specified at *https://prsinfo.clinicaltrials.gov*.

§ 11.10 What definitions apply to this part?

(a) The following definitions apply to terms used in this part:

Adverse event means any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. See also the definition of ''serious adverse event.''

Applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial. Expanded access use under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is not an applicable clinical trial.

Applicable device clinical trial means:

(1) A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes);

(2) A pediatric postmarket surveillance of a device product as required under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601); or

(3) A clinical trial of a combination product with a device primary mode of action under 21 CFR part 3, provided that it meets all other criteria of the definition under this part.

Applicable drug clinical trial means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where ''clinical investigation'' has the meaning given in 21 CFR 312.3 and ''phase 1'' has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

Approved drug means a drug product that is approved for any use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed for any use under section 351 of the Public Health Service Act (42 U.S.C. 262).

Approved or cleared device means a device product that is cleared for any use under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360(k)) or approved for any use under sections 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360e, 360j(m)).

Arm means a pre-specified group or subgroup of human subject(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

Clinical study means research according to a protocol involving one or more human subjects to evaluate biomedical or health-related outcomes, including interventional studies and observational studies.

Clinical trial means a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes.

Clinical trial information means the data elements, including clinical trial registration information and clinical trial results information, that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) and this part.

Clinical trial registration information means the data elements that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28, as applicable.

Clinical trial results information means the data elements that the responsible

party is required to submit to *ClinicalTrials.gov*, as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and (I)) or §11.48, as applicable. If a responsible party submits clinical trial results information voluntarily for a clinical trial, clinical trial results information also means §11.60(b)(2)(i)(B) or §11.60(c)(2)(i)(B), as applicable.

Comparison group means a grouping of human subjects in a clinical trial that is or may be used in analyzing the results data collected during the clinical trial.

Completion date means, for a clinical trial, including an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. For a pediatric postmarket surveillance of a device product that is not a clinical trial, completion date means the date on which the final report of the pediatric postmarket surveillance of the device product is submitted to FDA. For purposes of this part, completion date is referred to as ''primary completion date.''

Control or controlled means, with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (*e.g.*, historical controls, including a human subject's own baseline data), as reflected in the pre-specified primary or secondary outcome measures. For purposes of this part, all clinical trials with one or more arms and pre-specified outcome measure(s) are controlled.

Device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

Director means the NIH Director or any official of NIH to whom the NIH Director delegates authorities granted in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

Drug means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) or a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

Enroll or enrolled means a human subject's, or their legally authorized representative's, agreement to participate in a clinical trial following completion of the informed consent process, as required in 21 CFR part 50 and/or 45 CFR part 46, as applicable. For the purposes of this part, potential subjects who are screened for the purpose of determining eligibility for a trial, but do not participate in the trial, are not considered enrolled, unless otherwise specified by the protocol.

Human subjects protection review board means an institutional review board (IRB) as defined in 21 CFR 50.3 or 45 CFR 46.102, as applicable, that is responsible for assuring the protection of the rights, safety, and well-being of human subjects involved in a clinical trial and is adequately constituted to provide assurance of that protection. An IRB may also be known as an ''independent ethics committee.''

Interventional means, with respect to a clinical study or a clinical investigation, that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes.

Investigational Device Exemption (IDE) has the meaning given in 21 CFR part 812.

Investigational New Drug Application (IND) has the meaning given in 21 CFR 312.3.

NCT number means the unique identification code assigned to each record in *ClinicalTrials.gov*, including a record for an applicable clinical trial, a clinical trial, or an expanded access program.

Ongoing means, with respect to a clinical trial of a drug product (including a biological product) or a device product and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the primary completion date of the clinical trial. With respect to a pediatric

postmarket surveillance of a device product, ongoing means a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.

Outcome measure means a pre-specified measurement that will be used to determine the effect of an experimental variable on the human subject(s) in a clinical trial. See also the definitions of ''primary outcome measure'' and ''secondary outcome measure.''

Pediatric postmarket surveillance of a device product means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) about a marketed device product that is expected to have significant use in patients who are 21 years of age or younger at the time of diagnosis or treatment. A pediatric postmarket surveillance of a device product may be, but is not always, a clinical trial.

Primary completion date means, for purposes of this part, ''completion date.'' See the definition of ''completion date.''

Primary outcome measure means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical trials have one primary outcome measure, but a clinical trial may have more than one. For purposes of this part, ''primary outcome'' has the same meaning as primary outcome measure.

Principal investigator means the individual who is responsible for the overall scientific and technical direction of the study.

Protocol means the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.

Responsible party means, with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3; or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information. For a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity who FDA orders to conduct the pediatric postmarket surveillance of the device product.

Secondary outcome measure means an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial and is not specified as an exploratory or other measure. A clinical trial may have more than one secondary outcome measure. For purposes of this part, ''secondary outcome'' has the same meaning as secondary outcome measure.

Secretary means the Secretary of Health and Human Services or any other official(s) to whom the Secretary delegates the authority contained in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

Serious adverse event means an adverse event that results in any of the following outcomes: Death, a life-threatening adverse event as defined in 21 CFR 312.32, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder.

