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 (b)(1)(i) or (ii) of this section is an applicable device clinical trial:

(i) The study is a pediatric postmarket surveillance of a device product as required by FDA under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601).

(ii) The study is a clinical trial with one or more arms that meets all of the following criteria:

(A) Study Type is interventional;

(B) Primary Purpose of the clinical trial is other than a feasibility study;

(C) The clinical trial Studies a U.S. FDA-regulated Device Product; and

(D) One or more of the following applies:

(*1*) At least one Facility Location is within the United States or one of its territories,

(*2*) A device product under investigation is a Product Manufactured in and Exported from the U.S. or one of its territories for study in another country, or

(*3*) The clinical trial has a U.S. Food and Drug Administration IDE Number.

(2) *Applicable drug clinical trial.* A clinical trial with one or more arms that meets the following conditions is an applicable drug clinical trial:

(i) Study Type is interventional;

(ii) Study Phase is other than phase 1;

(iii) The clinical trial Studies a U.S. FDA-regulated Drug Product; and

(iv) One or more of the following applies:

(A) At least one Facility Location for the clinical trial is within the United States or one of its territories,

(B) A drug product (including a biological product) under investigation is a Product Manufactured in and Exported from the U.S. or one of its territories for study in another country, or

(C) The clinical trial has a U.S. Food and Drug Administration IND Number.

§ 11.24 When must clinical trial registration information be submitted?

(a) *General.* Except as provided in paragraph (b) of this section, the responsible party for an applicable clinical trial for which submission of clinical trial registration information is required must submit the clinical trial registration information 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(a), as applicable, not later than December 26, 2007, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(b) *Exceptions:.* (1) The responsible party for an applicable clinical trial that is a clinical trial and for which the submission of clinical trial registration information is required and that is not for a serious or life-threatening disease or condition must submit clinical trial registration information 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(a), as applicable, not later than September 27, 2008, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(2) The responsible party for an applicable device clinical trial that is a pediatric postmarket surveillance of a device product and is not a clinical trial must submit clinical trial registration information, as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C.