What is informed consent?

Informed consent is the process of sharing important information about a clinical trial with potential participants. This information includes the purpose of the study, the procedures involved, the potential risks and benefits, and the participant's rights. It is important for potential participants to fully understand the information provided so they can make an informed decision about whether or not to participate in the trial.

Who is involved in obtaining informed consent?

Informed consent is typically obtained by research coordinators or clinical trial investigators. Physicians and other health care professionals may also be involved in obtaining informed consent, depending on the specific trial and regulatory requirements.

What does it mean to be randomized?

Randomization is the process of assigning participants to different study groups. This is typically done to ensure that the groups are comparable and that any differences in outcomes can be attributed to the treatment being studied rather than other factors. Participants are randomly assigned to either the control group (which does not receive the new treatment) or the experimental group (which receives the new treatment).

Can I ask about the side effects that have been observed?

Yes, you can ask about any side effects that have been observed in previous trials. The research staff will be able to provide you with information about the side effects that have been reported.

How often will I see my doctor or research team?

The frequency of visits will depend on the specific trial and your participation in the study. You may be seen more frequently during the start of the study and less frequently as the trial progresses.

What will I have to do if I take part?

The specific tasks you will be required to perform as a participant in the trial will be outlined in the informed consent document. This may include taking medication, attending appointments, and completing questionnaires or other assessments.

What are the possible advantages and risks of taking part in this trial?

The possible advantages of participating in a clinical trial include the opportunity to receive new treatments that are not yet available to the general public. However, there may also be risks associated with participation, such as adverse events or the possibility of receiving a placebo.

Can you tell me why this trial is being done?

Clinical trials are conducted to evaluate the effectiveness and safety of new treatments. The specific goals of the trial will be outlined in the informed consent document and will be determined by the sponsor of the study.