members can assist in facilitating understanding is to ask questions to gauge how much the participant has understood after reviewing the consent document. Research

has indicated that comprehension is increased if the team member goes through the consent with the participant and then follows up with questions, such as:

> "If you were going to tell a friend what this study was about, what would you say?"
>
> "What are the main things that you will do or will happen to you while you are in this study?"
>
> "What are the risks, or bad things that might happen, if you join this study?"
>
> "What are the benefits, or good things that might happen, if you join this study?"
>
> "What can happen if you decide to join the study, but then change your mind?"

Flexible Approaches & Alternative Formats
The regulatory guidance suggests that researchers may utilize alternate platforms (e.g., video, PowerPoint) to help prospective subjects better comprehend the reasons why they might or might not want to participate in research. The use of different formats allows participants who are not as comfortable reading text to engage with audio and video.

Facilitating comprehension in the document might include:

- Making sure the grade reading level of the consent matches the targeted population.
- Providing charts or other formatting in the document to improve ease of reading.

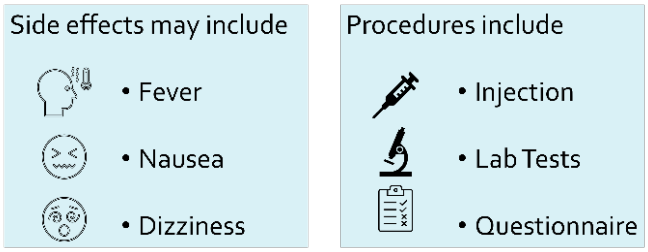
Reading Level
Information should be presented at a reading level comprehensible to the study population. Explanations should be provided for scientific and medical terms.

An assessment of the needs and characteristics of the prospective subject population, including their age, any relevant medical diagnosis, level of English proficiency, education level, and cognitive abilities, can be helpful in developing consent information that facilitates understanding. Information should be provided in the primary language of a prospective subject with limited English proficiency.

Although not required, one way to evaluate whether the information is presented in a way that facilitates understanding is to have the information reviewed by individuals unfamiliar with the research. This may be particularly helpful for forms translated into additional languages.

Borders, Columns, Charts, and Icons
The guidance recommends organizing information within a defined border (e.g., rounded boxes) creating a discrete unit of information, or including charts to make the content easy to read and understand. Other helpful approaches include formatting text into two columns, and/or using bullet points to simplify long explanations. (See examples in Appendix, below.)

Illustrations or inclusion of icons can also assist the participant with understanding risks or procedures as they read the consent language.



HawkIRB Application Attachments

If using an alternate format to present the key information summary, the IRB must approve what will be presented to subjects in a text version (i.e., transcript of a video).

If utilizing a video,

- provide a **transcript** on a blank stamped template (available in the dropdown menu in the Consent & Assent Document section) and attach it in the "other consent document" section.
- If the video is available on a study website, include the **hyperlink** in Section VII.D16.
- Attach any other alternative key information materials that cannot contain an IRB approval stamp (e.g., PowerPoint presentation, brochure) in the "miscellaneous attachment" category.

Other resources:

University of Michigan Illustrated research pamphlet
Johns Hopkin Consent Guidance

Related Research:

Improving the informed consent process for research subjects with low literacy: a systematic review.
Improving Patient Safety Through Informed Consent

See the Appendix (below) for three examples of alternate formatting for a key information summary.

Appendix

Example #1

Research Study Title: Treatment Consent Key Information Summary DRAFT

Principal Investigator: UI Researcher

This is a summary to help you decide if you want to learn more about being in the research study. The full informed consent document includes more detailed information. Please feel free to ask questions.

It is up to you whether you take part in the research. You do not need to take part in this study to receive care for your condition. You can stop taking part in this study at any time without any penalty.

Why are we doing the research?

[Use this space to provide information about the purpose of the research study. Provide enough information so the participant can understand the researcher's goals. This is a summary and does not need to include the detail that is in the full consent document.]

What will happen, how long will it take, and what will be done at each visit?

[Use this space to provide a summary of the procedures that will take place. Provide enough information so the participant can understand what they will be asked to do.]

What are the risks?

