

INSTRUCTIONS: This Key Summary section is a required section for all studies and may not be waived. Sub-headers in this section are optional, but may improve reading comprehension.

New required section 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 the 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.”

As explained in guidance provided with the Final Rule, if the information included in this Overview section contains sufficient detail to satisfy the required Basic and Additional Elements of informed consent, then the information included at the beginning does NOT need to be repeated later in the informed consent (Federal Register Vol. 82, No. 12, January 19, 2017, page 7214).

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.** Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the study’s purpose written in lay language. This could be a description of the study’s hypothesis or research question. Language may be modified as appropriate.

Basic element of consent 46.116(a)(1): “A statement that the study involves research [and] an explanation of the purposes of the research”

[Example 1] The purpose of this research study is to test the safety, tolerability, and effectiveness of the drug name when used to treat disease name. You are being asked to participate in this study because you have been diagnosed with disease name, and may meet the study entry requirements.

[Example 2] Disease causes symptoms or condition, which may involve **[insert short discussion of how or why the drug might affect the disease or condition. Do not promise efficacy or safety.]**

[If conducting the study in a prison setting with research project involving prison staff or inmates as participants, also include a description of the anticipated uses of the results of the research.] The results of this study will be used to ____.

What will happen if I participate?

INSTRUCTIONS: Insert a concise overview (no more than 1 page) of the research procedures explained from the participant's perspective. This information must be organized and presented in a way that facilitates comprehension.

This should briefly outline all the types of activities that they will be asked to do because full details can be given in a later section. Do not include activities that are done for usual care or other purposes (e.g. QI, regular education, etc.). Language may be modified as appropriate.

Basic element of consent 46.116(a)(1): "the expected duration of the subject's participation, a description of the procedures to be followed, identification of any procedures that are experimental"

Additional element of consent 46.116(b)(6): "The approximate number of subjects involved in the study"

[Example 1] Drug name is an investigational drug, which means it has not been approved by the U. S. Food and Drug Administration (FDA). In this study, drug name will be compared to ____, an approved drug, and to placebo (a look-alike inactive substance, a "sugar pill").

[Example 2] Usual care for your disease or condition involves _____. In this study, you will receive usual care, and in addition, you will be asked to _____. **[Or, if usual care will be replaced with another treatment/procedure/test, use "instead of _____, you will _____."]**

[If randomization occurs, insert:] You will be randomly assigned (like the flip of a coin) to receive either ____ or _____. **[Can also list as bullets if several arms.]** You have ____ chance in ____ of being assigned to placebo, and ____ chance in ____ of receiving _____. **[Or can say]** You have an equal chance of being assigned to any one of the groups.

[Example 3] In this study, you will be asked to do the following things:

1. Visit **[location]** __ times for study visits
2. Take either drug name or the placebo, depending upon which group you are assigned to
3. Have your blood drawn __ times
4. Have an MRI/EKG/ultrasound/CT __ times
5. Keep a diary at home
6. Take surveys and answer questions about **[describe general topics]**
7. Give permission for the researchers to collect information about **[describe general topics]** from your medical records.

Your participation in this study will last up to **[insert length of time]**. Approximately **[insert how many total]** individuals will participate in this study.

What alternative treatments or procedures are available?

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the alternatives or other options that would be available to individuals who do not participate in this study. Language may be modified as appropriate.

If the participant's only option is to not participate in this study, then this information may be deleted.

Identify whether any of the study's procedures and treatment options would be available outside of the study to individuals who do not want to participate (e.g. psychological treatment, coaching, drugs, devices).

If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, taking a survey home, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.

Basic element of consent 46.116(a)(4): "A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject"

[If this is a treatment study:] If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes [List the major drugs and/or therapies that are part of usual care]. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for [disease name].

[If the study involves a marketed drug or device or common activity:] You could receive [e.g. drug or device/yoga classes/weight loss coaching] without being in the study. Talk to the study staff or your regular doctor to see if this would be a good option for you.

[If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.]

What are the risks and benefits of participating?

INSTRUCTIONS: Insert a concise overview (no more than 1 page) of the most common risks or discomforts and of the anticipated benefits of being in the study. The template uses a table format to facilitate comprehension.

Risks must be described using lay terms. If the study involves many potential side effects, include only the most common side effects here and give a full description of all risks later in this consent form. Language may be modified as appropriate.

Basic element of consent 46.116(a)(2): "A description of any reasonably foreseeable risks or discomforts to the subject"

Basic element of consent 46.116(a)(3): “A description of any benefits to the subject or to others that may reasonably be expected from the research”

There are both risks and benefits of participating in research studies. **[Insert if applicable:]** We want you to know about a few key risks right now. We will give you more information in the “WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?” section.

Risks and Discomforts	Benefits to You and Others
<p>[Example 1 – example of experimental drug risks]</p> <ol style="list-style-type: none"> 1. There is a risk that study drug may not be as good as the usual approach for disease name. 2. There is also a risk that you could have side effects from taking study drug. Below are some of the most common side effects: <ul style="list-style-type: none"> • [Insert the most important risks in a bulleted list. This should be similar to the information that a doctor might deliver in the clinical context. It should be a brief list (i.e. generally around 5, although more may be necessary).] 3. There may be some risks that the study doctors do not know about yet, so we will let you know of any new findings. 	<p>[Example 1 – potential direct benefits] There is some evidence that [insert intervention] is effective in [insert description of how it may help]. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study doctors learn things that may help other people in the future.</p>
<p>[Example 2 – examples of procedural risks]</p> <ul style="list-style-type: none"> • Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn. • Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, 	<p>[Example 2 – potential direct benefits] There is no guarantee that you will receive any medical benefits from being in this study. However, possible benefits include _____. We hope the information learned from this study will provide more information about _____.</p>
	<p>[Example 3 – no anticipated direct benefits] This study is not likely to help you. However, the information learned in this research may help the study doctors understand how _____ works.</p>
	<p>[Example 4 – no anticipated direct benefits] This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with disease name.</p>

<p>chest pain, shortness of breath, headache, nausea, and/or fatigue.</p> <ul style="list-style-type: none"> • The study questionnaires ask questions that are [sensitive/personal/upsetting/offensive/disturbing/etc.] in nature and may make you feel uncomfortable. <p>[Example 3 – example of data storage risks]</p> <p>Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.</p>	<p>[If this study will include prisoners as subjects, insert:] If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison, or alternative facility), you should be aware that your participation in this research project will have no effect on consideration of sentencing, length of sentence, or parole.</p>
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INSTRUCTIONS: Insert the following if a break/transition is needed between the key summary and a full description of the study

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.