How to use this template:
For studies with lengthy and/or complex consent forms, the Health Sciences IRBs recommend providing a brief, high-level summary of the study to participants along with the consent form. The Health Sciences IRBs staff has developed this template to assist study teams in creating this brief summary information sheet.

- Instructions are highlighted in grey.
- The template provides model language appropriate for phase I, phase II, and phase III trials, and for non-therapeutic studies.
- HS IRBs-recommended language is in **black** type and should be used when possible. Sections with **black headings** must be included in the consent form.
- Sections with **blue headings** should be used when relevant and deleted if they do not apply to your study.
- **Blue text** should be edited or deleted as necessary to fit the specifics of your study.
- Aim for a finished summary information sheet ≤ 2 pages long.

Before submitting a summary information sheet for review by the HS IRB:
- **Delete this cover page and all instructions.**
- Make all text black.
- Use the [Preview Final Documents tool](#) in ARROW to check formatting.
Study Summary for [insert Study title for participants]

Important things to know:

- Taking part in research is voluntary. You can choose not to be in this study, or stop at any time.
- If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights.
- [For potentially therapeutic trials, add: You don’t have to be in this study to get care for your health condition.]

See the “Consent to Participate in Research” form for details about this study. The researchers will also discuss the study with you and answer your questions.

**What is this study about?**

Provide a brief, plain language description of the study’s purpose. Delete model language that does not apply to your study.

**Example for phase I trial:** We want to find out if Drug X is safe to use for Z condition, to find a safe dose to use in future studies, and to find out what side effects Drug X has in people with Z condition. Drug X is an investigational drug. This means that the US Food and Drug Administration (FDA) has not approved Drug X for the treatment of Z condition, and Drug X can only be given in a research study.

**Example for phase II trial:** We want to find out if a drug called Drug X can stop or slow Z condition. We also want to find out if Drug X is safe to use to treat Z condition. Drug X is an investigational drug. This means that the US Food and Drug Administration (FDA) has not approved Drug X for the treatment of Z condition, and Drug X can only be given in a research study.

**Example for phase III trial:** We want to find out if a drug called Drug X is a better treatment for Z condition than Drug Y. Drug X is investigational. This means that the US Food and Drug Administration (FDA) has not approved Drug X for the treatment of Z condition, and Drug X can only be given in a research study. Drug Y is approved by the FDA for the treatment of Z condition.

**Example for non-therapeutic study:** We want to find out if an investigational method for magnetic resonance imaging (MRI) can show X. “Investigational” means that the US Food and Drug Administration (FDA) has not approved this MRI method for diagnosing X, and this MRI method can only be used for research.

**What will happen during the study?**

Provide a brief, plain language description of the main research activities, such as investigational treatments or extra procedures that are performed for research purposes.

**Example for phase I trial:** We will test different doses of Drug X. We will test one dose level and see what side effects it has, and then test
higher or lower doses until we find the highest safe dose of **Drug X**. Everyone in this study will get **Drug X**, but the dose level you get will depend on when you enter the study.

**Drug X** is given through an IV, which involves putting a needle into a vein in your arm. You will need to come to the hospital once each week to get the IV.

We will also take small amounts of blood over a 24-hour period to see how much of the drug is in the body over time. This requires one overnight hospital stay.

You will have the same kinds of blood tests, physical exams and scans (x-rays, MRI, and CT scans) that you would have as part of standard cancer care to check your health.

**Example for phase II trial:**
Everyone on this study will receive **Drug X** by mouth in 28-day “courses.” In each course, you take **Drug X** 2 times a day for 21 days, then stop **Drug X** for 7 days.

At the start of each 28-day course, you will:
- have blood drawn for research tests
- fill out questionnaires about how you are feeling
- have the same kinds of blood tests, physical exams and scans (x-rays, MRI, and CT scans) that you would have as part of standard cancer care to check your health

**Example for phase III trial:**
People in this study will be assigned by chance to get either the investigational drug, **Drug X**, or the standard care drug, **Drug Y**. You will not be able to choose which drug you get. Study treatment will also be “blinded.” This means that, during the study, you and the researchers will not know if you are getting **Drug X** or **Drug Y**. Blinded study treatment is a way to keep people’s expectations from influencing the study results.

Both drugs are pills that you take once each day by mouth.

You will have the same kinds of blood tests, physical exams and scans (x-rays, MRI, and CT scans) that you would have as part of standard cancer care to check your health.

**Example for non-therapeutic study:**
You are having an MRI scan as part of your standard health care. If you take part in this study, you will be in the MRI scanner for an extra 15 minutes while we do the investigational scan. We will also use the results from your standard MRI scan for comparison purposes.

Being in this study will not affect your standard MRI scan. The investigational MRI is only for research and will not be used for your medical care.

**How much time will I spend on the study?**

The goal here is to give potential subjects a clear summary of the time commitment required by the study. Both the overall length of participation and the amount of time required for study visits or other study-related activities are relevant. Do NOT detail each visit or study procedure. Use ranges of time, frequency of visits, comparisons with standard care, and similar strategies.
Example: There is one study visit that will take about 4 hours.

Example: You will come to X location once a week for 6 weeks. The first and last visits will take about 2 hours. Visits in weeks 2 – 5 will take about an hour.

Example: For the first course of study treatment, you will need to come to the clinic once a week. After that, you will come to the clinic once at the start of each 28-day treatment course. Each visit will take 3 - 6 hours. You can be on study treatment until you have bad side effects, your disease gets worse, or you or the study doctor decide you should stop. Even after you stop study treatment, the research team would like to collect information from your medical records for up to 5 years.

Could taking part in the study help me?

Briefly state whether subjects can reasonably expect to benefit directly from taking part in the study.

For non-therapeutic studies: Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about [describe potential scientific/societal benefits].

For phase I study: We do not expect this study to help you directly. We are testing the study treatment to learn about its side effects and decide on a safe dose. We have no evidence yet about whether the study treatment is effective in treating disease.

For phase II or III study with therapeutic intent: The study treatment may work better than standard care for your condition, but we cannot promise this will happen.

For randomized, placebo-controlled study: If you are in the group that gets study treatment, this may work better than the standard treatment for your condition, but we cannot promise this will happen. If you are in the group that gets placebo treatment, we do not expect you to get any health benefits from being in this study.

What are the main risks of taking part in the study?

For treatment studies: All treatments have possible side effects. We will watch for side effects during study treatment and do what we can to relieve them. But you should know that side effects can be serious, even life-threatening, or may not go away.

For this study, the most important side effects to know about are:

Briefly summarize the risks most important to making a decision about study participation. For treatment studies, this might include side effects that are different from those associated with standard treatment. It could be those risks a clinician would consider essential to discuss with a patient. Do NOT simply copy and paste all of the common risks listed in the consent form.

Example: We expect the side effects of Drug X to be similar to those seen with other treatments used for your condition. These side effects include:
The MRI scanner uses a very strong magnet, making it unsafe for people with metal on or in their body to have an MRI scan.

We do not know if MRI scans are safe during pregnancy, so if you think you might be pregnant, you should not be in the study.

You might feel anxious in the small space of the MRI scanner. You will be able to stop the scan at any time.

You might be uncomfortable lying on your back during the scan.

The MRI scanner makes loud noises. You will wear ear protection.

For questions about the study, contact the research team:
insert phone #
for treatment studies, include:

Emergency contact: [insert instructions for 24-hour assistance]

For questions about research participants’ rights, or for complaints, contact: University of Wisconsin Hospital and Clinics Patient Relations Representative at 608-263-8009.