Clinical Research

Clinical Trial

Clinical Investigation

(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. Patient-oriented research includes mechanisms of human disease, therapeutic interventions, clinical trials, or development of new technologies.

(2) Epidemiologic and behavioral studies

(3) Outcomes research and health services research

Prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (such as drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Any experiment that involves a test article and one or more human subjects and that either:
- is subject to requirements for prior submission to the FDA or
- is not subject to requirements for prior submission to FDA, but results of which are intended to be submitted later to, or held for inspection by, FDA as part of application for research or marketing permit.