MEDPACE

STUDY PARTICIPANT INFORMATION

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Learn More About Medical Research

Before a new medication or procedure can be introduced to the public, it must undergo a series of rigorous studies to prove that it is safe and effective. Following the successful completion of these studies in the United States, the medicine or procedure is submitted to the Food and Drug Administration (FDA) for approval (in other countries, applications are reviewed by regulatory authorities similar to the FDA.)

There are four basic steps or phases of research that a drug, device or procedure must go through. Specific information is gathered in each phase, and that information determines how to approach research at the next phase. The Medpace Clinical Pharmacology Unit conducts mostly Phase I and Phase IIa studies, which are well-controlled studies where participants stay at our comfortable, centrally located facility overnight or for a series of days.

1. **Phase I** is the study of the drug or procedure in normal, healthy volunteers.
2. **Phase II** is the study of the drug or procedure in small groups of patients with the targeted disease.

By providing valuable information on how the drug or procedure affects the body, what side effects may be seen, and what the correct dosage may be, these phases together answer these two important questions:

- Is the drug or procedure safe to give to people?
- Does the drug or procedure work in people?

Before a study can be started a study protocol must be written to outline the processes and procedures the study must follow, with a focus on patient safety and scientific accuracy. The protocol outlines the history of the drug or device, why the study is needed, exactly what will happen in the study, the rules about who may or may not participate in the study, and what medical measurements will be reviewed.

The key person conducting the study is usually a medical doctor known as the **Principal Investigator** (PI). This person, who you will meet and interact with, is responsible for making sure the study adheres to the protocol while protecting your safety and well-being.

The PI is aided in this process by an independent oversight body known as an Institutional Review Board (IRB), made up of scientific experts, physicians, ethicists, lay persons, and possibly others from the community. The IRB's purpose is to make sure the study is needed, conducted in an ethical manner and that the rights of the study participants are protected.