What Does Volunteering For Research Studies/Clinical Trials Involve And What Questions To Ask Before Agreeing To Participate In A Research Study.

Many scientific breakthroughs in finding new ways to treat and even cure both mental health and physical health conditions often occur through research and clinical trial participation. Therefore, the importance of research and volunteering to be part of an ongoing research study can't be understated in helping universities, pharmaceutical companies or other researchers find and/or develop new and cutting edge treatment options or cures. If you are interested in volunteering your time as a research participant, below are some tips, guidelines and a link from the National Institute of Health (NIH) that should help you make the best informed decision about what study to participate in and what questions to ask the researchers before volunteering your time.

Please click on the link below to learn more from the NIH's Clinical Research Trials And You

http://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

Why Are Human Subjects Used In Research/Clinical Trials?

Researchers use human subjects to answer a specific question or find information that may benefit all people. These studies can involve a wide variety of procedures, ranging from filling out surveys and questionnaires to taking experimental drugs or even surgical procedures. Some studies last a few minutes while others last for many years.

Who Conducts The Research Or Clinical Trials?

Research studies are conducted by students, staff, and faculty of Universities or of staff at research institutions or pharmaceutical companies. Research studies can be conducted by students to fulfill an educational requirement such as a thesis or dissertation, or by a faculty member searching for the answer to a social, behavioral, or medical question. The researcher in charge of the study is called the Principal Investigator (PI). The PI has the ultimate responsibility for the management of the study and for the rights, welfare and safety of the human subject.

Are There Any Benefits To Being In A Research Study?

Some individuals will receive novel treatments for the particular conditions being investigated. However, not everyone who participates in a research study will benefit personally. Your participation may benefit humanity by helping researchers learn more about issues that affect people in many aspects of life.

Who Determines If The Researcher Has Approval To Do His Or Her Research?

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) in order to ensure that the risks are minimal and are worth any potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. Potential research participants should ask the sponsor or research coordinator whether the research they are considering participating in was reviewed by an IRB.

What Are The Risks Of Being In A Research Study?

Research studies may involve some degree of risk. A study that asks you to anonymously fill out a survey usually has only minor risks, such as the discomfort or fatigue that may follow filling out the survey. For other studies, risk can be much greater; for example, having a bad reaction to a drug.

Researchers are required to explain the risks of being in a study to you before you decide whether or not to participate. Participation in a research study is voluntary and you may choose not to participate at any time. Your decision will in no way affect your relationship with researching institution.

What Should You Ask Before Agreeing to Participate In A Research Study?

The decision to participate in a research study should be made after careful consideration of the risks, benefits, and alternatives, and should involve input from a variety of sources including friends, family members, and health care providers. The series of questions that follow are meant to serve as a guide to help with this decision-making process.

What Is The Purpose Of The Study?

You should have a clear understanding of what questions are being addressed and how the information will be used to better understand or treat the illness or symptoms under investigation.

Questions You Need To Ask, Or Think About Before Deciding To Participate In A Research Study.

- Am I feeling pressure or obligation to participate in this study?
- How long does my participation in this study last?
- When does this study take place?
- Is the study anonymous or confidential?
- How is my privacy being protected?
- Would I be able to quit without harming my relationship with the researcher or the university?
- Who can I contact if I have questions or complaints?
- Is the study safe?
- Am I going to learn anything from participating?

What Are The Risks?

- Are painful or uncomfortable procedures included in the research study?
- What are the known risks involved using treatments or procedures in this protocol?
- What are possible risks based upon what is known in the scientific and medical literature?
- Are there any known long-term or irreversible risks?
- If new information becomes available during the course of the study concerning additional risks, how will I be informed of this information?
- Who will be responsible for my care if I suffer an adverse consequence as a result of participation in this study?
- If I suffer adverse consequences from the study participation, what are my legal rights?

What Follow-up Care Can I Expect When My Participation In The Study Terminates (Even If This Occurs Before The Trial Is Completed)?

- Will medication or treatment be reinstated prior to my being discharged from the protocol?
- Will the investigators help coordinate my follow-up care?
- Will I be able to receive the study treatment if it appears to be beneficial to my condition?

How Will This Affect My Daily Life?

- How will the research protocol differ from my current treatment?
- What is the time commitment required for my participation in this study?
- Will I be compensated for my time?
- Will I be provided transportation to and from the study site?
- Is daycare available?
- What criteria will be used to exclude or terminate me from the study?

What Are The Benefits I Can Expect to Receive From Participation in this Study?

- Are there any direct benefits to me?
- If not, how will this research contribute to a better understanding or treatment of my disorder?
- Will I be informed about the results of this study? If so, when?

Will My Medical Information Be Kept Confidential?

- Who will have access to my medical records?
- How will confidentiality be assured?

What Are Your Rights If You Decide To Participate In A Research Study?

If you volunteer to participate in research studies you should understand what is being asked of you and why the research is being done. It is also important that you know your rights, which include:

- Being told what the study is trying to find out.
- Being told what will happen to you and what is required of you during the study.
- Being told about the frequent and/or important risks, side effects.
- Being told whether you can expect any benefit from participating and, if so, what that benefit might be.
- Being told about other choices you may have and how they may be better or worse than being in the study.
- You may ask questions about the study before you agree to participate and during the course of the study.
- Being told if medical treatment is available if injury occurs.
- Being able to change your mind about participating after the study has started.
- Receiving a copy of the consent form.