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://prsinfo.clinicaltrials.gov*.

§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://prsinfo.clinicaltrials.gov/* 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://prsinfo.clinicaltrials.gov/* 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)).

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)).