Study participant's discussion guide to clinical trials

Thank you for considering a clinical trial

We appreciate that you're taking the time to think about joining a clinical trial. We understand that this may be a difficult and emotional time for you, filled with lots of information.

It is important to know that taking part in clinical trials is always **completely voluntary**. You can also choose to leave the trial at any time. Keep in mind that the choices you make will **not** affect your relationship with your healthcare team.

We created this discussion guide to help you navigate through the process of taking part in a clinical trial. This guide covers the following topics:

Clinical trials and why they are important

Clinical trials are **research studies that include human participants**. Clinical trials can explore how an **investigational drug** might act in the body and affect a disease.

An **investigational drug** is a drug that is still being researched. It is not yet approved for doctors to prescribe to the general public.

In clinical trials, an investigational drug is often compared to a **placebo**. A **placebo** is an inactive pill, liquid, or powder, that has no treatment value.

Clinical trial research is carried out in a series of steps, known as phases, to study whether the investigational drug is safe and effective for people to use.

Overview of how a drug typically becomes available to the general public

Researchers run lab and animal studies	This is the stage before an investigational drug is tested in humans.
Researchers run clinical trials (phases 1, 2, and 3)	Researchers run clinical trials, and test the safety and effectiveness of an investigational drug in human participants.
FDA approves the drug	After the US Food and Drug Administration (FDA) approves the drug to help treat a specific disease(s), doctors are allowed to prescribe it to patients.
Researchers sometimes run more clinical trials (phase 4)	The long-term effects of the approved drug are studied to improve the understanding of its safety and effectiveness.

Why do people take part in clinical trials?

People take part in clinical trials for a variety of reasons that are unique to them. For example, some people may decide to take part for the following reasons:

- to help researchers better understand a disease, and
- to help researchers find new treatments for people in the future.

How can I get information about a specific clinical trial?

Ask your doctor about whether there are clinical trials that may be right for you.

Read any documents that your doctor or your study team gives you, including the **Informed Consent Form (ICF).**

What is a clinical trial's Informed Consent Form (ICF)?

The ICF is a document that is made to help you understand a specific clinical trial. This document guides you through what you can expect in the clinical trial before you make your decision of whether to take part in it.

You can take as long as you need to read the ICF and make your decision. If you decide to take part in the clinical trial, then you will be asked to sign the ICF to provide your informed consent.

An overview of your journey through a clinical trial

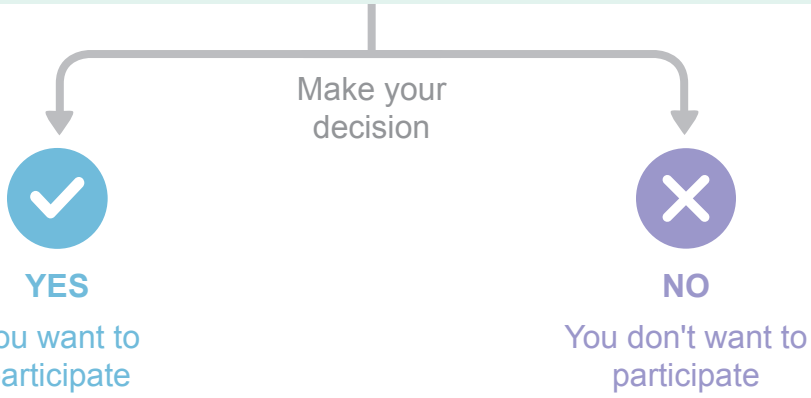
Keep in mind that everyone's journey through a clinical trial is unique. You can always choose to stop taking part in the trial at any time, and this will not affect your future medical care in any way.

Before you make the decision about participating

You'll receive information about a specific clinical trial. The information will include an Informed Consent Form (ICF).