Sponsor means either a ''sponsor'' or ''sponsor-investigator,'' as each is defined in 21 CFR 50.3.

Study completion date means, for a clinical trial, the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (*e.g.*, last subject's last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated.

U.S. FDA-regulated device product means, for purposes of this part, a device product subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m), 21 U.S.C. 360l).

U.S. FDA-regulated drug product means, for purposes of this part, a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act (21 U.S.C. 355, 42 U.S.C. 262) .

(b) The following definitions apply to data elements of clinical trial information referenced in this part, unless otherwise specified:

(1) *Brief Title* means a short title of the clinical trial written in language intended for the lay public, including any acronym or abbreviation used publicly to identify the clinical trial.

(2) *Official Title* means the title of the clinical trial, corresponding to the title of the protocol.

(3) *Brief Summary* means a short description of the clinical trial, including a brief statement of the clinical trial's hypothesis, written in language intended for the lay public.

(4) *Primary Purpose* means the main objective of the intervention(s) being evaluated by the clinical trial.

(5) *Study Design* means a description of the manner in which the clinical trial will be conducted, including the following information:

(i) *Interventional Study Model.* The strategy for assigning interventions to human subjects.

(ii) *Number of Arms.* The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, it means the maximum number of arms during all periods or phases.

(iii) *Arm Information.* A description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

(iv) *Allocation.* The method by which human subjects are assigned to arms in a clinical trial.

(v) *Masking.* The party or parties, if any, involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual human subjects.

(6) *Study Phase* means, for a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21, such as phase 2 or phase 3, and in 21 CFR 312.85 for phase 4 studies.

(7) *Study Type* means the nature of the investigation or investigational use for which clinical trial information is being submitted, *e.g.*, interventional, observational.

(8) *Pediatric Postmarket Surveillance of a Device Product* means a clinical trial or study that includes a U.S. FDA-regulated device product as an intervention and is a pediatric postmarket surveillance of a device product ordered under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3691).

(9) *Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study* means the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial. Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH)-controlled vocabulary thesaurus or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus.

(10) *Intervention Name(s)* means a brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical trial. A non-proprietary name of the intervention must be used,

if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(11) *Other Intervention Name(s)* means other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers.

(12) *Intervention Description* means details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical trial. For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.

(13) *Intervention Type* means, for each intervention studied in the clinical trial, the general type of intervention, *e.g.*, drug, biological/vaccine, or, device.

(14) *Device Product Not Approved or Cleared by U.S. FDA* means that at least one device product studied in the clinical trial has not been previously approved or cleared by FDA for one or more uses.

(15) *Product Manufactured in and Exported from the U.S.* means that any drug product (including a biological product) or device product studied in the clinical trial is manufactured in the United States or one of its territories and exported for study in a clinical trial in another country.

(16) *Study Start Date* means the estimated date on which the clinical trial will be open for recruitment of human subjects, or the actual date on which the first human subject was enrolled.

(17) *Primary Completion Date* means the estimated or actual primary completion date. If an estimated primary completion date is used, the responsible party must update the Primary Completion Date data element once the clinical trial has reached the primary completion date to reflect the actual primary completion date.

(18) *Enrollment* means the estimated total number of human subjects to be enrolled (target number) or the actual total number of human subjects that are enrolled in the clinical trial. Once the trial has reached the primary completion date, the responsible party must update the Enrollment data element to reflect the actual number of human subjects enrolled in the clinical trial.

(19) *Primary Outcome Measure Information* means a description of each primary outcome measure, to include the following information:

(i) Name of the specific primary outcome measure;

(ii) Description of the metric used to characterize the specific primary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(20) *Secondary Outcome Measure Information* means a description of each secondary outcome measure, to include the following information:

(i) Name of the specific secondary outcome measure;

(ii) Description of the metric used to characterize the specific secondary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(21) *Eligibility Criteria* means a limited list of criteria for selection of human subjects to participate in the clinical trial, provided in terms of inclusion and exclusion criteria and suitable for assisting potential human subjects in identifying clinical trials of interest.

(22) *Sex/Gender* means the sex and, if applicable, gender of the human subjects who may participate in the clinical trial.

(23) *Age Limits* means the minimum and maximum age of human subjects who may participate in the clinical trial, provided in relevant units of time.

(24) *Accepts Healthy Volunteers* means that human subjects who do not have a disease or condition, or related conditions or symptoms, under study in the clinical trial are permitted to participate in the clinical trial.

(25) *Overall Recruitment Status* means the recruitment status for the clinical trial as a whole, based on the status of the individual sites. If at least one facility in a multi-site clinical trial has

an individual site status of ''recruiting,'' then the overall recruitment status for the trial must be ''recruiting.''

(26) *Why Study Stopped* means, for a clinical trial that is suspended or terminated or withdrawn prior to its planned completion as anticipated by the protocol, a brief explanation of the reason(s) why the clinical trial was stopped.

