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30 business days from issuance and serve as the final agency decision unless:

(1) Within 30 business days of issuance, reconsideration occurs under § 10.24; or

(2) Within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision.

(d) The OPA Director will determine any necessary corrective action or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.24 340B ADR Panel decision reconsideration process.

(a) Either party may initiate a reconsideration request, or the HRSA Administrator may decide to initiate the process without such a request. In the event of a reconsideration request, the 340B ADR Panel's decision is held in abeyance until such time the HRSA Administrator makes a reconsideration decision of the 340B ADR Panel decision (or in the event of a declination). A reconsideration decision will affirm or supersede a 340B ADR Panel decision.

(b) The request for a reconsideration of the 340B ADR Panel's decision must be made to the HRSA Administrator within 30 business days of the date of the 340B ADR Panel's decision letter.

(1) The request for reconsideration must include a copy of the 340B ADR Panel decision letter, and documentation indicating why a reconsideration is warranted.

(2) New facts, information, legal arguments, or policy arguments may not be submitted as part of the reconsideration process in order to remain consistent with the facts that were reviewed by the 340B ADR Panel in determining their decision.

(3) In the case of joint or consolidated claims, the reconsideration request must include an attestation confirming that all of the entities have agreed to be part of the reconsideration process.

(c) The standard for review of the reconsideration request by the HRSA Administrator, or their designee, will include a review of the record, including the 340B ADR Panel decision, and a determination of whether there was an error in the 340B ADR Panel's decision. The HRSA Administrator, or designee, may consult with other HHS officials, as necessary.

(d) The HRSA Administrator, or their designee, will make a determination based on the reconsideration request by either issuing a revised decision or declining to issue a revised decision.

(e) The reconsideration decision letter will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court.

(f) The OPA Director will determine any necessary corrective action, or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.25 Severability.

If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof.

PART 11—CLINICAL TRIALS REGISTRATION AND RESULTS INFORMATION SUBMISSION

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AUTHORITY: 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b).

SOURCE: 81 FR 65138, Sept. 21, 2016, unless otherwise noted.

Subpart A—General Provisions

§ 11.2 What is the purpose of this part?

This part implements section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) by providing requirements and procedures for the submission of clinical trial information for certain applicable clinical trials and other clinical trials to the Director of the National Institutes of Health (NIH) to be made publicly available via ClinicalTrials.gov, the Internet-accessible clinical trial registry and results data bank established by the National Library of Medicine (NLM) at *https://clinicaltrials.gov*.

§ 11.4 To whom does this part apply?

(a) This part applies to the responsible party for an applicable clinical trial that is required to be registered under § 11.22, a clinical trial for which clinical trial registration information or clinical trial results information is submitted voluntarily in accordance with § 11.60, or an applicable clinical trial that is required by the Director to have clinical trial information submitted to protect the public health under § 11.62.

(b) The responsible party must communicate the identity and contact information of the responsible party to the Director by submitting the Responsible Party, by Official Title and Responsible Party Contact Information data elements under § 11.28(a)(2)(iii)(B) and (a)(2)(iv)(F) as part of the clinical trial information submitted at the time of registration. Changes must be communicated to the Director by updating information in accordance with § 11.64(a).

(c) *Determination of responsible party*. For purposes of this part, each applicable clinical trial or other clinical trial must have one responsible party. With respect to a clinical trial, the sponsor of the clinical trial will be considered the responsible party unless and until a principal investigator has been designated the responsible party, in accordance with paragraph (c)(2) of this section. With respect to a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity that the U.S. Food and Drug Administration

(FDA), under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601), orders to conduct the pediatric postmarket surveillance of a device product.

(1) *Determination of sponsor*. For purposes of this part, each applicable clinical trial or other clinical trial must have one sponsor.

(i) When an applicable clinical trial or other clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor.

(ii) When an applicable clinical trial or other clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority and control over the trial, will be considered the sponsor.

(2) *Designation of a principal investigator as the responsible party*.

(i) The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements:

(A) Is responsible for conducting the trial;

(B) Has access to and control over the data from the trial;

(C) Has the right to publish the results of the trial; and

(D) Has the ability to meet all of the requirements for submitting and updating clinical trial information as specified in this part.

(ii) With regard to an applicable clinical trial or other clinical trial, a designation by the sponsor under paragraph (c)(2)(i) of this section shall consist of the sponsor obtaining from the principal investigator an acknowledgment of the principal investigator's responsibilities under this part as responsible party, and the principal investigator acknowledging the designation as responsible party to the Director in the format specified at *https://clinicaltrials.gov* or successor site.

(3) *Withdrawal of the designation of a principal investigator as the responsible party*.

In the event that a principal investigator who has been designated the responsible party no longer meets or is no longer able to meet all the requirements for being so designated under paragraph (c)(2)(i) of this section, the sponsor must withdraw the designation in the format specified at *https://clinicaltrials.gov* or successor site at which time the sponsor will be considered the responsible party unless and until the sponsor makes a new designation in accordance with paragraph (c)(2) of this section.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

§ 11.6 What are the requirements for the submission of truthful information?

The clinical trial information submitted by a responsible party under this part shall not be false or misleading in any particular. A responsible party who submits false and/or misleading information is subject to civil monetary penalties and/or other civil or criminal remedies available under U.S. law.

§ 11.8 In what format must clinical trial information be submitted?

Information submitted under this part must be submitted electronically to ClinicalTrials.gov, in the format specified at *https://clinicaltrials.gov* or successor site.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

§ 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 (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. 282(j)(2)(A)(ii)) or §11.28(b), not later than December 26, 2007, or 21 calendar days after FDA approves the postmarket surveillance plan, whichever date is later.

§ 11.28 What constitutes clinical trial registration information?

(a) For each applicable clinical trial that must be registered with ClinicalTrials.gov, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information:

(1) For such applicable clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(2) For such applicable clinical trials that are initiated on or after January 18, 2017, the responsible party must submit the data elements listed below:

(i) Descriptive information:

(A) Brief Title;

(B) Official Title;

(C) Brief Summary;

(D) Primary Purpose;

(E) Study Design;

(F) Study Phase, for an applicable drug clinical trial;

(G) Study Type;

(H) Pediatric Postmarket Surveillance of a Device Product, for an applicable device clinical trial that is a Pediatric Postmarket Surveillance of a Device Product;

(I) Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study;

(J) Intervention Name(s), for each intervention studied;

(K) Other Intervention Name(s), for each intervention studied;

(L) Intervention Description, for each intervention studied;

(M) Intervention Type, for each intervention studied;

