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?

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.

This section discusses potential benefits that may be reasons for the reader 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.