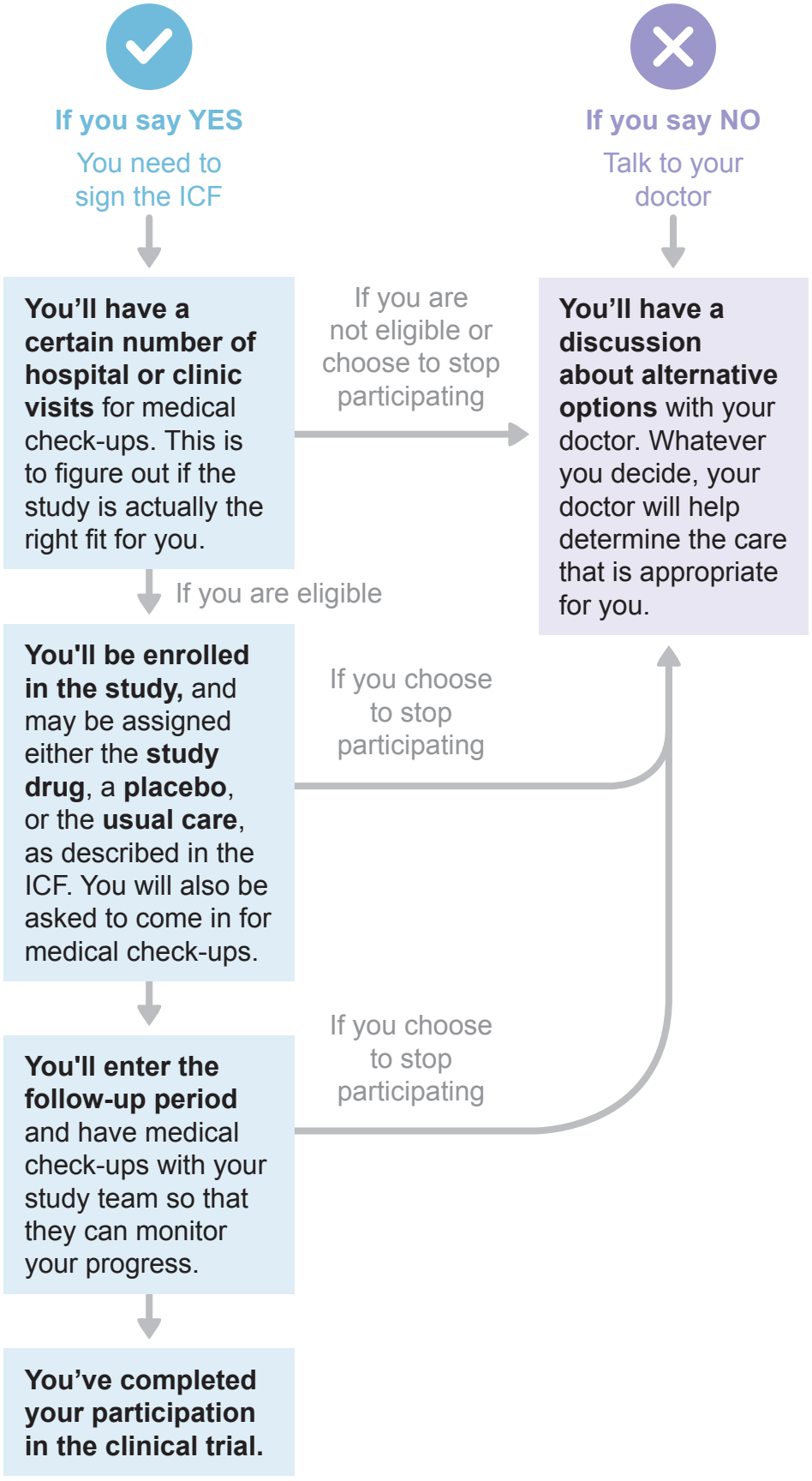
You'll have time to read the ICF. You may want to take it home, take time to review the information, and talk to your family and friends as well as your doctor. You will have the chance to ask questions at any time.

You'll make a decision about whether you want to take part in the clinical trial. You can take as long as you need to make this decision. If you decide to take part in the clinical trial, then you will be asked to sign the ICF.



(Continue reading on the next page to learn about what happens after you make your decision.)

After you make the decision about participating



Preparing yourself to make the decision

It is important to understand what you will experience in a specific clinical trial, before deciding to take part in it. You and your doctor will talk about clinical trials that may be right for you. You should only take part in a clinical trial if:

you have read through the entire Informed Consent Form (ICF),

you understand the information in the ICF, and

you and your healthcare team think that it is a good option for you.

What factors are important for me to consider?

To help you get started, here's a list of factors that you may want to think about as you learn more about a specific clinical trial:

- Will I have a convenient way of getting to the clinic?
- Do I have support or a caregiver to help me through this?
- If I choose to take part in this clinical trial, will that affect my chances of taking part in other clinical trials later on?
- Will I be able to choose which study drug to receive?
- Will I have to take time off work?
- Will I still be able to take part in the activities that are important to me?
- If I move, can I continue the study at another hospital?
- Will I be allowed to get pregnant while on the study?

