Are You Thinking About Being in a Research Study?

DEFINITIONS OF COMMONLY USED TERMS

- **Adverse event** - An undesirable or unfavorable incident in a human subject participating in a research study. These incidents include both physical and psychological harms.
- **Anonymous** – Not involving a name or any identifiable information about a research subject. For example, an anonymous survey would not ask the person filling out the survey for their name or any other identifying information (demographics) when in combination could identify the subject. Anonymous is not to be confused with confidential (see below).
- **Assent**– The agreement to participate in a research study from a child or an adult Who is not capable of consenting for themselves.
- **Clinical Trial/experimental/study** – Research involving new drugs, devices (e.g. catheter, pacemaker), vaccines, or therapies attempting to answer specific questions (also known as medical research).
- **Coercion** – Too much or unnecessary influence to encourage an individual to participate in a research study. Influence can be actual (paying someone an extremely large sum of money to participate), or perceived (a teacher asking one of their students to participate in a research study they are conducting).
- **Confidential (also see anonymous)** – Where an individuals participation and protected by the researcher. The researcher promises not to share the individual's information with anyone other than those in which the subject has agreed to have their information shared. Not to be confused with anonymous. A confidential study may collect the names or identities of human subject, but just maintain strict privacy.
- **Control group** – The group in a study that is given the standard (not experimental) treatment. For example, in a clinical trial that is examining the effects of a new headache medicine; one group (experimental) of human subjects will get the new headache medicine while the other group (control) will get an over-the-counter pain medication.
- **Focus group** – A group of people gathered together in a study, which is asking about their attitudes or opinions towards a product, service, concept, or idea, or to just talk about a particular topic.
- **Human Subject** – A living person participating in a research study or experiment. May also be called a study participant or volunteer.
- **Informed consent** – An ongoing process in a study in which the researchers explains and describes the research study. The key word here is "ongoing"; meaning that it is the researcher's responsibility to keep the study subjects updated or notified of any new information throughout the entire study.
- **Interview** – The process of asking a subject questions.
- **Investigator** – The person who is actually conducting the research study (also known as researcher). In some large-scale studies, there may be more than one investigator.
- **Institutional Review Board (IRB)** – A group of individuals (scientists, nonscientists, statisticians, clergy, etc.) that review and approve research involving human subjects and ensure that the

rights and welfare of all human subjects are protected. All human subjects research must be approved by an IRB before they begin.

- **Legally Authorized Representative (LAR)** – A person authorized under state or federal law, or a legal body (such as a court) to consent on behalf of another individual to participate in research.
- **Monitor** – A person who constantly tracks and reviews the progress of the study and the study subjects.
- **Participation** – In human subject research, the act of agreeing to be a part of a research study.
- **Phases of research** – The four stages of a clinical trial. Phase I studies consist of testing a new drug in a small group of healthy human subjects aimed at studying the effects and interaction of the drug in the subjects (determines safety and side effects). Phase II studies consist of a larger group of human subjects aimed at studying how effective a drug is in treating the specific condition, disease, ailment it was produced for (determines whether the treatment works). Phase III studies consist of an even larger group of human subjects intended to gather additional information to evaluate the overall effectiveness (risks and benefits) of the drug and is built on the results of the phase I and II trials (determines if it is better than current therapies). The last phase, Phase IV, is conducted after the drug has been licensed and marketed to the public and is intended to gather additional information about the drug's risk, benefit, and its' best use (determines the long-term safety and effectiveness of a new treatment).
- **Placebo** – An inactive pill, liquid, or powder that has no value or effect on the person taking it. It is also known as a "sugar pill."
- **Placebo-controlled studies** – A study that has at least two groups; one being the group that receives the placebo and the other group receiving the new treatment. For example, a study examining the effects of a new pain drug (like aspirin) will have one group receiving a placebo while the other group receives the new pain drug.
- **Protocol** – The document that describes, in detail, the study plan. This is a detailed explanation of the purpose, procedures, methods, etc. of a research study.
- **Questionnaire/survey** – A method of obtaining information by using organized questions. Often this method is used in social-behavioral research.
- **Randomization** – A method of assigning individuals to a group or treatment not using a specific matrix, but a random process (*v. randomized*).
- **Research** - An organized method, design or study in which researchers (scientists, physicians, students, etc.) attempt to obtain information or answer a question (also known as an experiment).
- **Risk/benefit ratio** – The method in which risks are compared with benefits. IRBs use the risk/benefit ratio to evaluate human subject studies to see whether the benefits of the study outweigh the risks.
- **Screening** – The process of evaluating potential volunteers for a research study. This process is done before the actual study is started and may consist of a variety of tests or questions in an effort to find the exact type(s) of people appropriate for the study.
- **Study population** – The type of people who meet the criteria to be in a study. For example, a study involving experimental methods to reduce stress in senior citizens will have a study population of: male and females, age 55 and over, who are showing signs of suffering from stress.
- **Therapeutic misconception** – Where the subject thinks the research study they are involved in is treatment (will definitely help them) rather than research (which is testing to see if the drug/device/procedure will help them.

- **Treatment vs. Research** – A treatment involves using an approved drug, method, therapy, etc. to help mental or physical disorder, disease, illness. Research, on the other hand, is the process of obtaining information or answering a question and may involve a treatment. Not all research studies involve treatment.
- **Unanticipated problem** – an unexpected event that may add additional risks to a research study. For example, if a research subject becomes so upset that medical intervention is required, an investigator of the research study only expected that subjects might become mildly upset, instead one or more subjects(s) become so upset that medical treatment is required.