[Describe risks that are the most likely and/or the most serious. This section should be a brief summary, not a duplicate of the risk section of the informed consent document.]

What are the benefits?

[Provide an explanation of the specific benefits or state that there are none.]

What can you do instead of being in the research?

[Include a clear and concise description of alternative procedures or courses of treatment, if any. For clinical studies, consider first informing prospective subjects about care they would likely receive if not involved in the study, then explain how the care they would receive in the study differs from the standard of care. Focus on increasing awareness of alternatives that may vary based on individual values and preferences.]

What if I am injured during the research?
[DELETE FOR A NON-CLINICAL/NON-TREATMENT TRIAL.

Indicate whether medical treatments and/or compensation are available if injury occurs as a result of participation. It is especially important to include this information when there are no plans to compensate for costs related to treatment of research-related injuries.]

- There is/is not medical care for injury related to being in the study. Conditions for this coverage are described in the consent document.

What are the costs or payments?
[DO NOT INCLUDE IF THERE ARE NO COSTS TO SUBJECTS AND/OR THEIR HEALTH INSURANCE WILL NOT BE CHARGED.]

- You will have the following costs from being in this study: [SUMMARIZE]. Consult with your insurance company about whether you will have any charges for research-related procedures.

[DO NOT INCLUDE IF THERE IS NO REIMBURSEMENT, INCENTIVES OR COMPENSATION FOR STUDY PARTICIPATION.]

- You will receive payment/reimbursement for participating in this study. [DESCRIBE]

How participating in the research may affect your daily life:

[Provide contextual information that considers the needs and interests of the subject populations and/or study design. This section is an opportunity to explain how participation may impact the subjects' daily life.] Examples:

The number and length of the visit(s) may affect time you would need to take off from work, daycare needs, etc.

The side effects of the study drug(s) may affect your daily quality of life or ability to work.

Participating in the study may limit some of your normal activities (provide examples, such as the ability to drive, the need to limit exposure to the sun).

Example #2

Example of Part of a Key Information Section

Note that this example is **not** intended to include all or the minimum amount of the information that could be included in a key information section of a consent form.

The specific protocol and the population of individuals who will be asked to participate in the study will determine what information should be included in a key information section.

Format the document with clear headings and proper spacing.

Research Study on Drug B for Acute Pancreatitis

This consent form begins by clearly indicating that this section provides key information about the research study.

Please first review the following key information about this research project.

Section heading is written as a question to help the reader understand the relevance.

What is this research study about?

The paragraph that follows provides a concise response to the question.

This research study is about finding out if Drug B can be used to reduce the inflammation and associated effects of acute pancreatitis, improve outcomes for patients, and lessen the time they spend in the hospital.

Why are researchers studying Drug B?

Doctors have years of experience using Drug B to treat other inflammatory diseases. There is some evidence that Drug B may also be able to reduce the inflammation in acute pancreatitis. This could improve patient outcomes and lessen the time they spent in the hospital.

Why are you asking me to be in this study?

This section tells prospective participants why the research study concerns them.

We ask you to be in the study because you have acute pancreatitis.

This section describes how the study is being done. It explains special terms like randomization, placebo, and blinding in a context that is likely relevant to the reader deciding about participation.

The section also provides an overview of the most relevant information about the two study groups.

What will happen if I decide to be in this study?

We will assign you to 1 of the 2 study groups by chance, like flipping a coin.

- Group 1 participants will receive the current standard treatment for acute pancreatitis plus Drug B for a week.
- Group 2 participants will receive the same standard treatment plus a placebo pill for a week too. The placebo is a fake pill that looks exactly like Drug B and is taken the same way, but it doesn't have any medical effects.

Your group is not based on what you want or what seems best for you. You will have an equal chance of being in either group. You will not be told which group you are in during the study. The study researchers and your doctors will not know which group you're in. So, if you agree to participate, you will need to be okay with being in either group and not knowing which group you're in.

Could being in this study benefit me?

This section discusses potential benefits that may be reasons for the reader to want to be in the study.

There is no guarantee that participating in this study will benefit you. Drug B may reduce the inflammation of acute pancreatitis and improve the outcome of participants in the group getting it, but we don't know. You will have a 50% chance of receiving Drug B.

