

# NIH Commonly Used Terms and Acronyms

- **Clinical Research:** Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research.
- **Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- **Delayed Onset Study:** Research is anticipated within the period of award but definite plans are not yet known and cannot be described in the application.
- **Delayed Start:** Research plans can be described at time of application, but research will not immediately begin (will occur later in the funding period)
- **Funding Opportunity Announcement (FOA):** A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.
- **Health-related biomedical or behavioral outcome:** the pre-specified effect of an intervention on the study subjects.
- **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.
- **Institutional Review Board (IRB):** An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated.
- **Intervention:** a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints.
- **NIH-Defined Phase III Clinical Trial:** An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments.
- **Person Months:** The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project.
- **Planned Enrollment Report:** The Planned Enrollment Report is used when you are planning to conduct a study that meets the NIH definition for clinical research.
- **Program Director/Principal Investigator (PD/PI):** The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award.
- **Renewal Application:** An application requesting additional funding for a period subsequent to that provided by a current award.
- **Resubmission:** An unfunded application that has been modified following initial review and resubmitted for new consideration.
- **Senior/Key Personnel:** The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
- **Specific Aims:** A component of an application's Research Plan which describes concisely the goals of the proposed research and summarizes the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- **Study:** A research protocol or set of experiments designed to investigate a scientific question.
- **Study Record:** A set of data elements about a research investigation involving human subjects that describes a proposed or on-going study, most commonly used in the context of the PHS Human Subjects and Clinical Trials Information form.