

GLOSSARY OF TERMS

510(K) Device- A medical device that has been deemed substantially equivalent to a device that was or is marketed.

Activated- The study has been approved by the IRB and all administrative requirements have been satisfied.

Active- The study is still open for participant enrollment and currently enrolled participants are currently undergoing study intervention.

Adverse Effect- An undesirable and unintended, although not entirely unexpected, event.

Amendment- A revision or change in the current version of the protocol, consent form or other study-related document(s). All amendments must be submitted to and approved by the IRB prior to initiation.

Approved- The submission (new protocol, amendment, continuing review, etc.) has met IRB requirements for approval.

Assent- Agreement by an individual not competent to give legally valid informed consent to participate in research.

Biologic- Any therapeutic serum, toxin, anti-toxin, or analogous product.

Closed study- No new enrollment may take place. However, participants enrolled prior to the closure date may continue to receive study treatment/intervention. Data collection and analysis may also continue on a closed protocol. "Closed" status may be temporary or permanent.

Cognitively Impaired*- Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders), an organic impairment (*e.g.*, dementia) or a developmental disorder (*e.g.*, mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Completed study- All data is collected, analyzed and the trial objectives met. No further research may take place. All trial activities must cease.

Conditionally Approved- Minor modifications of, or addition to, a protocol or accompanying documents is required. Approval is contingent upon such changes.

Confidentiality*- Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Continuing Review- The annual review by the IRB of all previously approved and currently ongoing research. Continuing review must be conducted at least once per year.

Data and Safety Monitoring Board (DSMB) *- A committee of scientists, physicians, statisticians, and others that collects and analyzes accumulating data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial, or notification of participants about new information that might affect their willingness to continue in the trial.

Deferred- During the IRBs review of a proposal, significant questions/issues were raised requiring further clarification from the investigator and/or sponsor. The review is tabled until such clarification is available.

Deviation- Changes in the IRB-approved protocol procedures that have the approval of the trial sponsor and the IRB prior to initiation.

Drug*- Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

Epidemiology- The study of the cause, prevalence and spread of disease in a community.

Equitable*- Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed.

Exception- A request to enroll a single participant onto a trial even though the participant does not meet the eligibility criteria. Request must be submitted to and approved by the IRB prior to enrollment.

Expedited Review- Review by the IRB chair or designee rather than by the full committee. Federal regulations allow expedited review of research that involves no more than minimal risk and of minor changes to previously approved research.

Federalwide Assurance (FWA)- A written commitment submitted by an institution to the Office of Human Research Protections (OHRP) promising to comply with the regulations governing human participants research. The FWA is also a mechanism for registering IRBs with OHRP.

Full Board Review- Review conducted at a convened meeting at which a majority of the IRB voting members must be present.

Gene Transfer*- The treatment of genetic disease accomplished by altering the genetic structure of either somatic (nonreproductive) or germline (reproductive) cells.

Grant*- Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

Human Participant- A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Investigational Device Exemption (IDE)- A submission to the FDA requesting approval to use an investigational device in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA

In Vitro- Research conducted in an artificial environment, outside of the body (i.e. test tube or culture medium).

In Vivo- Research conducted in the human body.

Investigational New Drug (IND)- Exemption from Food, Drug & Cosmetic Act to study an investigational drug or biologic. Research involving the use of an investigational drug or biologic requires an IND.

Informed Consent*- One of the primary ethical requirements underpinning research with human participants; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.

Medical Device*- A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

Minimal Risk- The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Monitoring- The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and participant protections.

New Drug Application (NDA)- The application used by the sponsor of an unapproved drug or biologic to formally propose that the FDA approve the product for sale and marketing in the U.S. The data gathered in order to prove safety and efficacy (IND) are incorporated into the NDA.

Overall Principal Investigator (Overall PI)- Individual who is ultimately responsible for the conduct of the research trial.

Pharmacology*- The scientific discipline that studies the action of drugs on living systems (animals or human beings).

Placebo- An inert compound, identical to the product being tested. The participant and perhaps the investigator and study team may not know which is which.

Protocol*- The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Remuneration- Payment for participation in research.

Research- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Risk- The probability of harm. The possibility of loss or injury.

Site Principal Investigator (Site PI)- An individual designated by the Overall PI to oversee the conduct of the trial at a particular institution. This term may be specific to DF/HCC.

Sponsor - A person or entity that initiates a clinical investigation of a drug - usually the drug manufacturer or research institution that developed the drug.

Sponsor-Investigator*- An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

Therapy*- Treatment intended and expected to alleviate a disease or disorder.

Vaccine - A biologic product generally made from an infectious agent that is either inactive or active, although weakened. May also be biochemically synthesized or made through recombinant DNA techniques.

Violation- Accidental or unintentional changes to the IRB approved protocol procedures. This includes changes necessary to eliminate apparent immediate hazards to a trial participant.

Voluntary*- Free of coercion, duress, or undue inducement. Used in the research context to refer to a participant's decision to participate (or to continue to participate) in a research activity.

*Definition taken from OHRP's *IRB Guidebook*