Annotated Key Information Samples

The Common Rule was revised in January 2019. It now requires a concise and focused presentation of key information. This is meant to assist a participant in understanding why they might or might not want to participate. The key information must be organized and presented in a way that facilitates comprehension.

The following two samples of key information sections were annotated to demonstrate the principles of formatting and plain language. The first is sample with good readability, and the second (found on page 3) has poor readability.

Key Information Sample with Good Readability

Key Information Sample

What is the purpose of this study?

This is a study led by Dr. John Doe. This study tests a new drug that may slow down Alzheimer's disease. Alzheimer's disease is a type of dementia that causes problems with memory, thinking and behavior. You do not have to take part in this study. Read this information to find out more before you decide. The National Institute of Aging is funding the study.

What will I do?

You will take some tests to see if you can take part in the study. If you can take part, you will be put in one of the study groups by chance. You and the research team will not know if you are in Group 1 or Group 2:

- **Group 1: Gets new active drug**
- **Group 2: Gets a pill with no medicine (called placebo)**

The study will take place at Blodgett Medical Clinic in Boston, Massachusetts. The following table describes the major events of this study for you.

Events	What will I do?
Study Visits for Drug Treatments	You will come to clinic every 6 weeks for 16 visits. At each visit, you will get the active or non-active drug by a needle in your vein for 60-90 minutes.
Positron Emission Tomography (PET)	You will lie in a machine that takes pictures of your brain and measures how it is functioning. There are 4 scans during the study.
Lumbar Puncture (Spinal Tap)	You will receive a needle injection in your spine to get a sample of fluid. This happens at your last clinic visit. This is optional.
Additional tests	You will have memory and thinking tests, height and weight measures, and urine and blood samples.
Total Time: 5 years	

You can choose to stop taking part in the study at any time. The study team may still use the information already collected about you.

What are the risks?

There are some risks if you agree to take part. **You may or may not experience these risks.** You can read the risks in more detail later in the consent document. The main risks and their symptoms in this study are:

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Simple words and phrases such as "by chance" or "a pill with no medicine" replaced complicated words such as randomization or placebo.

Technical terms like Positron Emission Tomography (PET) are defined and explained. Define technical terms when necessary.

The table helps the reader to see what is involved in the study, easily and quickly. Tables can help present complex information more clearly to the readers.

Risk 1: Study Drug

- Most common
  - Rash
  - Itching
  - Fever
- Less common but serious
  - Internal bleeding
  - Odd heart rhythms
  - Hearing damage

Risk 2: Positron Emission Tomography (PET)

- Most common
  - Headache
- Less common
  - Rash where injection happens (bleeding, irritation, and pain)
- You will be exposed to radiation during your PET scans. There is a very low risk that this can increase the chances of cancer.

Risk 3: Lumbar Puncture (Spinal Tap)

- Most common
  - Very bad headache
  - Back pain or stiffness
- Less common
  - Possible leak of spinal fluid

What are the benefits?

There is no direct benefit to you. Your participation may help someone else in the future.

What other treatment options are there?

Your doctor will discuss if there are any other options with you. There are currently no approved treatments for Alzheimer's disease.

Is there payment for participating?

There are no costs for you if you take part in this study. You will receive payment up to $1500 if you finish the whole study.

Ask the research team any questions you may have before you decide to participate.

Bold font is used instead of underlining or *italics* for emphasis.

Long paragraph describing the risks has become a bulleted list. Creating a list using bullets helps break up dense paragraphs of text.

There are six key content headers and the headers are in **bold**. Use headers to organize information and guide readers to specific content.

The document uses 12-point font size.

Ragged right margins are used to create more white space.

The margins are a minimum of 1-inch, which creates more white space in the document.

Using active voice clearly indicates who is supposed to do what. Active voice is also clear, direct, and easy to understand.

Paragraphs are short and contain only one topic. In general, paragraphs should be less than 150 words.

Wordy, complex, and long sentences have become shorter and simpler sentences (20 words or less).

