



Initial Protocol Submission Application Definitions

Ethical Review Committee (ERC) created this document to be used as a reference tool when completing the initial protocol application. The following terms are in alphabetical order by section. Please keep in mind that not all sections will appear on this form. If additional clarification is needed, please see the Initial Protocol Instructions document.

Section B: Protocol Information

3. Institutional Review Board (IRB) - 1. A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the United States must be approved by an IRB before they begin. 2. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants.

4. Phase of Study

- Phase I** - Evaluates the new drug or treatment in a small group of people (less than 100). Humans do not necessarily need to participate in such a trial. Experiments in the lab using microbiological cultures or tissue cells may suffice. The trial's purpose is to provide early indications of a drug or treatment's safety, safe dosage range, and reveal any side effects.
- Phase II** - Follows a phase I trial. A promising drug or treatment is tested on a larger group of people (100–300) to better determine the effectiveness and to monitor safety more critically. Use of a larger population can help reveal side effects that could be hidden by the use of only a few volunteers.
- Phase III** - Evaluates a drug or treatment that has proven effective in the phase I and II trials and is tested on a large population (1,000–3,000) to confirm its effectiveness, reveal any rarer side effects, and gather information that will allow the drug or treatment to be safely marketed.
- Phase IIIB** - Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.
- Phase IV** - Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use. Monitoring of a drug or treatment in very large numbers of people provides further information on benefits and risks.

5. Hypothesis -A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

6. Study Design

- Crossover** - Participants are randomly assigned to take a new treatment, a treatment already in use, and/or a placebo for a specified time period. When that portion of the study ends, participants "crossover" to one of the remaining treatments for another specified time period. Compares the results of two treatments on the same group of patients.
- Dose Ranging** - A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.
- Double Blind** - A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome.
- Multi-Arm** - Multiple (more than 2) treatment groups (a.k.a. arms) in a randomized trial.
- Open-Label** - A type of study in which both the health providers and the patients are aware of the drug or treatment being given.
- Parallel** - Compares the results of a treatment on two separate groups of patients. The sample size calculated for a parallel design can be used for any study where two groups are being compared.
- Placebo-Controlled** - Refers to a clinical study in which the control patients receive a placebo.
- Randomized** - A study in which the participants are assigned by chance to separate groups that compare different treatments; neither the researchers nor the participants can choose which group. Using chance to assign people to groups is intended to make the groups similar so that the treatments they receive can be compared objectively. At the time of the trial, it is not known which treatment is best. It is the patient's choice to be in a randomized trial.
- Single Blind** - A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking.

- Supportive Care** - Trials that explore ways to improve comfort and quality of life for individuals with a chronic illness.
- Two-Arm** - Only 2 treatment groups (a.k.a. arms) are randomized.

7. Testing

- Biologics** - A preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from living organisms or their products and used as a diagnostic, preventive, or therapeutic agent.
- Device(s)** - A contrivance or an invention serving a particular purpose, especially a machine used to perform one or more tasks.
- Drug(s)** - Any substance, other than food, that is used to prevent, diagnose, treat or relieve symptoms of a disease or abnormal condition. Also refers to a substance that alters mood or body function, or that can be habit-forming or addictive, especially a narcotic.

8. Types of Cancer Studies

- Ancillary/Companion** - Stimulated from a required portion of a main clinical trial that also uses resources, including subjects from the main trial to generate information relevant to it. Should include only subjects accrued from the main study.
- Correlative** - Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc.
- Intervention** - In medicine, a treatment or action taken to prevent or treat disease, or improve health in other ways.
- Observational** - A type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given).
- Prevention** - In medicine, action taken to decrease the chance of getting a disease or condition. For example, cancer prevention includes avoiding risk factors (such as smoking, obesity, lack of exercise, and radiation exposure) and increasing protective factors (such as getting regular physical activity, staying at a healthy weight, and having a healthy diet).
- Screening/Early Detection** - A study that may help to detect cancer earlier. They are often conducted to determine whether finding cancer before it causes symptoms decreases the chance of dying from the disease. These trials involve people who do not have any symptoms of cancer.
- Therapeutic** - A study to help treating with therapy using drugs, radiation, surgery, and/or biological agents.
- Treatment** - A study conducted with people who have cancer. They are designed to answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way of using a standard treatment. These trials test many types of treatments, such as new drugs, vaccines, new approaches to surgery or radiation therapy, or new combinations of treatments.