(27) *Individual Site Status* means the recruitment status of each participating facility in a clinical trial.

(28) *Availability of Expanded Access* means, for an applicable drug clinical trial of a drug product (including a biological product) that is not an approved drug product (including a biological product), and for which the responsible party is both the manufacturer of the drug product (including a biological product) and the sponsor of the applicable clinical trial:

(i) An indication of whether there is expanded access to the investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for those individuals who do not qualify for enrollment in the applicable clinical trial, under one or more of the following types of expanded access programs: for individual patients, including for emergency use, as specified in 21 CFR 312.310; for intermediate-size patient populations, as specified in 21 CFR 312.315; or under a treatment IND or treatment protocol, as specified in 21 CFR 312.320; and

(ii) If expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), the NCT number of the expanded access record.

(29) *Name of the Sponsor* means the name of the entity or individual who is the sponsor of the clinical trial, as defined in this part.

(30) *Responsible Party, by Official Title* means an:

(i) Indication of whether the responsible party is the sponsor of the clinical trial, as that term is defined in 21 CFR 50.3; the sponsor-investigator, as that term is defined in 21 CFR 50.3; or a principal investigator designated pursuant to this part; and

(ii) Either:

(A) The official name of the entity, if the responsible party is an entity; or

(B) The official title and primary organizational affiliation of the individual, if the responsible party is an individual.

(31) *Facility Information* means, for each participating facility in a clinical trial, the following information:

(i) Facility Name, meaning the full name of the organization where the clinical trial is being conducted;

(ii) Facility Location, including city, state, country and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries; and

(iii) Either:

(A) For each facility participating in a clinical trial, Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed; or

(B) Central Contact Person, including the name or title, toll-free telephone number, and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed.

(32) *Unique Protocol Identification Number* means any unique identifier assigned to the protocol by the sponsor.

(33) *Secondary ID* means:

(i) Any identifier(s) other than the organization's unique protocol identifier or NCT number that is assigned to the clinical trial, including any unique clinical trial identifiers assigned by other publicly available clinical trial registries. If the clinical trial is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID.

(ii) A description of the type of Secondary ID.

(34) *U.S. Food and Drug Administration IND or IDE Number* means an indication of whether there is an IND or IDE for the clinical trial and, if so, each of the following elements:

(i) Name or abbreviation of the FDA center with whom the IND or IDE is filed;

(ii) IND or IDE number assigned by the FDA center; and

(iii) For an IND, the IND serial number, as defined in 21 CFR 312.23(e), if any, assigned to the clinical trial.

(35) *Human Subjects Protection Review Board Status* means information to indicate whether a clinical trial has been reviewed and approved by a human subjects protection review board or whether such review is not required per applicable law (*e.g.*, 21 CFR part 56, 45 CFR part 46, or other applicable regulation). Human Subjects Protection Review Board Status must be listed as ''approved'' if at least one human subjects protection review board has approved the clinical trial.

(36) *Record Verification Date* means the date on which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the clinical trial, even if no additional or updated information was submitted at that time.

(37) *Responsible Party Contact Information* means administrative information to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

(38) *Studies a U.S. FDA-regulated Device Product* means that a clinical trial studies a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)).

(39) *Studies a U.S. FDA-regulated Drug Product* means a clinical trial studies a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(40) *Post Prior to U.S. FDA Approval or Clearance* means, for an applicable device clinical trial of a device product that has not been previously approved or cleared, the responsible party indicates to the Director that it is authorizing the Director, in accordance with §11.35(b)(2)(ii), to publicly post its clinical trial registration information, which would otherwise be subject to delayed posting, as specified in §11.35(b)(2)(i), prior to the date of FDA approval or clearance of its device product.

(41) *Study Completion Date* means the estimated or actual study completion date. Once the clinical trial has reached the study completion date, the responsible party must update the Study Completion Date data element to reflect the actual study completion date in accordance with §11.64(a)(1)(ii)(J) .

Subpart B—Registration

§ 11.20 Who must submit clinical trial registration information?

The responsible party for an applicable clinical trial specified in §11.22 must submit clinical trial registration information for that clinical trial.

§ 11.22 Which applicable clinical trials must be registered?

(a) *General specification.* (1) Any applicable clinical trial that is initiated after September 27, 2007, must be registered.

(2) Any applicable clinical trial that is initiated on or before September 27, 2007, and is ongoing on December 26, 2007, must be registered.

(3) *Determining the date of initiation for an applicable clinical trial.* An applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled. A pediatric postmarket surveillance of a device product that is not a clinical trial is considered to be initiated on the date on which FDA approves the plan for conducting the surveillance.

(b) *Determination of applicable clinical trial for a clinical trial or study initiated on or after January 18, 2017.* A clinical trial or study that, at any point in time, meets the conditions listed in paragraph (b)(1) or (2) of this section will be considered to meet the definition of an applicable clinical trial.

(1) *Applicable device clinical trial.* A clinical trial or study that meets the conditions listed in either paragraph