(N) Studies a U.S. FDA-regulated Device Product;
(O) Studies a U.S. FDA-regulated Drug Product;
(P) Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product;
(Q) Post Prior to U.S. FDA Approval or Clearance, for an applicable device clinical trial that studies at least one device product not previously approved or cleared by the U.S. FDA;
(R) Product Manufactured in and Exported from the U.S., if the entry for U.S. Food and Drug Administration IND or IDE Number in §11.28(a)(2)(iv)(C) indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for Facility Information in §11.28(a)(2)(iii)(C) include no facility locations in the United States or its territories;
(S) Study Start Date;
(T) Primary Completion Date;
(U) Study Completion Date;
(V) Enrollment;
(W) Primary Outcome Measure Information, for each primary outcome measure; and
(X) Secondary Outcome Measure Information, for each secondary outcome measure.
(ii) Recruitment information:
(A) Eligibility Criteria;
(B) Sex/Gender;
(C) Age Limits;
(D) Accepts Healthy Volunteers;
(E) Overall Recruitment Status;
(F) Why Study Stopped;
(G) Individual Site Status; and
(H) Availability of Expanded Access. If expanded access is available for an investigational drug product (including a biological product), an expanded access record must be submitted in accordance with §11.28(c), unless an expanded access record was submitted previously in accordance with that provision.
(iii) Location and contact information:
(A) Name of the Sponsor;
(B) Responsible Party, by Official Title; and
(C) Facility Information.
(iv) Administrative data:
(A) Unique Protocol Identification Number;
(B) Secondary ID;
(C) U.S. Food and Drug Administration IND or IDE Number;
(D) Human Subjects Protection Review Board Status;
(E) Record Verification Date; and
(F) Responsible Party Contact Information.

(b) Pediatric postmarket surveillance of a device product that is not a clinical trial. For each pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information:
(1) For such applicable device clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).
(2) For such applicable device clinical trials that are initiated on or after January 18, 2017, the responsible party must submit the data elements listed below:
(i) Descriptive information:
(A) *Brief Title*. A short title of the pediatric postmarket surveillance of a device product in language intended for the lay public. If an acronym or abbreviation is used to publicly identify the surveillance, it must be provided.
(B) *Official Title*. The title of the pediatric postmarket surveillance of a device product, corresponding to the title of the protocol or the FDA-approved plan for conducting the surveillance
(C) *Brief Summary*. A short description of the pediatric postmarket surveillance of a device product, including a brief statement of the hypothesis or objective, written in language intended for the lay public, and a general description of the surveillance design, including relevant population information
(D) *Study Type*. The type of study being registered. In the case of a pediatric postmarket surveillance of a device product that is not a clinical trial, a study type of ''observational'' is required.
(E) *Pediatric Postmarket Surveillance of a Device Product*. For a study that includes an FDA-regulated device product as an intervention and is a pediatric postmarket surveillance of a device product

(F) *Primary Disease or Condition Being Studied, or the Focus of the Study*. The name(s) of the disease(s) or condition(s) being studied in the pediatric postmarket surveillance of a device product, or the focus of the surveillance study. Use, if available, appropriate descriptors fromNLM's MeSH-controlled vocabulary thesaurus or terms from another vocabulary, such as the SNOMED CT, that has been mapped to MeSH within the UMLS Metathesaurus.

(G) *Intervention Name(s)*. A brief descriptive name used to refer to each intervention studied in the pediatric postmarket surveillance of a device product. 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.

(H) *Other Intervention Name(s)*. Any other current and former name(s) or alias(es), 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

(I) *Intervention Description*. Details that can be made public about each 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 or pediatric postmarket surveillance of a device product that is not a clinical trial

(J) *Intervention Type*. For each intervention studied in the pediatric postmarket surveillance of a device product, the general type of intervention

(K) *Study Start Date*. The date on which FDA approves the pediatric postmarket surveillance plan, as specified in 21 CFR 822.19(a).

(L) *Primary Completion Date*. The estimated or actual date on which the final report of the pediatric postmarket surveillance of a device product is expected to be submitted to FDA. Once the final report has been submitted, this is the actual date on which the final report is submitted to FDA.

(ii) Location and contact information:

(A) Name of the Sponsor.

(B) Responsible Party, by Official Title:

(*1*) If the responsible party is an entity, the official name of the entity; or

(*2*) If the responsible party is an individual, the official title and primary organizational affiliation of the individual.

(C) *Contact Information*. The name or official title, toll-free telephone number, and email address of a person to whom questions concerning the pediatric postmarket surveillance of a device product can be addressed.

(iii) Administrative data:

(A) *Unique Protocol Identification Number*. The unique identifier assigned to the pediatric postmarket surveillance of a device product by the sponsor, if any.

(B) *Secondary ID:* (*1*) Identifier(s) other than the organization's unique protocol identifier or NCT number that is assigned to the pediatric postmarket surveillance of a device product, if any, including any unique identifiers assigned by other publicly available clinical study registries. If the pediatric postmarket surveillance of a device product 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.

(*2*) For each secondary ID listed, a description of the type of secondary ID.

(C) *Human Subjects Protection Review Board Status*. Information to indicate whether a pediatric postmarket surveillance of a device product 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 pediatric postmarket surveillance.

(D) *Record Verification Date*. The date on which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the pediatric postmarket surveillance of a device product, even if no additional or updated information was submitted at that time

(E) *Responsible Party Contact Information*. Administrative information sufficient 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.

(c) *Expanded access record*. If expanded access is available, as specified in 21 CFR 312.315 (for an intermediate-size patient population) or 21 CFR 312.320 (under a treatment IND or treatment protocol), for an investigational drug product (including a biological product) studied in an applicable drug clinical trial, and the data elements set forth in paragraphs (c)(1) through (4) of this section have not been submitted in an expanded access record for that investigational product, the responsible party, if both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, must submit the clinical trial information specified in paragraphs (c)(1) through (4) of this section to ClinicalTrials.gov in the form of an expanded access record. If expanded access is available only as specified in 21 CFR 312.310 (for individual patients, including for emergency use) for an investigational drug product (including a biological product) studied in an applicable drug clinical trial, and the data elements set forth in paragraphs (c)(1)(i), (iii), (iv), (vi), (ix), (x), (c)(2)(iv), (c)(3), (c)(4)(i), (iii),(iv), and (v) of this section have not been submitted in an expanded access record for that investigational product, the responsible party, if both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, must submit the clinical trial information specified in those paragraphs to ClinicalTrials.gov in the form of an expanded access record.

(1) Descriptive information:

(i) *Brief Title*. A short title identifying the expanded access, written in language intended for the lay public. If an acronym or abbreviation is used publicly to identify the expanded access, it must be provided.

(ii) *Official Title*. The title, if any, of the expanded access program corresponding to the title that has been submitted to FDA for that program

(iii) *Brief Summary*. A short description of the availability of expanded access, including the procedure for requesting the investigational drug product (including a biological product).

(iv) *Study Type*. The nature of the investigation or investigational use for which clinical trial information is being submitted, *i.e.*, ''expanded access''.

(v) *Primary Disease or Condition*. The name(s) of the disease(s) or condition(s) for which expanded access to the investigational drug product (including a biological product) is available. Use, if available, appropriate descriptors from NLM's MeSH-controlled vocabulary thesaurus, or terms from another vocabulary, such as the SNOMED CT, that has been mapped to MeSH within the UMLS Metathesaurus.

(vi) *Intervention Name(s)*. A brief descriptive name used to refer to the investigational drug product (including a biological product) that is available through expanded access. 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.

