Texas Back Institute

Frequently Asked Questions about Clinical Research

What is a clinical trial?

A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. A clinical trial is a research study with human volunteers that tests the efficacy, safety, and dosing of investigational drugs and devices.

Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

What happens during a clinical trial?

The clinical trial team includes doctors, nurses, research coordinators, as well as other healthcare professionals. They check the health of the participants at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch during and after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff. This also ensures that a participant's health and progress is closely monitored while they are on a study.

How is the safety of the participant protected?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, almost all clinical research is federally regulated with built in safeguards to protect participants. The trial follows a carefully constructed and controlled protocol which is a study plan detailing what researchers will do in the study. At the completion of a clinical trial (or sometimes as it progresses), researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies, such as the FDA. Individual participants' names are not mentioned in these reports. Data is referred to by a study number and or initials.

What is an Institutional Review Board?

As in any medical research facility, an institutional review board (IRB) must review and approve every new study before the study can begin. The IRB is made up of medical specialists, statisticians, nurses, social workers, medical ethicists, and members of the community. The IRB's responsibility is to ensure that the rights of persons participating in research studies are upheld. These IRBs review the protocol and the informed consent form to make sure that any risks are minimized to the greatest extent possible and that all risks are explained before a person agrees to participate.

What does informed consent mean?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. Before entering into a study, it is important that the research participant fully understands the study and what involvement in the study would entail. Research staff members will help by providing the patient an informed consent statement, which has detailed information about the study, including the length of the study, the number of visits required, and medical procedures and medications and/or devices included. The informed consent also details what compensation if any, will be given as well. It also provides expected outcomes, potential benefits, and possible risks.

Research staff will review the informed consent statement with the participant and answer all questions. If the participant decides to participate after reviewing the statement and talking with staff and family members, they will need to sign the informed consent statement. Informed consent is not a contract, and the participant may withdraw from the trial at any time. The participant's signature indicates that they understand the study and agree to participate voluntarily.