Section C: Subject Selection and Recruitment

2. Target Population

- Cognitively Impaired** - Any person disabled from the mental process of thinking, learning, remembering, being aware of surroundings, and using judgment.
- Comatose/Traumatized** - A condition in which a patient is in a state of deep sleep and cannot be awakened. Injury to the body, or an event that causes long-lasting mental or emotional damage.
- Patients** - Individuals under the care and treatment of a physician or surgeon.
- Terminally Ill** - Individuals approaching or close to death or being in the final stages of a fatal disease.

4. Inclusion - The medical or social standards determining whether a person **may be allowed** to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion criteria's also help to identify appropriate participants and keep them safe.

5. Exclusion - The medical or social standards determining whether a person **may NOT be allowed** to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that exclusion criteria's are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

6. Standard of Care (SOC) - In medicine, treatment that experts agree is appropriate, accepted, and widely used. Health care providers are obligated to provide patients with the standard of care. Also called standard therapy or best practice.

8. Subject Participation Location - Location where the subjects will:

- Inpatient** - A patient who visits a health care facility for diagnosis or treatment while spending the night.
- Outpatient** - A patient who visits a health care facility for diagnosis or treatment without spending the night.

Section D: Drugs and Biologics

1B. Food and Drug Administration (FDA) - The U.S. Department of Health and Human Services agency responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices, including those used in the diagnosis, treatment, and prevention of HIV infection, AIDS, and AIDS-related opportunistic infections. The FDA also works with the blood banking industry to safeguard the nation's blood supply. Internet address: <http://www.fda.gov/>.

1E. Investigational New Drug (IND) - A substance that has been tested in a laboratory and has gotten approval from the FDA to be tested in people. A drug may be approved by the FDA for use in one disease or condition but be considered investigational in other diseases or conditions. Also called experimental drug.

2A. Investigational Pharmacy - A location that will store and dispense the drug rather than the principal investigator.

2E. **Cytotoxic** - Cell-killing. **Gene Therapy** - Treatment that alters a gene.

Section E: Devices

1C. Humanitarian Use Device (HUD)- A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

Section F: Study Procedures

5. Placebo - An inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

8. Recombinant DNA - DNA, proteins, cells, or organisms that are made by combining genetic material from two different sources.

9. Genetic Testing - Analyzing DNA to look for a genetic alteration that may indicate an increased risk for developing a specific disease or disorder.

10. Radiation - Energy released in the form of particles or electromagnetic waves

- A. Radioisotopes** - An unstable form of a chemical element that releases radiation as it breaks down and becomes more stable. In medicine, they are used in imaging tests and in treatment. Also called radionuclide.
- B. Isotope** - Any of two or more atoms of a chemical element with the same atomic number and position in the periodic table and nearly identical chemical behavior but with differing atomic mass or mass number and different physical properties.
- E. Dexa Scan** -An imaging test that measures bone density (the amount of bone mineral contained in a certain volume of bone) by passing x-rays with two different energy levels through the bone. Also called bone mineral density scan, BMD scan, dual energy x-ray absorptiometric scan, dual x-ray absorptiometry, DXA, and DEXA.

Section G: Consent Form Procedures

1. Written Consent Form - A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

- Back Translation** - A consent that has been translated into a foreign language then back to the original language.
Example ("→" indicates translated to): English Consent → Spanish Consent → English Consent
- Notarized Certification** - A consent that has been certified by a notary.
- Surrogate Decision Maker** - A consent that will be reviewed and signed by any person authorized (by statute or by common law) to make decisions on behalf of the person enrolling in the study.

2. Oral Consent Form - An oral presentation of informed consent information in conjunction with the written consent document.

Section H: Additional Contact Information

CRO - Clinical Research Organization - May be an independent organization involved in the conduct of a clinical trial which is responsible for the Data Management and the communication between medical sponsors, the coordinating investigators, the investigators, and the IRB.

SMO - Site Management Organization - May be an individual, a network of individuals, or an organization that sub-contracts clinical trial-related responsibilities from a contract research organization (CRO).