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

(viii) *Intervention Description*. Details that can be made public about each intervention, other than the Intervention Name(s) or Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions that are available through expanded access or in clinical trials.

(ix) *Intervention Type*. For each investigational drug product (including a biological product) for which expanded access is available, the general type of intervention, *e.g.*, drug.

(x) *Expanded Access Type*. The type(s) of expanded access for which the investigational drug product (including a biological product) is available, as specified in §11.10(b)(28).

(2) Recruitment information:

(i) *Eligibility Criteria*. A limited list of criteria for determining who is eligible to receive the investigational drug product (including a biological product) through expanded access, provided in terms of inclusion and exclusion criteria and suitable for assisting potential patients in identifying investigational drug products (including biological products) of interest for which expanded access is available.

(ii) *Sex/Gender*. The sex and gender (if applicable) of the patients for whom expanded access is available.

(iii) *Age Limits*. The minimum and maximum age of patients for whom expanded access is available, provided in relevant units of time.

(iv) *Expanded Access Status*. The status of availability of the investigational drug product (including a biological product) through expanded access.

(3) Contact information:

(i) *Name of the Sponsor*.

(ii) *Responsible Party, by Official Title*. The official name of the entity.

(iii) *Contact Information*. The name or official title, toll-free telephone number, and email address of a person to whom questions concerning expanded access can be addressed.

(4) Administrative data:

(i) *Unique Protocol Identification Number*. Any unique identifier assigned by the sponsor to refer to the availability of its investigational drug product (including a biological product) for expanded access use or to identify the expanded access record.

(ii) *Secondary ID:* (A) Any identifier(s) other than the Unique Protocol Identification Number or the NCT number that is assigned to the expanded access record, including any unique identifiers assigned by other publicly available clinical trial or expanded access registries.

(B) For each Secondary ID listed, a description of the type of Secondary ID.

(iii) *U.S. Food and Drug Administration IND Number*. An indication of whether there is an IND and, if so, each of the following elements:

(A) Name or abbreviation of the FDA center with whom the IND is filed (*i.e.*, CDER or CBER), if applicable;

(B) IND number (assigned by the FDA center) under which the investigational drug product (including a biological product) is being made available for expanded access, if applicable; and

(C) IND serial number. as defined in 21 CFR 312.23(e), if any, assigned to the expanded access.

(iv) *Record Verification Date*. The date on which the responsible party last verified the information in the expanded access record, even if no additional or updated information was submitted at that time.

(v) *Responsible Party Contact Information*. Administrative information sufficient to identify and allow communication with the responsible party entering the clinical trial information into the expanded access record 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.

§11.35 By when will the NIH Director post clinical trial registration information submitted under §11.28?

(a) *Applicable drug clinical trial*. The Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, for an applicable drug clinical trial not later than 30 calendar days after the responsible party has submitted such information, as specified in §11.24.

(b) *Applicable device clinical trial*. (1) For an applicable device clinical trial of a device product that was previously approved or cleared, the Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, as soon as practicable, but not later than 30 calendar days after clinical

trial results information is required to be posted, as specified in § 11.52.

(2) For an applicable device clinical trial of a device product that has not been previously approved or cleared:

(i) The Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, not earlier than the date of FDA approval or clearance of the device product and not later than 30 calendar days after the date of such approval or clearance, except as otherwise provided in paragraph (b)(2)(ii) of this section.

(ii) If, prior to the date of approval or clearance of the device product, the responsible party for an applicable clinical trial that is initiated on or after January 18, 2017, indicates to the Director, by submitting the Post Prior to U.S. FDA Approval or Clearance data element under § 11.28(a)(2)(i)(Q), that it is authorizing the Director to publicly post its clinical trial registration information, which would otherwise be subject to delayed posting as specified in paragraph (b)(2)(i) of this section, prior to the date of FDA approval or clearance of its device product, the Director will publicly post the registration information, except for certain administrative data, as soon as practicable.

Subpart C—Results Information Submission

§ 11.40 Who must submit clinical trial results information?

The responsible party for an applicable clinical trial specified in § 11.42 must submit clinical trial results information for that clinical trial.

§ 11.42 For which applicable clinical trials must clinical trial results information be submitted?

(a) *Applicable clinical trials for which the studied product is approved, licensed, or cleared by FDA.* Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information must be submitted for any applicable clinical trial for which the studied product is approved, licensed, or cleared by FDA for which submission of clinical trial registration information is required in accordance with the following:

(1) If the primary completion date is before January 18, 2017, the responsible party must submit the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)); or

(2) If the primary completion date is on or after January 18, 2017, the responsible party must submit the clinical trial results information specified in § 11.48.

(b) *Applicable clinical trials for which the studied product is not approved, licensed, or cleared by FDA.* Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information specified in § 11.48 must be submitted for any applicable clinical trial with a primary completion date on or after January 18, 2017 for which clinical trial registration information is required to be submitted and for which the studied product is not approved, licensed, or cleared by FDA.

§ 11.44 When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?

(a) *Standard submission deadline.* In general, for applicable clinical trials subject to § 11.42, clinical trial results information 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 42 U.S.C. 282(j)(3)(I)) or in § 11.48, as applicable, must be submitted no later than 1 year after the primary completion date of the applicable clinical trial.

(b) *Delayed submission of results information with certification if seeking approval, licensure, or clearance of a new use*—(1) *General requirements.* If, prior to the results information submission deadline specified under paragraph (a) of this section, the responsible party submits a certification that an applicable clinical trial involves an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the applicable clinical

trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug product (including a biological product) or device product) has been filed or will be filed within 1 year with FDA, the deadline for submitting clinical trial results information, 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 42 U.S.C. 282(j)(3)(I)) or §11.48, as applicable, will be 30 calendar days after the earliest of the following events:

(i) FDA approves, licenses, or clears the drug product (including a biological product) or device product for the use studied in the applicable clinical trial;

(ii) FDA issues a letter that ends the regulatory review cycle for the application or submission but does not approve, license, or clear the drug product (including a biological product) or device product for the use studied in the applicable clinical trial; or

(iii) The application or premarket notification seeking approval, licensure, or clearance of the new use is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines specified in paragraph (b)(1) of this section, the responsible party must submit clinical trial results information specified in paragraph (b)(1) of this section not later than the date that is 2 years after the date that the certification was submitted, except to the extent that paragraph (d) of this section applies.

(3) *Additional requirements.* If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification in accordance with paragraph (b)(1) of this section, that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria:

(i) The applicable clinical trial is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; and

(ii) The applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted.

(c) *Delayed submission of results with certification if seeking initial approval, licensure, or clearance.*—(1) *General requirements.* If, prior to the submission deadline specified under paragraph (a) of this section, a responsible party submits a certification that an applicable clinical trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed, or cleared by FDA for any use before the primary completion date of the trial, and that the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study, the deadline for submitting clinical trial results information, as specified in §11.48, will be 30 calendar days after the earlier of the date on which:

(i) FDA approves, licenses, or clears the drug product (including a biological product) or device product for any use that is studied in the applicable clinical trial; or

(ii) The marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines established in paragraph (c)(1) of this section, the responsible party must submit clinical trial results information specified in paragraph (c)(1) of this section not later than 2 years after the date on which the certification was submitted, except to the extent that paragraph (d) of this section applies.