✎ Consider using the space below to add your own questions.

Questions that you might have for your study team

If you are ready to get into the details of the study, please refer to your **Informed Consent Form (ICF)**. The ICF covers the following topics:

1. Key points about this study
2. Study flow and time commitment
3. Risks and benefits
4. Costs, reimbursements, and compensation for research-related injury
5. Rights, responsibilities, privacy, and data collection

To help you prepare for conversations with your study team, the **next 4 pages have some example questions** that you may want to ask at your next appointment.

There is empty space beside each question for you to jot down answers that you may receive from your study team.

1. Key points about this study

Example questions:

Consider writing your answers in all available white spaces.

Is it possible that I won't be eligible for the study?	
Have other people like me received this study drug?	
Will I get to choose which study drug I receive?	
Is there a chance that I might get a placebo?	
Other than this clinical trial, what are my options?	

Consider writing your own questions in the empty rectangles.

2. Study flow and time commitment

Example questions:

What happens if I miss an appointment?	Consider writing your answers in all available white spaces.
Is there support available if I can't get to a certain location?	
How do I prepare for each visit?	
Where do I need to go for each procedure?	
How will I know if the study drug is working?	

Consider writing your own questions in the empty rectangles.

3. Risks and benefits

Keep in mind that each person's experience is unique. Some people may experience risks, while others may not. Examples of some of the risks you may face are:

- **Study drug risks,** called side effects, may be caused by the study drug(s) themselves,
- **Study procedure risks,** may be caused by doing procedures like x-rays, by dyes in CT scans, or by needle punctures from blood collection, and
- **Unknown risks** are also possible because the study drug(s) are still being researched. These may include risks to reproduction, and risks to taking other drugs at the same time.

There may not be any benefit to you from taking part in a clinical trial, and researchers are still trying to figure out if the study drug(s) will have any positive effect on you or your disease.

Researchers hope that the information they collect from a clinical trial will help them understand the study drug(s) better. The results of a clinical trial can help researchers find benefits for people in the future.

Example questions:

What kind of side effects might I experience?	
What can I do to manage my side effects?	
What are my options if I can't manage my side effects?	
Who should I talk to if I experience side effects?	
How will this study benefit me?	
What happens if my disease gets worse while I am in the study?	

Consider writing your answers in all available white spaces.

Consider writing your own questions in the empty rectangles.

4. Costs, reimbursements, and compensation for research-related injury

Example questions:

Will I need to pay for the study drugs that I receive?	
Who will cover the cost of the tests that I need to have?	
Will I get paid for taking part in the study?	
Will I be reimbursed for traveling to the hospital or clinic?	
How do I get reimbursed?	
Who should I talk to if I have questions about costs?	
If I get injured from taking the study drug, who will cover the cost?	
Who will take care of me if I get injured from being in this study (family doctor, study doctor, etc.)?	

Consider writing your answers in all available white spaces.

Consider writing your own questions in the empty rectangles.

5. Rights, responsibilities, privacy, and data collection

Example questions:

What should I do if I don't want to participate anymore?	Consider writing your answers in all available white spaces.
Can my study doctor stop me from taking part in a clinical trial?	
Can I take my scans and lab results home?	
What will happen to my samples? How will they be used?	
Who will have access to my medical and personal information?	
Will I eventually find out which study drug I received?	
If I am given a Participant Alert Card, do I have to carry it everywhere with me?	

Consider writing your own questions in the empty rectangles.

Your next steps and links to resources

Now that you have read through this document, here is a simple checklist that you can follow for your next steps:

- [ ] **1.** Read the Informed Consent Form (ICF). You should only sign the document if you:
  - understand what is involved,
  - had a chance to ask questions,
  - have a member of your study team beside you as you sign the document, and
  - want to take part in the clinical trial.
- [ ] **2.** Prepare for your next appointment with your study team and consider writing down any questions. There is space provided within this guide (pgs. 7-11) or within your copy of the ICF if you choose to write your questions in these documents.
- [ ] **3.** Review the ICF with your study team and ask any questions that you may have prepared.

For more information about clinical trials, here are a few online resources for you to consider:

- BMS Study Connect **www.bmsstudyconnect.com**
- ClinicalTrials.gov **www.clinicaltrials.gov**
- National Institutes of Health:
  NIH Clinical Research Trials and You
  www.nih.gov/health/clinicaltrials

✎ Consider using the space below to add other resources of your choice.