

### **1. What is a clinical research study/trial?**

A clinical research trial is a research study designed to evaluate the safety and/or effectiveness of treatment on a human condition or illness. The treatment can involve an investigational medication or a device.

### **2. Who oversees a clinical trial?**

Laureate physicians and research professionals supervise our trials. The primary physician on a trial is called the Principal Investigator, or PI. Several physician and/or non-physician staff members, known as Sub-Investigators or Sub-I's, may assist the PI. The Clinical Research Coordinator, or CRC, coordinates all aspects of the study, and is the Laureate staff member with whom the patient has the most contact.

### **3. Why are clinical trials important?**

Clinical trials provide the information necessary for a regulatory agency to safely approve new treatments and medications. In the United States, the Food and Drug Administration (FDA) requires that new drugs or devices be tested and shown to be safe and effective before they can be approved. Clinical trials also help to answer questions on whether medications have side effects and how serious these are.

### **4. Who can participate in a clinical trial?**

In order to help the researchers determine the appropriate people to study, each clinical trial is designed with inclusion and exclusion criteria that allow or disallow certain people in the study. These criteria may require that participants be of a certain age, gender, or race, and that they have certain medical conditions, treatment history, or laboratory test results. By following the inclusion and exclusion criteria, researchers are able to assure patient safety, while obtaining answers to their research questions.

### **5. Why should I participate in a clinical trial?**

The decision to participate in a clinical trial is a personal one that an individual should discuss with his or her physician. Beneficial reasons may include access to medical care, or a new treatment that is not yet available for use in the general population. Some may participate to learn more about a disease or condition. Others

may choose to participate to allow researchers to gain knowledge that may help others in the future.

**6. What are the benefits?**

An individual may or may not benefit from participating in a clinical trial. In addition to learning more about a product not yet approved, a patient may benefit from the opportunity to receive health care from a physician who specializes in the field being studied.

**7. What are the risks?**

Taking even the most common medication can pose risk to an individual. The risks of participating in a clinical trial may range from minor to possibly life-threatening. It is vital that you obtain complete information about the trial. You should ask questions of the researchers to enable you, as a participant, to evaluate the risks and benefits.

**8. What is a sponsor?**

The sponsor of a clinical trial is the individual or group who provides funding for the research. Sponsors can include pharmaceutical companies, foundations, hospitals, and non-profit, disease-specific organizations (such as the American Heart Association, the American Cancer Society, or others). Other sponsors may include federal agencies, such as the National Institutes of Health (NIH).

**9. What is a protocol?**

A protocol is the detailed plan written by the research scientists to protect the patient, while answering researchers' questions regarding the product being tested. It is important for all research staff to follow the protocol carefully. The protocol defines who can participate, and outlines the procedures to be done within a specified timeframe. It includes medications to be used, the length of the study, and which lab tests and procedures are to be performed.

**10. Who is responsible for protecting the rights of research participants?**

An Institutional Review Board (IRB) must approve each clinical trial protocol and its informed consent. This Board is comprised of

physicians, healthcare workers, clergy, statisticians, and community representatives, who make sure that the study is conducted in an ethical manner. It is the responsibility of this body to make sure that the benefits of a particular study outweigh the risks, that the risks are minimized, and that the confidentiality and rights of the participants are protected. After initial approval by the IRB, a clinical trial is monitored by the IRB at regular intervals.

### **11. What is informed consent?**

Informed consent is the process by which a participant learns the key facts about a clinical trial. A signed informed consent document is required for all trials involving humans. The informed consent document must be reviewed and approved by the IRB prior to the start of the study. The informed consent document describes the reason for performing the study, the procedures involved, the number of visits, the treatments, risks and benefits, costs, and other important information. Following a detailed discussion with the researchers, whereby all questions are answered, each participant and/or a parent or guardian must sign the informed consent. This must occur prior to enrollment in a clinical trial.

### **12. What does it mean if the study is blinded?**

When the outcome of the study can be influenced by the expectations of those involved, study designers may decide to blind a study. Blinding is a process by which the treatment information including the drug and dosage is withheld from the participant and/or the research staff.

### **13. What is a placebo?**

A placebo is an inactive substance that has no treatment value. It can be one of the treatment options in some, but not all, clinical trials. When the results of using an active medication are compared with those of a placebo, researchers can learn more about the effectiveness, as well as side effects, of the medication being studied.

### **14. What is randomization?**

Randomization is a process, usually computerized, where study participants are assigned to one of two or more treatment options

by chance. The validity of the study design is considered optimal because researcher bias is removed in this way.

### **15. What are the phases of clinical trials?**

There are 4 phases of clinical trials, each with a different purpose and to answer different questions. Each phase provides important information.

- Phase I trials test a new drug or treatment for the first time in humans, in a small number of volunteers (20-80). This phase provides information on safety, dose range, and side effects. These participants are often healthy volunteers. Phase I studies may involve significant risk, since the treatment is being studied in humans for the first time.
- Phase II trials study the treatment in larger groups (100-300) evaluating safety and effectiveness in individuals with the disease or condition being studied. Phase II studies are often randomized and controlled (using placebo as the control).
- Phase III trials study the treatment in even larger groups (1000-3000) to define effectiveness, side effects, safety, and comparison to other treatments. During this phase, the study drug may be compared to a placebo or an already approved treatment. Phase III studies can last for many years. After researchers have completed data collection in these trials, the sponsor may request FDA approval to license the drug or device as a treatment for the condition being studied.
- Phase IV trials are conducted after the treatment has obtained approval by the FDA. These trials can further identify risks and benefits to human subjects. They often involve comparing a drug to other marketed (already FDA approved) drugs.

### **16. Once I sign the consent, can I change my mind?**

Your participation in a clinical trial is always voluntary. You are free to withdraw at any time.