The *National Statement on Ethical Conduct in Human Research (2025)* requires that you be given information about a trial before you agree to take part as a research participant. This is known as informed consent.

Research participants must be told:

- Information about an unproven drug or device if involved in the trial.
- The purpose of the research.
- The duration of the trial.
- What will happen in the trial and which parts of the trial are experimental.
- Possible risks or discomforts.
- Possible benefits.
- Other options that you might want to consider instead of the treatment being studied (i.e. other procedures or treatments) if involved in a clinical trial.
- Who to contact with questions about the trial, your rights, and any injuries related to the research
- Being in the trial is voluntary and you can withdraw at any time.

Before you agree to participate in a trial, you must be given complete information about the research. This is usually in the form of a Participant Information Sheet. It must include possible side effects and benefits, and you must be given the opportunity to ask questions. You must sign an agreement called an *Informed Consent Form* before taking part in the trial.

At any time, you can leave the trial and you do not have to give a reason.

The Participant Information Sheet

The Participant Information Sheet provides information to potential research participants to enable them to reach an informed decision regarding their involvement in the research.

A Participant Information Sheet must accompany each Consent Form. It must not replace personal communication between the researcher and the participant. Informed consent information should be written so you can understand it. If you do not, be sure to ask your doctor, the researcher, or other medical persons to explain it. Make sure you understand all of it before you agree to be in the trial. The informed consent form should state that you can leave the study at any time, for any reason after you have joined, without penalty to you. The researcher must ensure that you are given sufficient time to consider the verbal and written information provided, and given the opportunity to discuss it with other people (your general practitioner, friends and/or your family) before being asked to consent to being involved. You should be allowed to bring someone along with you during the consent process. The Participant Information Sheet is to remain your property and a copy of the signed Consent Form must also be provided to you.

Risks and discomforts

Any foreseeable risks, side effects, discomforts, inconveniences and restrictions that may occur to you during the trial, including travel and absence from work should be stated in the information sheet. These should be explained in simple language and should help you decide to participate in the trial or not.

Consent Form

The Consent Form should include the following:

- A statement about the purpose and reason for conducting the trial.
- A statement to the effect that you may freely withdraw from the project at any time without prejudice to further treatment.
- A statement informing you that there may be no direct clinical benefit to you as a result of the trial.
- Where reimbursement for out-of-pocket expenses is to be made, the terms should be clearly set out.
- A statement that information collected will be kept confidential, however consent for access for specific purposes such as quality assurance, auditing and in the event of serious adverse events must be obtained.
- A statement that you have been given the opportunity to ask questions about the study.

References

National Statement on Ethical Conduct in Human Research (2025)
TP G1 General information on trials
TP F1.1.2 Questions to ask
TP F1.1.3 Definitions