(d) *Submitting partial results information.* (1) If clinical trial results information 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 42 U.S.C. 282(j)(3)(I)) or §11.48, as applicable, has not been collected for a secondary outcome measure(s) or additional adverse event information by

the primary completion date, the responsible party must submit the remaining required clinical trial results information for secondary outcome measure(s) or additional adverse event information for that clinical trial by the following deadlines:

(i) For secondary outcome measure(s), by the later of:

(A) One year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure, whether the clinical trial was concluded according to the pre-specified protocol or was terminated; or

(B) If a certification to delay results information submission has been submitted under paragraph (b) or (c) of this section, the date on which results information for the primary outcome measures is due pursuant to paragraph (b) or (c) of this section.

(ii) For additional adverse event information, by the later of:

(A) One year after the date of data collection for additional adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated; or

(B) If a certification to delay results information submission has been submitted under paragraph (b) or (c) of this section, the date on which results information for the primary outcome measures is due pursuant to paragraph (b) or (c) of this section.

(2) Except, if clinical trial results information was submitted for the primary outcome measure(s) prior to the effective date of these regulations but data collection for all of the secondary outcome measure(s) or additional adverse event information is not completed until on or after January 18, 2017, clinical trial results information for all primary and secondary outcome measures and adverse event information for the clinical trial must be submitted 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 42 U.S.C. 282(j)(3)(I)).

(3) For each submission of partial results information for a clinical trial, as specified in paragraph (d)(1) of this section:

(i) If any amendments were made to the protocol and/or statistical analysis plan as described in §11.48(a)(5) since the previous submission of partial results information, the responsible party must submit a copy of the revised protocol and/or statistical analysis plan; and

(ii) If information about certain agreements as described in §11.48(a)(6)(ii) has changed since the previous submission of partial results information, the responsible party must submit information to reflect the new status of certain agreements between the principal investigator and the sponsor.

(e) *Extensions for good cause.* (1) A responsible party may request an extension of the deadline for submitting clinical trial results information subject to paragraphs (e)(1)(i) and (ii) of this section or section 402(j)(3)(E)(vi) of the Public Health Service Act (42 U.S.C. 282(j)(3)(E)(vi)), as applicable, and may request more than one extension for the same applicable clinical trial.

(i) The responsible party must submit a request for an extension to *ClinicalTrials.gov* prior to the date on which clinical trial results information would otherwise be due in accordance with paragraph (a), (b), (c), (d), (e), or (f) of this section.

(ii) A request for an extension must contain the following:

(A) Description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to allow for the evaluation of the request; and

(B) Estimate of the date on which the clinical trial results information will be submitted.

(2) *Decision and submission deadline.* The Director will provide a response electronically to the responsible party indicating whether the requested extension demonstrates good cause and has been granted.

(i) If the extension request is granted, the responsible party must submit clinical trial results information not later than the date of the deadline specified in the electronic response.

(ii) If the extension request is denied, the responsible party must either appeal in accordance with paragraph

(e)(3) of this section or submit clinical trial results information specified in §11.48 by the later of the submission deadline specified in paragraph (a), (b), (c), (d), (e), or (f) of this section, as applicable, or 30 calendar days after the date on which the electronic notice of the denial is sent to the responsible party.

(3) *Appealing a denied extension request.* (i) A responsible party who seeks to appeal a denied extension request or the deadline specified in a granted extension must submit an appeal to the Director in the format specified at *https://clinicaltrials.gov* or successor site not later than 30 calendar days after the date on which the electronic notification of the granting or denial of the request is sent to the responsible party.

(ii) An appeal must contain an explanation of the reason(s) why the initial decision to deny the extension request or to grant the extension request with a shorter deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal.

(iii) The Director will provide an electronic notification to the responsible party indicating whether the requested extension has been granted upon appeal.

(iv) If the Director grants the extension request upon appeal, the responsible party must submit clinical trial results information not later than the deadline specified in the electronic notification specified in paragraph (e)(3)(iii) of this section.

(v) If the Director denies the appeal of a denied extension request, the responsible party must submit clinical trial results information by the later of the deadline specified in paragraph (a), (b), (c), (d), (e), or (f) of this section, or 30 calendar days after the electronic notification of the denial of the appeal, specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(vi) If the Director denies an appeal of a denied deadline specified in a granted extension request, the responsible party must submit clinical trial results information by the later of the deadline specified in the notification granting the extension request, specified in paragraph (e)(2)(i) of this section, or 30 calendar days after the electronic notification denying the appeal, specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(f) *Pediatric postmarket surveillance of a device product that is not a clinical trial.* For each pediatric postmarket surveillance of a device product that is not a clinical trial as defined in this part, the responsible party must submit clinical trial results information as specified in §11.48(b) or section 402(j)(C)(3) of the Public Health Service Act (42 U.S.C. 282(j)(C)(3)), as applicable, not later than 30 calendar days after the date on which the final report of the approved pediatric postmarket surveillance of a device product, as specified in 21 CFR 822.38, is submitted to FDA.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

§11.48 What constitutes clinical trial results information?

(a) For each applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, for which clinical trial results information must be submitted under §11.42, the responsible party must provide the following:

(1) *Participant flow.* Information for completing a table documenting the progress of human subjects through a clinical trial, by arm, including the number who started and completed the clinical trial. This information must include the following elements:

(i) *Participant Flow Arm Information.* A brief description of each arm used for describing the flow of human subjects through the clinical trial, including a descriptive title used to identify each arm;

(ii) *Pre-assignment Information.* A description of significant events in the clinical trial that occur after enrollment and prior to assignment of human subjects to an arm, if any; and

(iii) *Participant Data.* The number of human subjects that started and completed the clinical trial, by arm. If assignment is based on a unit other than participants, also include a description

of the unit of assignment and the number of units that started and completed the clinical trial, by arm.

(2) *Demographic and baseline characteristics.* Information for completing a table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of human subjects who participated in the clinical trial. This information must include the following elements:

(i) *Baseline Characteristics Arm/Group Information.* A brief description of each arm or comparison group used for describing the demographic and baseline characteristics of the human subjects in the clinical trial, including a descriptive title used to identify each arm or comparison group.

(ii) *Baseline Analysis Population Information*—(A) *Overall Number of Baseline Participants.* The total number of human subjects for whom baseline characteristics were measured, by arm or comparison group and overall.

(B) *Overall Number of Units Analyzed.* If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which baseline measures were measured and analyzed, by arm or comparison group and overall.

(C) *Analysis Population Description.* If the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to the arm or comparison group and overall, a brief description of the reason(s) for the difference.

