understanding the

informed consent process

CenterWatch

www.centerwatch.com

:: about this pamphlet

Millions of volunteers participate in government-and industry-sponsored clinical trials each year. Prior to agreeing to participate, every volunteer has the right to know and understand what will happen during a clinical trial. This is called informed consent and it is a process that can help you decide whether or not participating in a trial is right for you.

This pamphlet provides an overview of the informed consent process and helps you understand your rights and responsibilities as a study volunteer.

:: your bill of rights

If you have given consent to participate in a clinical trial, or if you have given consent on behalf of another person, you both are entitled to the following rights:

- To be told the purpose of the clinical trial
- To be told about all the risks, side effects, or discomforts that might be reasonably expected
- To be told of any benefits that can be reasonably expected
- To be told what will happen in the study and whether any procedures, drugs, or devices are different than those that are used in standard medical treatment
- To be told about all options available to you and how they are better or worse than being in a clinical trial
- To be allowed to ask any questions about the trial prior to consenting and/or at any time during the course of the trial
- To be allowed ample time, without pressure, to decide whether or not to consent to participate
- To refuse to participate, for any reason, before and after the trial has started
- To receive a signed and dated copy of the informed consent form
- To be told of any medical treatments available if complications occur during the trial

:: what you should know

When you give written consent to participate in a clinical trial, you are acknowledging that you understand and accept all aspects of the study—including any risks or benefits. However, informed consent is not strictly about signing a document. It is a process that involves ongoing conversations between the research staff and you before, and even after, you decide to become a study volunteer.

To begin, the research staff is obligated to discuss all the pertinent information about the trial—its purpose, the procedures involved, the potential risks and benefits—with you. It is your responsibility to ask questions if there is something you do not understand.

If you do not understand any part of the process, ask the researcher to repeat the information or to explain it in another way, using everyday words. If English is not your first language, inform the researcher that you are not comfortable speaking about a clinical trial in English. Upon request, research centers can and should produce documents that explain every aspect of the study and study personnel should be able to explain the information to you in your preferred language. If this is not possible, you should not participate in the study.

It is the responsibility of the research staff to help you understand the information they provide you and to give you enough time to ask any additional questions you may have. In some instances, this may not be possible to accomplish in a single visit, therefore it is essential to take the time you need to make an informed decision. You may discover important concerns that you did not think about during the first visit.

:: what questions you should ask

The following represents a sample list of questions that you should ask during the informed consent process:

:: about the clinical trial

- What is the main purpose of the study?
- Why is this study important to me?
- What are the chances that this drug will work?
- What kinds of risks are involved?
- How much of my time will this take?
- Does the study involve a placebo or a treatment already on the market?

:: about your care

- What kinds of tests will be done? Will they hurt? If so, for how long?
- How will the tests in the study compare to tests I would have outside the study?
- Will I be able to continue to see my own doctor during the study?
- Will I be able to continue to take my regular medications during the study?
- If I have side effects, can they be treated during the study?

:: about personal matters

- Who will review information collected about me during the trial?
- What happens if I decide to quit the study?
- Can the investigator take me out of the study even if I want to continue?

:: about compensation and costs

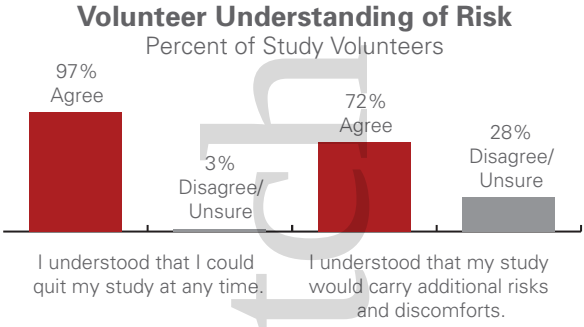
- Do I have to pay for any part of the study? If so, will insurance cover these costs?

:: take time to understand

A recent CenterWatch survey of 590 study volunteers offers insight into the informed consent process and whether or not it is working to help volunteers understand their roles and responsibilities. Some key takeaways from the study are:

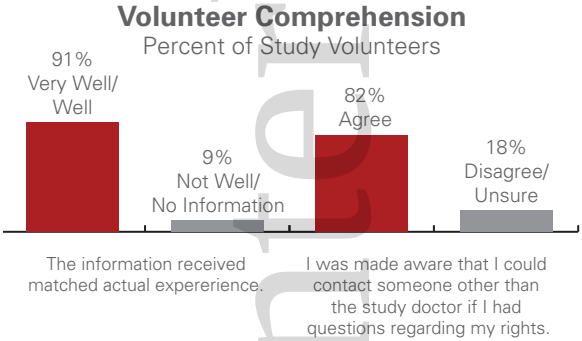
- Nearly 96% of volunteers said they received the informed consent form and 86% said they read the form completely.
- The vast majority of volunteers said they understood the expectations of the study, including additional risks and their ability to withdraw at any time.
- More than three-quarters understood that they could contact someone outside the study if they had additional questions about their rights during the trial.
- More than half the volunteers were unaware that neither their doctor nor they would know what medication they would receive during the study; more than two-thirds understood that they could receive a placebo in the trial.
- Nine out of 10 volunteers said that the information received prior to the trial matched their actual experience during the trial.
- Approximately 75% of the volunteers indicated that the main reason for participating in a study was to help themselves or others and to advance science.

Research studies are very involved so it is important to learn as much as possible about the study you may participate in before you consent. The U.S. Food and Drug Administration (FDA) guidelines state that study volunteers should understand the risks they're taking, which may



Source: CenterWatch Survey of 672 Study Volunteers, 2009

mean spending additional time with the research staff to make sure you get the information you need. If you want to know details, such as any documented side effects of a particular drug observed in earlier clinical trials, you must ask for that information as well as any other information you may want to know.



Source: CenterWatch Survey of 672 Study Volunteers, 2009

The decision to participate in a clinical trial is a personal one and one that you are entitled to make freely, without influence or coercion. Being properly informed so that you fully understand the responsibilities of becoming a study volunteer is the best way to ensure that you are making the right decision for you.

:: about CenterWatch

Founded in 1994, CenterWatch is a trusted source and global destination for clinical trials information for both professionals and patients. A Boston-based publishing and information services company focusing on the clinical research industry, We provide proprietary data and information analysis on clinical trials through a variety of newsletters, books, databases, and information services used by pharmaceutical and biotechnology companies, contract research organizations (CROs), site management organizations (SMOs), and investigative sites involved in the management and conduct of clinical trials.

As a pioneer in publishing clinical trials information, CenterWatch was the first Internet site to publish detailed information about active clinical trials that could be accessed by patients and their advocates. Today, we have one of the largest databases of clinical trials actively seeking patients on the Internet. For a comprehensive listing and detailed information about our publications and services, please visit our web site at www.centerwatch.com.