You may also find satisfaction in helping doctors understand if Drug B may be helpful in reducing inflammation of the pancreas and improving outcomes of patients with acute pancreatitis. These may be reasons for you to want to be in the study.

What may be the risks of being in this study?

Participants receiving Drug B may experience side effects. These are generally mild but please review the details on *p. X* of this consent form. Drug B may also not work to reduce inflammation and improve the outcome of the participants receiving it.

The study does not present any additional risks to participants in the group getting the placebo.

This section discusses risks with information potentially relevant to both study groups.

This section provides information on alternative options.

What are my other options if I decide not to be in this study?

You don't have to participate in this research study. The following are some options for you to consider:

- Get clinical care from a doctor.
- Participate in a different study for your condition.

(...cont.)

Now that you have the key information for what being in this research study is about, please review the rest of this document for other important details.

This provides a clear transition from the key information section to the rest of the consent form.

What follows will include the regulatory required information that's left out in the key information section as well as any other details that may be helpful to potential participations making a decision about being in the study or not.

Example #3

Contains Nonbinding Recommendations

Draft — Not for Implementation

APPENDIX: A HYPOTHETICAL CLINICAL TRIAL

Title: A trial to evaluate the use of product X to treat health condition Y

Key Information You Should Know Before Agreeing to Participate

The key information that follows can help you learn more about this clinical trial. It can also help you decide whether or not to take part in the trial. **Please read the entire consent form or have someone read it with you.** If there is anything that you do not understand, please talk to the trial doctor or team to have your questions answered before signing the consent form.

Voluntary Participation and Right to Discontinue Participation

We are asking you to consent to participate in this research study. Your participation is voluntary and should be based on what is important to you. It is your choice to participate in this trial. If you agree to participate, you may leave at any time without penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

The purpose of the trial is to find out if product X, the product that is being studied, is safe and effective in treating adults like you who have health condition Y.

Key Reasonably Foreseeable Risks and Discomforts (see page #)

- If you take product X, you have a chance of side effects, such as fever or rash.
- Nausea or vomiting may be related to your health condition and is a rare but serious side effect of product X. If product X is suspected to cause these or other symptoms, product X may be stopped.
- We do not know if product X will help you. There is a chance that product X could worsen condition Y.
- More information on risks is available in the consent form.

Reasonably Expected Benefits (see page #)

- Prior research suggests product X may improve condition Y.
- Researchers are studying product X in this trial to learn more about whether product X will improve condition Y.
- If you are randomly assigned to take product X, product X may improve your health condition Y. If you are randomly assigned to take the inactive pill, you will not receive product X and will not benefit directly.
- By participating in this trial, you will help researchers learn how product X may help people with condition Y.

~ MORE ~

Expected Duration and Procedures to Be Followed (see pages #)

- To learn if product X makes a difference, it is important for the trial to include people who will get a placebo (inactive pill). With this information, researchers can compare the effects of product X or the placebo on your health condition.
- A computer will assign you randomly, like flipping a coin, to a group taking product X or to a group taking the inactive pill.
- You and your doctors cannot choose which group you will be assigned to.
- This trial will take 6 months and require weekly clinic visits (24 visits total), with each visit expected to take 1 hour. At each visit, you will have blood drawn and a procedure to test your blood oxygen content.

Appropriate Alternative Procedures (see page #)

- In this trial, if you are assigned to take the placebo, you cannot take product X.
- Before joining the trial, you should talk to your doctor about alternative approved treatment options for your condition, and whether or not this trial is a good choice for you.
- Before agreeing to join, you should review information in the rest of the consent form.

Compensation and Medical Treatments for Research-Related Injuries (see page #)

- If you experience an injury caused by your participation in this research, the medical treatment of your injury will be paid for.
- More information on medical treatments for research-related injuries is available in the consent form.

Costs Related to Subject Participation (see page #)

- You may incur costs by participating in this trial.
- The sponsor will reimburse you for any travel costs for mileage, parking, and other expenses.
- In addition, the sponsor will pay you for your time participating in the trial.

Additional Information (see page #)

- If trials show that product X is effective in treating your health condition, you may be able to continue to take product X in a related trial.