(iii) *Baseline Measure Information.* A description of each baseline or demographic characteristic measured in the clinical trial, including age, sex/gender, race, ethnicity (if collected under the protocol), and any other measure(s) that were assessed at baseline and are used in the analysis of the primary outcome measure(s) in accordance with §11.48(a)(3). The description of each measure must include the following elements:

(A) Name and description of the measure, including any categories that are used to submit Baseline Measure Data.

(B) *Measure Type and Measure of Dispersion:* For each baseline measure submitted, an indication of the type of data to be submitted and the associated measure of dispersion.

(C) *Unit of Measure.* For each baseline measure for which data are collected, the unit of measure.

(iv) *Baseline Measure Data.* The value(s) for each submitted baseline measure, by arm or comparison group and for the entire population of human subjects for whom baseline characteristics were measured.

(v) Number of baseline participants (and units), by arm or comparison group and overall, if different from the Overall Number of Baseline Participants or Overall Number of Units Analyzed in §11.48(a)(2)(ii)(A) and (B), respectively.

(3) *Outcomes and statistical analyses.* Information for completing a table of data for each primary and secondary outcome measure by arm or comparison group, including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any. This information must include the following elements:

(i) *Outcome Measure Arm/Group Information.* A brief description of each arm or comparison group used for submitting an outcome measure for the clinical trial, including a descriptive title to identify each arm or comparison group.

(ii) *Analysis Population Information*—(A) *Number of Participants Analyzed.* The number of human subjects for whom an outcome was measured and analyzed, by arm or comparison group.

(B) *Number of Units Analyzed.* If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which an outcome was measured and analyzed, by arm or comparison group.

(C) *Analysis Population Description.* If the Number of Participants Analyzed or Number of Units Analyzed differs from the number of human subjects or units assigned to the arm or comparison group, a brief description of the reason(s) for the difference.

(iii) *Outcome Measure Information.* A description of each outcome measure, to include the following elements:

(A) Name of the specific outcome measure, including the titles of any

categories in which Outcome Measure Data in §11.48(a)(3)(iv) are aggregated.

(B) Description of the metric used to characterize the specific outcome measure.

(C) Time point(s) at which the measurement was assessed for the specific metric.

(D) *Outcome Measure Type*. The type of outcome measure, whether primary, secondary, other pre-specified, or post-hoc.

(E) *Measure Type and Measure of Dispersion or Precision*. For each outcome measure for which data are collected, the type of data submitted and the measure of dispersion or precision.

(F) *Unit of Measure*. For each outcome measure for which data are collected, the unit of measure.

(iv) *Outcome Measure Data*. The measurement value(s) for each outcome measure for which data are collected, by arm or comparison group and by category (if specified).

(v) *Statistical Analyses*. Result(s) of scientifically appropriate tests of the statistical significance of the primary and secondary outcome measures, if any.

(A) A statistical analysis is required to be submitted if it is:

(*1*) Pre-specified in the protocol and/or statistical analysis plan and was performed on the outcome measure data,

(*2*) Made public by the sponsor or responsible party prior to the date on which clinical trial results information is submitted for the primary outcome measures(s) studied in the clinical trial to which the statistical analysis applies, or

(*3*) Conducted on a primary outcome measure in response to a request made by FDA prior to the date on which clinical trial results information is submitted for the primary outcome measure(s) studied in the clinical trial to which the statistical analysis applies.

(B) Information for each statistical analysis specified in paragraph (a)(3)(v)(A) of this section must include the following elements:

(*1*) *Statistical Analysis Overview:* Identification of the arms or comparison groups compared in the statistical analysis; the type of statistical test conducted; and, for a non-inferiority or equivalence test, a description of the analysis that includes, at minimum, the power calculation and non-inferiority or equivalence margin.

(*2*) One of the following, as applicable:

(*i*) *Statistical Test of Hypothesis:* The p-value and the procedure used for the statistical analysis; or

(*ii*) *Method of Estimation:* The estimation parameter, estimated value, and confidence interval (if calculated).

(4) *Adverse event information*. (i) Information to describe the methods for collecting adverse events during an applicable clinical trial:

(A) *Time Frame*. The specific period of time over which adverse event information was collected and for which information is submitted in paragraph (a)(4)(iii) of this section.

(B) *Adverse Event Reporting Description*. If the adverse event information collected in the clinical trial is collected based on a different definition of adverse event and/or serious adverse event than defined in this part, a brief description of how those definitions differ.

(C) *Collection Approach*. The type of approach taken to collect adverse event information, whether systematic or non-systematic.

(ii) Information for completing three tables summarizing anticipated and unanticipated adverse events collected during an applicable clinical trial:

(A) Table of all serious adverse events grouped by organ system, with the number and frequency of each event by arm or comparison group;

(B) Table of all adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with the number and frequency of each event by arm or comparison group; and

(C) Table of all-cause mortality, with the number and frequency of deaths due to any cause by arm or comparison group.

(iii) Information for each table specified in paragraph (a)(4)(ii) of this section must include the following elements, unless otherwise specified:

(A) *Adverse Event Arm/Group Information*. A brief description of each arm or comparison group used for submitting

adverse event information from the clinical trial, including a descriptive title used to identify each arm or comparison group.

(B) *Total Number Affected*. The overall number of human subjects affected, by arm or comparison group, by:

(*1*) Serious adverse event(s);

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial; and

(*3*) Deaths due to any cause.

(C) *Total Number at Risk*. The overall number of human subjects included in the assessment, by arm or comparison group, for:

(*1*) Serious adverse events;

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial; or

(*3*) Deaths due to any cause.

(D) *Adverse Event Information*. For the two tables described in paragraphs (a)(4)(ii)(A) and (B) of this section, a description of each type of serious adverse event and other adverse event that is not a serious adverse event and exceeds a frequency of 5 percent within any arm of the clinical trial, consisting of the following attributes:

(*1*) Descriptive term for the adverse event; and

(*2*) Organ system associated with the adverse event.

(E) *Adverse Event Data*. For the two tables described in paragraphs (a)(4)(ii)(A) and (B) of this section and for each adverse event listed in accordance with paragraph (a)(4)(iii)(D) of this section:

(*1*) Number of human subjects affected by such adverse event.

(*2*) Number of human subjects at risk for such adverse event.

(5) *Protocol and statistical analysis plan*. A copy of the protocol and the statistical analysis plan (if not included in the protocol), including all amendments that have been approved by a human subjects protection review board (if applicable) before the time of submission under this subsection and that apply to all clinical trial Facility Locations. The responsible party must include the Official Title (as defined in §11.10(b)(2)), NCT number (as defined in §11.10(a)) (if available), and date of the protocol and the statistical analysis plan on the cover page of each document. The responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted under this part. The protocol and statistical analysis plan must be submitted in a common electronic document format specified at *https://clinicaltrials.gov* or successor site..

(6) *Administrative information*—(i) *Results Point of Contact*. Point of contact for scientific information about the clinical trial results information, including the following:

(A) Name or official title of the point of contact

(B) Name of the affiliated organization, and

(C) Telephone number and email address of the point of contact.