Key Information Sample with Poor Readability

Key Information Sample

This is a research study conducted by Dr. John Doe that is testing a new *drug* to determine if it may slow the progression of Alzheimer Disease for people with mild symptoms of the disease. Randomization will be used to assign the participant to one of the study groups: Group 1 with the active *new drug* and Group 2 with the placebo, a non-active drug. Neither the participant nor the study personnel will know if the participant is taking the *new drug* or the placebo. The information in this consent document should be carefully considered by the participant and discussed with a research team member. The participant should understand why they might want to participate, or why they might not want to participate. The study is sponsored by The National Institute of Aging.

A series of tests will be conducted to make sure the participant is eligible for the study if the participant agrees to participate. If the participant is eligible, they will be randomized to one of the study groups (Group 1 or Group 2) to start *new drug* or the placebo. Once the study starts, clinic visitations will occur every 6 weeks for a total of 16 visits to receive an intravenous infusion (IV) of the *new drug* or placebo for approximately 60 - 90 minutes. Also, during these visits, the participant will undergo additional tests, which will take about 4 hours on average, and they will be asked to come for additional appointments during the study. Overall, the participant will be in the study for about 5 years.

The procedures of this study will take place in Blodgett Medical Clinic in Boston, Massachusetts. Some procedures will occur only once while other procedures will be repeated throughout the study. These procedures will include memory and thinking tests; measuring your height, weight, and vital signs like blood pressure, heart rate, breathing rate, and temperature; providing urine and blood samples; undergoing neuroimaging scans including Positron Emission Tomography (PET) scans; having a lumbar puncture where a minuscule amount of fluid is taken from your spine using a needle; completing questionnaires, and other activities. The participant may choose to stop participating and withdraw from the study at any time. The research team reserves the right continue to use the information already collected about the participant if they decide to withdraw from the study.

It is important to note that there are some risks if the participant agrees to volunteer for this study. Not everyone will receive the active *new drug* and the participant will not know the group they are assigned to. There are risks associated with PET scans because PET scans involve radiation exposure that may increase the chances of developing cancer. The radiation exposure may also cause side effects such as headache, infusion site rash, injection site reaction (bleeding, irritation, and pain), hives, and itching. The risks of lumbar puncture include side effects such as severe headache, possible seepage of spinal fluid, and back pain/stiffness. With the active new drug, the most common risks are allergic reactions such as rash, itching, fever, chills, nausea, or a headache; less common but more serious risks of *the new drug* include seizures, unsettled stomach, vertigo, internal bleeding, abnormal heart rhythms, hearing impairment, and nerve damage; and injection reactions of *the new drug* may cause symptoms such as inflammation, irritation, infection, and minor bleeding. There is also an increased risk of suicidal thoughts if the participant is given the active *new drug*. Not everyone will experience all of these side effects that are associated with the listed risks, but some are serious enough that they could cause death. The risks to the participant are described in more detail later in this consent document.

There is no direct benefit to the participant, but the participant's involvement may help someone else in the future. There is no cost to the participant, but they will be paid for some of the procedures and study visits for *a maximum amount of $1500 for their participation.* All of the above information will be further explained and is listed in more detail in the consent document below.

A signature is requested by the participant at the end of this document if the participant decides to participate, after they have had a chance to review all of the information. The participant must understand the purpose of the study, what they will be asked to do, and the risks that may be involved. Once signed, the research team must give the participant a copy of this signed consent document. The research team is also available when needed if the participant has any questions, concerns, or complaints about their rights as a research participant.

The document uses 11-point font size. Fonts should be 12 point or larger.

All paragraphs contain complicated words such as randomization or placebo. Replace complicated words with simple words and phrases.

Technical terms, acronyms, and abbreviations, for instance, Positron Emission Tomography (PET), are not defined or explained. Define technical terms when necessary.

Use **bold** instead of underlining or *italics* for emphasis.

Use ragged right margins. Do not justify margins.

The document has narrow, 0.5-inch margins. The margins should be a minimum of 1-inch.

Sentences are complex, wordy, and long (30 words or more). Edit sentence structure to create short and simple sentences (15-20 words).

Passive voice is used throughout the document. Use active voice instead. Active voice is direct and easy to understand.

There are no headings. Headings should be used to organize information and guide the reader to specific content. Headings should be in **bold** and be one font size larger than the body text, if possible.

Long, dense paragraphs should be broken up into smaller paragraphs or bulleted lists. Paragraphs should not exceed 250 words, and contain only one topic.