GLOSSARY OF TERMS FOR RESEARCH PARTICIPANTS

Adverse Event: Complications or drug side effects that may occur during the research study. An anticipated adverse event is known to occur from past experience with the treatment. An unanticipated adverse event is an unexpected complication. These events may or may not be related to your participation in the research study, and will be closely monitored and recorded by the Principal Investigator.

Assent: Acknowledgement from a child that they want to participate in a research study. Assent is obtained from children older than 7 years of age (where possible) and permission is obtained from the child's parent(s) or legal guardian(s).

Bias: Factors, such as human choice or opinion, that may affect the results of the study when, in reality, these factors are not related to the treatment under study.

Blinded: An approach to avoid bias, when a researcher and/or study participant is not aware of whether the study participant is on the drug being studied or a placebo.

Biomedical: Having to do with the life sciences, medicine, dentistry, nursing, and public health.

Clinical Trial: A carefully controlled and developed study or research study designed to test and evaluate new drugs or treatment plans.

Clinical Research: Medical research that may involve patients and sometimes healthy volunteers. These research studies are designed to uncover better ways to treat, prevent, diagnose, and understand human disease. Sometimes they help patients feel or get better but sometimes they don't. In rare cases, the studies can make patients worse.

Cognitive Impairment: Reduction in mental functioning and ability to carry out tasks that require thinking, planning, and memory. This may include those who use drugs or alcohol, suffer from a disease that affects the brain, are terminally ill, and have severe physical handicaps. These groups of people may not be able to make decisions in their best interest.

Confidentiality: Refers to how the information that a research participant has given to the investigators is handled; this information is normally given with the expectation that it will not be given to others without the participant's permission.

Identifiable Private Information: Information that can identify an individual, including: name, birth date, Social Security number, address, telephone number, email address, computer ID, and others.

Inclusion/Exclusion Criteria: The predetermined criteria that are used to select the correct participants for the study. These include the presence or absence of certain conditions, medications, or physical characteristics.

Informed Consent: The dialogue between potential participants and researchers that takes place before anyone decides whether to take part in a study. This

process of communication should be free of pressure or rushing, should include all key information, and a chance to ask questions and have them answered. Informed consent can be more than just a one-time conversation. As a study goes on, participants can renew their agreement to be in the study, and they can also decide to quit without penalty. The important thing is open and clear communication. This process includes signing an Informed Consent Form that describes the risks and benefits that may occur if the person decides to take part in the study.

Informed Consent Form (ICF): The form participants sign to agree to be in the study. The ICF includes details about the study, such as its purpose, duration, required procedures, risk, benefits, and who to contact for further information. Sometimes, a signature is not needed, but participants may still keep a copy of the ICF. In these cases it may be called an Information Sheet instead, but the contents are the same. The ICF is not a contract. Participants do not give up any legal rights by signing an ICF. Participants are free to withdraw at any time.

Institutional Review Board (IRB): A group of scientists, doctors, and lay persons who review each clinical research study before it starts to ensure that the study is well-designed, does not involve unnecessary risks, and ensures the safety of participants.

Investigator: A scientist who is working on a research study to answer certain questions, test a theory, or explore a new area in hopes of designing a future study. Also called a researcher.

National Institutes of Health (NIH): An agency within the U.S. Department of Health and Human Services that provides funding for research and conducts studies.

Oral Consent: Written information that describes what will be told to research participants who cannot read or feel uncomfortable signing forms for cultural reasons.

Parent/Guardian Permission: This form is signed by parents/legal guardians in order to allow children to participate in a study. For children 7 and older, an assent form is also provided to the child.

Phases: The steps of a clinical trial. Usually describes the type of study and is an indication of the degree of knowledge that has been obtained on the drug.

Placebo: An inactive substance that may resemble an active drug but has no medical value; often referred to as a sugar pill.

Principal Investigator (PI): The chief researcher on a study. The PI is responsible for everything that takes place in a study.

Protected Health Information (PHI): Health information that can identify an individual, including: name, birth date, Social Security number, address, telephone number, email address, computer ID, medical record number, and others.

Protocol: The scientific plan of the research study. A protocol describes the purpose of the study, who is eligible to participate, details about the research

procedures, the length and steps of the study, and what information will be gathered.

Research: An organized way of finding out about something. Most scientists conduct research, but not all research involves human volunteers. Most research is done with the hope of learning something valuable enough to share with others by publishing articles in scientific journals. Research can turn up both expected and unexpected results. Research usually involves some sort of risk-taking, whether small or great.

Research Study: This is a kind of study that is developed to answer a basic question on any subject, such as testing a new drug or treatment or comparing commonly used interventions.

Research Participants (or Research Subjects): The participants in a research study. These individuals voluntarily agree to participate in the study.

Risk versus Benefit: A comparison of the risks involved for the research participants and whether the expected benefits justify those risks.

Social-Behavioral: Involving the social sciences, the formal study of societies and human behavior. The areas of anthropology, sociology, psychology, religion, and political science are examples of disciplines that may conduct research of this kind. Common ways of collecting information include surveys, focus groups, interviews, and observing behavior in a specially designed setting.

Sponsor: The organization that oversees and pays for the study or provides in-kind support (like medications). This can be a single person, a charitable foundation, a medical institution, a drug-making company, or a federal agency like the National Institutes of Health or Department of Defense.

Unanticipated Problem: Any problem that happens during a study that is related to the research and was not predicted to happen.

U.S. Food and Drug Administration (FDA): A department in the U.S. Department of Health and Human Services. The FDA ensures the safety of prescription and non-prescription drugs and medical devices in the United States, including those that are being tested by research studies and clinical trials.