(ii) Certain Agreements. An indication of whether the principal investigator is an employee of the sponsor and, if not, whether there exists any agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of human subjects participating in the clinical trial) between the sponsor or its agent and the principal investigator that restricts in any manner the ability of the principal investigator, after the primary completion date of the clinical trial, to discuss the results of the clinical trial at a scientific meeting or any other public or private forum or to publish in a scientific or academic journal information concerning the results of the clinical trial

(7) *Additional clinical trial results information for applicable device clinical trials of unapproved or uncleared device products*. (i) For an applicable device clinical trial of an unapproved or uncleared device product and for which clinical trial registration information has not been posted publicly on Clinical Trials.gov by the Director in accordance with §11.35(b)(2)(i), the responsible

party must provide the following data elements, as the data elements are defined in §11.10(b): Brief Title; Official Title; Brief Summary; Primary Purpose; Study Design; Study Type; Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study; Intervention Name(s); Other Intervention Name(s); Intervention Description; Intervention Type; Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product; Study Start Date; Primary Completion Date; Study Completion Date, Enrollment; Primary Outcome Measure Information; Secondary Outcome Measure Information; Eligibility Criteria; Sex/Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Name of the Sponsor; Responsible Party, by Official Title; Facility Name and Facility Location, for each participating facility in a clinical trial; Unique Protocol Identification Number; Secondary ID; Human Subjects Protection Review Board Status; and Record Verification Date.

(ii) The responsible party shall submit all the results information specified in paragraph (a)(7)(i) and must submit an affirmation that any information previously submitted to *ClinicalTrials.gov* for the data elements listed in paragraph (a)(7)(i) of this section have been updated in accordance with §11.64(a) and are to be included as clinical trial results information.

(b) *Pediatric postmarket surveillance of a device product that is not a clinical trial.* For each pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit a copy of any final report that is submitted to FDA as specified in 21 CFR 822.38. The responsible party may redact names, addresses, and other personally identifiable information or commercial confidential information contained in the final report prior to submission to NIH, unless such information is otherwise required to be submitted under this part. The final report must be in a common electronic document format specified at *https://clinicaltrials.gov* or successor site.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

§11.52 By when will the NIH Director post submitted clinical trial results information?

Except for clinical trial results information submitted under section 402(j)(4)(A) of the PHS Act and §11.60, the Director will post publicly clinical trial results information on *ClinicalTrials.gov* not later than 30 calendar days after the date of submission.

§11.54 What are the procedures for requesting and obtaining a waiver of the requirements for clinical trial results information submission?

(a) *Waiver request.* (1) A responsible party for an applicable clinical trial with a primary completion date on or after January 18, 2017 may request a waiver from any applicable requirement(s) of this subpart C by submitting a waiver request in the format specified at *https://clinicaltrials.gov* or successor site to the Secretary or delegate prior to the deadline specified in §11.44(a) for submitting clinical trial results information.

(2) The waiver request must contain:

(i) The NCT number, Brief Title, and Name of the Sponsor of the applicable clinical trial for which the waiver is requested;

(ii) The specific requirement(s) of this subpart C for which the waiver is requested; and

(iii) A description of the extraordinary circumstances that the responsible party believes justify the waiver and an explanation of why granting the request would be consistent with the protection of public health or in the interest of national security.

(3) The responsible party will not be required to comply with the specified requirements of this subpart for which a waiver is granted.

(4) The responsible party must comply with any requirements of this subpart for which a waiver is not granted or must submit an appeal as set forth in paragraph (b) of this section. The deadline for submitting any required clinical trial results information will be the later of the original submission deadline or 30 calendar days after the notification of the denial is sent to the responsible party.

(b) *Appealing a denied waiver request.* (1) A responsible party for an applicable clinical trial with a primary completion date on or after January 18, 2017 may appeal a denied waiver request by submitting an appeal to the Secretary or delegate in the format specified at *https://clinicaltrials.gov* or successor site not later than 30 calendar days after the date on which the electronic notification of the denial in paragraph (a)(4) of this section denying the request is sent to the responsible party.

(2) The responsible party is not required to comply with any requirements of this subpart for which a waiver is granted upon appeal.

(3) The responsible party must submit clinical trial results information to comply with any requirements of this subpart that are not waived upon appeal by the later of the original submission deadline or 30 calendar days after the notice of the denial upon appeal is sent to the responsible party.

(c) If a waiver is granted under paragraph (a) or (b) of this section:

(1) The Director will include a notation in the clinical trial record that specified elements of the requirements of this part have been waived.

(2) The Secretary will notify, in writing, the appropriate committees of Congress and provide an explanation for why the waiver was granted, not later than 30 calendar days after any waiver is granted.

(d) A responsible party for an applicable clinical trial with a primary completion date before January 18, 2017 may request a waiver from any applicable requirement(s) for clinical trial results information submission by submitting a waiver request, as specified in section 402(j)(3)(H) of the Public Health Service Act (42 U.S.C. 282(j)(3)(H)).

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 99759, Dec. 9, 2024]

Subpart D—Additional Submission of Clinical Trial Information

§ 11.60 What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?

(a) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (a)(1) of this section, the responsible party must meet the conditions specified in paragraph (a)(2) of this section.

(1) The requirements of paragraph (a) of this section apply to a clinical trial that was initiated before January 18, 2017 and has a primary completion date before January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial, or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (a)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraphs (b)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit 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)).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which 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)) has not been submitted, the responsible party must submit the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)).

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both 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)) and clinical trial results information 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 42 U.S.C. 282(j)(3)(I)).

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (a)(1) of this section, the responsible party specified in paragraph (a)(1) of this section must also submit the information specified in paragraph (a)(2)(iii) of this section by the deadline specified in paragraph (a)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (a)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (a)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (a)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (a)(1) of this section consists only of 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)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist, at minimum, of 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)).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of both 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)) and the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of both 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)) and the clinical trial results information 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 42 U.S.C. 282(j)(3)(I)).

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily submitted clinical trials, under paragraph (a) of this section:

(1) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (a) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in section 402(j)(3)(C) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C)) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(2) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in section 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(I)) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (a)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (a)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (a)(2)(i) of this section for the clinical trial specified under paragraph (a)(1) of this section is submitted to *ClinicalTrials.gov*.

(b) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (b)(1) of this section, the responsible party must meet the conditions specified in paragraph (b)(2) of this section.

(1) The requirements of paragraph (b) of this section apply to a clinical trial that was initiated before January 18, 2017 and has a primary completion date on or after January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial; or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (b)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraph (b)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit 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)).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which 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)) has not been submitted, the responsible party must submit the data elements specified in §11.48, as well as the data elements listed below, as those data elements are defined in §11.10(b) and apply to the clinical trial and the intervention(s) studied: Brief Title; Official Title; Brief

Summary; Primary Purpose; Study Design; Study Phase, for a clinical trial of a drug product (including a biological product); Study Type; Pediatric Postmarket Surveillance of a Device Product; Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study; Intervention Name(s), for each intervention studied; Other Intervention Name(s), for each intervention studied; Intervention Description, for each intervention studied; Intervention Type, for each intervention studied; Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product; Product Manufactured in and Exported from the U.S.; Studies a U.S. FDA-regulated Device Product; Studies a U.S. FDA-regulated Drug Product; Study Start Date; Primary Completion Date; Study Completion Date; Enrollment; Eligibility Criteria; Sex/Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Availability of Expanded Access, if any studied intervention is an investigational drug product (including a biological product); Name of the Sponsor; Responsible Party, by Official Title; Facility Information, for each participating facility; Unique Protocol Identification Number; Secondary ID; U.S. Food and Drug Administration IND or IDE Number; Human Subjects Protection Review Board Status; Record Verification Date; and Responsible Party Contact Information.

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both 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)) and the clinical trial results information specified in §11.48.

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (b)(1) of this section, the responsible party specified in paragraph (b)(1) of this section must also submit the information specified in paragraph (b)(2)(iii) of this section by the deadline specified in paragraph (b)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (b)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (b)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (b)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (b)(1) of this section consists only of 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)), the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must consist, at minimum, of 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)).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (b)(1) of this section consists of the clinical trial results information specified in §11.60(b)(2)(i)(B), the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must

consist of the clinical trial results information specified in §11.60(b)(2)(i)(B).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (b)(1) of this section consists of both 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)) and the clinical trial results information specified in §11.48, the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must consist of both 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)) and the clinical trial results information specified in §11.48.

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily submitted clinical trials, under paragraph (b) of this section:

(*1*) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (b) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in §11.48(a)(3) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(*2*) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in §11.48(a)(4) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (b)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (b)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (b)(2)(i) of this section for the clinical trial specified under paragraph (b)(1) of this section is submitted to *ClinicalTrials.gov*.

(c) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (c)(1) of this section, the responsible party must meet the conditions specified in paragraph (c)(2) of this section.

(1) The requirements of paragraph (c) of this section apply to a clinical trial that was initiated on or after January 18, 2017 and has a primary completion date on or after January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial; or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (c)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraph (c)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit the clinical trial registration information specified in §11.28(a).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in §11.28(a) has not been submitted, the responsible party must submit the data elements specified in paragraph (b)(2)(i)(B) of this section.

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both the clinical trial registration information specified in §11.28(a) and the clinical trial results information specified in §11.48.

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (c)(1) of this section, the responsible party specified in paragraph (c)(1) of this section must also submit the information specified in paragraph (c)(2)(iii) of this section by the deadline specified in paragraph (c)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (c)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (c)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (c)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (c)(1) of this section consists only of the clinical trial registration information specified in §11.28(a), the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in §11.28(a).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (c)(1) of this section consists of the clinical trial results information specified in §11.60(c)(2)(i)(B), the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist of the clinical trial results information specified in §11.60(c)(2)(i)(B).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (c)(1) of this section consists of both the clinical trial registration information specified in §11.28(a) and the clinical trial results information specified in §11.48, the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist of both the clinical trial registration information specified in §11.28(a) and the clinical trial results information specified in §11.48.

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily-submitted clinical trials, under paragraph (c) of this section:

(*1*) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (c) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in §11.48(a)(3) must be submitted by the later of the date that the

clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(2) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in §11.48(a)(4) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse events information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (c)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (c)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (c)(2)(i) of this section for the clinical trial specified under paragraph (c)(1) of this section is submitted to *ClinicalTrials.gov*.

(v) All submissions of clinical trial information under paragraph (c) of this section are subject to the applicable update and corrections requirements specified in §11.64.

(d) Statement to accompany applicable clinical trials submitted under paragraphs (a), (b), and (c) of this section. Each applicable clinical trial for which clinical trial information is submitted under paragraphs (a), (b), and (c) of this section and posted on *ClinicalTrials.gov* will include the statement ''This clinical trial information was submitted voluntarily under the applicable law and, therefore, certain submission deadlines may not apply. (That is, clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.)''

§ 11.62 What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?

(a) A responsible party who receives notification that the Director has determined that posting of clinical trial information for an applicable clinical trial described in paragraph (b) of this section is necessary to protect the public health must submit clinical trial information as specified in paragraph (c) of this section.

(b) An applicable clinical trial subject to this section must be either:

(1) An applicable clinical trial of an approved, licensed, or cleared drug product (including a biological product) or device product that has a primary completion date on or after September 27, 1997; or

(2) An applicable clinical trial that is subject to registration under §11.22(a) and studies a drug product (including a biological product) or device product that is unapproved, unlicensed, or uncleared, regardless of whether approval, licensure, or clearance was, is, or will be sought, and that is not otherwise subject to results information submission in accordance with the regulation.

(c) Deadline for submission of clinical trial information:

(1) *General.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, a responsible party for an applicable clinical trial that is subject to this section must submit the clinical trial registration information specified in §11.28(a) and the clinical trial results information specified in §11.48(a) not later than 30 calendar days after the

submission date specified in the notification described in paragraph (a) of this section.

(2) *Exception*. If a responsible party submits a certification consistent with §11.44(b) or (c) not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, the responsible party must submit the clinical trial results information specified in §11.48(a) not later than the deadline specified in §11.44(b) or (c), as applicable.

(3) If a responsible party submitted clinical trial registration information describing the applicable clinical trial specified in the notification described in paragraph (a) of this section prior to the date on which the notification is sent to the responsible party, the responsible party must update such clinical trial information to reflect changes, if any, in the applicable clinical trial not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, irrespective of the deadline for updates specified in §11.64.

§11.64 When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?

(a) *Updates*. (1) Clinical trial registration information:

(i) The responsible party for an applicable clinical trial for which clinical trial registration information was required to be submitted if the clinical trial was initiated before January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to 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)) that was required at the time of submission must be updated not less than once every 12 months.

(B) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status.

(C) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date.

(ii) The responsible party for an applicable clinical trial, or for another clinical trial for which registration information was voluntarily submitted pursuant to §11.60(c), if the clinical trial was initiated on or after January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to clinical trial registration information specified in §11.28 must be updated not less than once every 12 months.

(B) If the first human subject was not enrolled in the clinical trial at the time of registration, the Study Start Date data element must be updated not later than 30 calendar days after the first human subject is enrolled.

(C) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for any intervention included in the Intervention Name(s) data element.

(D) Availability of expanded access:

(*1*) If expanded access to an investigational drug product (including a biological product) becomes available after an applicable clinical trial of that product has been registered, the responsible party, if both the manufacturer of the investigational drug product (including a biological product) and the sponsor of the applicable clinical trial, must, not later than 30 calendar days after expanded access becomes available, update the Availability of Expanded Access data element for that applicable clinical trial and, unless an expanded access record has already been created as required by §11.28(a)(2)(ii)(H), submit the data elements in accordance with §11.28(c) to create an expanded access record.

(*2*) No later than 30 calendar days after the date on which the responsible party receives an NCT number for an expanded access record created as required by §11.28(a)(2)(ii)(H), the responsible party must update the Availability of Expanded Access data element by entering the NCT number in the clinical trial record for the applicable clinical trial.

(E) Expanded access record:

(*1*) Expanded Access Status, under §11.28(c)(2)(iv), must be updated not later than 30 calendar days after a change in the availability of expanded

access to an investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(*2*) Expanded Access Type, under §11.28(c)(1)(x), must be updated not later than 30 calendar days after a change in the type(s) of expanded access available for an investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(F) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status. If, at any time, Overall Recruitment Status is changed to ''suspended,'' ''terminated,'' or ''withdrawn,'' the responsible party must also submit the Why Study Stopped data element.

(G) Individual Site Status must be updated not later than 30 calendar days after a change in status for any individual site.

(H) Human Subjects Protection Review Board Status must be updated not later than 30 calendar days after a change in status.

(I) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date. At the time, the date is changed to ''actual,'' and the Enrollment data element specifying the actual number of participants enrolled must be submitted.

(J) Study Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual study completion date.

(K) Responsible Party, by Official Title must be updated not later than 30 calendar days after a change in the responsible party or the official title of the responsible party.

(L) Responsible Party Contact Information must be updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party.

(M) Device Product Not Approved or Cleared by U.S. FDA must be updated not later than 15 calendar days after a change in approval or clearance status has occurred.

(N) Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

(O) If a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, updates to any relevant clinical trial registration information data elements must be submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board.

(iii) In addition to the update requirements established in paragraphs (a)(1)(i) and (a)(1)(ii) of this section, clinical trial registration information must be updated at the time that clinical trial results information for that clinical trial is initially submitted.

(A) If the clinical trial was initiated before January 18, 2017, a responsible party must submit updates to the clinical trial registration information described in §11.64(a)(1)(i).

(B) If the clinical trial was initiated on or after January 18, 2017, the responsible party must submit updates to the clinical trial registration information in accordance with §11.64(a)(1)(ii).

(2) *Clinical trial results information*. The responsible party for an applicable clinical trial, or for another clinical trial for which results information was voluntarily submitted pursuant to §11.60(b) or (c), where the clinical trial has a Primary Completion Date on or after January 18, 2017, must submit updates in accordance with the following:

(i) In general, changes to required clinical trial results information, other than the protocol and statistical analysis plan specified in §11.48(a)(5) and certain agreements specified in §11.48(a)(6)(ii),must be updated not less than once every 12 months.

(ii) For applicable device clinical trials of unapproved or uncleared device products, the responsible party must update the following data elements, as defined in §11.10(b), in accordance with the following:

(A) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-

proprietary name is established for any intervention included in the Intervention Name(s) data element.

(B) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date. At the time the date is changed to ''actual,'' the Enrollment data element specifying the actual number of participants enrolled must be submitted.

(C) Study Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual study completion date.

(D) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status. If, at any time, Overall Recruitment Status is changed to ''suspended,'' ''terminated,'' or ''withdrawn,'' the responsible party must also submit the Why Study Stopped data element.

(E) Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

(3) A responsible party's obligation to submit updates as specified in this section ends on the date on which all required clinical trial results information has been submitted 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 42 U.S.C. 282(j)(3)(I)) or as specified in §11.48, as applicable, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1). If no clinical trial results information is required to be submitted, a responsible party's obligation to submit updates to clinical trial registration information ends on the date on which all required clinical trial registration information has been submitted 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, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1).

(4) *Public availability of updates.* (i) Updates to clinical trial registration information and clinical trial results information will be posted in accordance with §11.35 and §11.52, respectively.

(ii) The Director will retain prior clinical trial registration information and clinical trial results information and make it publicly available in accordance with §11.35 and §11.52, respectively, through *ClinicalTrials.gov* so that updates do not result in the removal of any information from the original submission or any preceding update.

(b) Corrections—(1) *Quality control.* After clinical trial registration information has been submitted 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, or clinical trial results information has been submitted 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 42 U.S.C. 282(j)(3)(I)) or §11.48, as applicable, including the updates specified in paragraph (a) of this section, the Director may provide electronic notification to the responsible party of apparent errors, deficiencies, and/or inconsistencies in the submitted information identified during procedures for quality control review established by the Director, as specified at*https://clinicaltrials.gov* or successor site. The responsible party must correct or address all apparent errors, deficiencies, and/or inconsistencies identified in the notification not later than 15 calendar days for clinical trial registration information, or 25 calendar days for clinical trial results information, after the date of the electronic notification sent to the responsible party.

(2) *Other corrections.* (i) A responsible party who becomes aware of errors, other than those specified in paragraph (b)(1) of this section, in any clinical trial information submitted under this part shall have not more than 15 calendar days for clinical trial registration information, or 25 calendar days for clinical trial results information, to correct or address such errors.

(ii) A responsible party's obligation to correct or address errors as specified in paragraph (b)(2) of this section ends

on the date on which all required clinical trial results information has been submitted 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 42 U.S.C. 282(j)(3)(I)) or §11.48, as applicable, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1). If no clinical trial results information is required to be submitted, a responsible party's obligation to correct or address errors ends on the date on which all required clinical trial registration information has been submitted 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, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1).

(3) Compliance with the quality control review process, including the requirements of this section, does not constitute a legal defense to enforcement pursuant to section 301(jj) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331(jj)), section 303(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 333(f)(3)), or any other Federal law.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

Subpart E—Potential Legal Consequences of Non-Compliance

§11.66 What are potential legal consequences of not complying with the requirements of this part?

(a) *Civil or criminal judicial actions.* Failure to comply with the requirements of this part, issued under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), is a prohibited act under one or more provisions of section 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(jj)):

(1) Failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service (42 U.S.C. 282(j)(5)(B)) that all applicable requirements of section 402(j) have been met, or knowingly submitting a false certification under section 402(j)(5)(B), is a prohibited act under section 301(jj)(1) of the Federal Food, Drug, and Cosmetic Act.

(2) Failure to submit clinical trial information required under section 402(j) of the Public Health Service Act is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act.

(3) Submission of clinical trial information under section 402(j) that is false or misleading in any particular is a prohibited act under section 301(jj)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Civil monetary penalty actions.* Any person who violates section 301(jj) of the Federal Food, Drug, and Cosmetic Act is subject to civil monetary penalties under section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(3)).

(c) *Grant funding actions.* Under section 402(j)(5)(A) of the Public Health Service Act (42 U.S.C. 282(j)(5)(A)), if an applicable clinical trial is funded in whole or part by the Department of Health and Human Services, any required grant or progress report forms must include a certification that the responsible party has made all required registration and results submissions. If it is not verified that the required registration and results clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted, any remaining funding for a grant or funding for a future grant to such grantee will not be released. If the head of an HHS agency verifies that a grantee has not submitted such required clinical trial information, the agency head will provide notice to the grantee of the noncompliance and allow the grantee 30 days to correct the non-compliance and submit the required clinical trial information.

PART 12—TELEMEDICINE FLEXIBILITIES

Subpart A—Special Exceptions Related to Telemedicine

Sec.

12.1 Temporary extension of certain COVID–19 telemedicine flexibilities for prescription of controlled medications.
12.2 [Reserved]