

(21) Nebraska Administrative Code Title 126 Chapter 1.001, 1.005, 1.011, 1.013, 1.020–1.022, 1.024, 1.030.01, 1.031, 1.033–1.034, 1.036–1.038, 1.040, 1.045.

(22) Nebraska Administrative Code Title 126 Chapter 18.

(23) Nebraska Administrative Code Title 178 Chapters 12.001, 12–03, 12–06–12–07, 12–09, 12–011.01–12–011.01B1, 12–011.01C–12–012.08B, 12–012.08D–12–012.08F2, 12–012.09–12–14, the tables and figures, and the following definitions found at Title 178, Chapter 12–002 Annular Fill, Annular Space, Aquifer, Aquifer Seal, Primary Aquifer Seal, Surface Seal, Backflow Preventer, Bentonite, Bentonite Seal, Bored or Dug Well, Casing, Cesspool, Clay, Community Water System, Confining Layer, Construction of Water Wells, Contamination, Decommissioned when used in relation to a water well, Department, Dewatering Well, Discharge Pipe, Distribution Piping, Good Cause, Gravel Pack, Ground Water, Grout, Installation of Pumps and Pumping Equipment, Monitoring Well, Non-potable Well, Observation Well, Person, Pitless Unit, Pollution, Potable Well, Primary Aquifer Seal, Public Water System, (Licensed) Pump Installation Contractor, (Licensed) Pump Installation Supervisor, Pumps and Pumping Equipment, Recovery Well, Sanitary Well Seal, Screen Apertures, Screened Vent, Secure Cover or Cap, Seepage Pit, Septic Tank, Soil Absorption System (Septic Lateral Field), Static Water Level, Substantially Equivalent, Subsurface Disposal System, Supervision or its derivatives, Surface Seal, Test Hole, Tremie Pipe, Watertight Casing, Watertight Secure Cover, Water Well, (Licensed) Water Well Contractor, (Licensed) Water Well Drilling Supervisor, Well Development, Well Pit, Well Screen.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 11

[Docket No. NIH–2024–0001]

RIN 0925–AA71

### Clinical Trials Registration and Results Information Submission

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Department of Health and Human Services (HHS), through the National Institutes of Health (NIH), is amending its regulation governing clinical trials registration and results information submission to update throughout the regulation the internet web address or uniform resource locator (URL) of the site that provides information about formatting of information for submission, procedures, and tools as specified in the regulation.

**DATES:** This final rule is effective December 9, 2024.

**FOR FURTHER INFORMATION CONTACT:** Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, Division of Management Support, 6011 Executive Boulevard, Suite 601, Rockville, Maryland 20852–7669, telephone 301–435–3343, email [dhernandez@od.nih.gov](mailto:dhernandez@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** NIH is completing a multiyear initiative to modernize the *ClinicalTrials.gov* website to deliver an improved user experience on an updated platform that enhances efficiency. The modernized website integrates content from the [prsinfo.clinicaltrials.gov](https://prsinfo.clinicaltrials.gov) website, which is referenced in several sections of 42 CFR part 11 as the web address for obtaining information on formatting and other guidance, into the centralized *ClinicalTrials.gov* website at <https://clinicaltrials.gov> for convenience and ease of access. This address change necessitates amending the regulation to update the URL for the [prsinfo.clinicaltrials.gov](https://prsinfo.clinicaltrials.gov) successor site. NIH considered other options and concluded that this final rule technical amendment is necessary because the current codified URL is referenced throughout the regulation itself (*i.e.*, as opposed to the Preamble alone). Moreover, the “or successor site” modifier is not always used in the regulation; for example, 42 CFR 11.8 states “Information submitted under this part must be submitted electronically to *ClinicalTrials.gov*, in the format specified at <https://prsinfo.clinicaltrials.gov>.”

The address change necessitates amending the regulation codified at 42 CFR part 11 by removing the URL address <https://prsinfo.clinicaltrials.gov> wherever it appears in part 11, and adding, in its place, the URL <https://clinicaltrials.gov> or successor site.

Specifically, this action results in removing the URL <https://prsinfo.clinicaltrials.gov> and adding, in its place, the URL <https://clinicaltrials.gov> or successor site in §§ 11.4(c)(2)(ii) and (c)(3), 11.8, 11.44(e)(3)(i), 11.48(a)(5) and (b), 11.54(a)(1) and (b)(1), and 11.64(b)(1) in part 11.

Amending the regulation is time sensitive, as NIH completed integration of content from the [prsinfo.clinicaltrials.gov](https://prsinfo.clinicaltrials.gov) website into the modernized *ClinicalTrials.gov* website in June 2024. The address change is cost neutral, editorial in nature, and does not impose any new regulatory requirements on affected parties.

## Matters of Regulatory Procedure Administrative Procedure Act

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA generally exempts rules from the requirements of notice and comment rulemaking when an agency “for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest” (5 U.S.C. 553(b)(B)).

HHS has determined that notice and public comment are unnecessary because this amendment to the regulation provides only technical or non-substantive, administrative changes to specify the location of information about formatting of information for submission, procedures, and tools as specified in the regulation.

Additionally, HHS finds good cause for these amendments to become effective on the date of publication of this rulemaking action. The APA allows an effective date of less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, HHS finds good cause for this correction to become effective on the date of publication of this rulemaking action.

Further, it is in the public interest that correct and up-to-date information be contained in the affected sections of the regulation at 42 CFR part 11 as soon as possible.

## Regulatory Impact Analysis

NIH examined the impacts of this rule under Executive Order 12866, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review; Executive Order 14094, Modernizing Regulatory Review; Executive Order 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601–612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

## Executive Orders 12866, 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled “Modernizing Regulatory Review” amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “not significant” under section 3(f) and does not meet the criteria set forth in 5 U.S.C. 804(2) under subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Thus, a RIA is unnecessary.

#### Executive Order 13132

Executive Order 13132, “Federalism,” requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Secretary, HHS, has reviewed this rule as required under the Executive order and determined that it will not have federalism implications. The Secretary, HHS, certifies that the rule will not have effect on the States or on the distribution of power and responsibilities among various levels of government.

#### Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires agencies to analyze regulatory options that would minimize the significant economic impact of a rule on small entities. The Secretary has determined that this rule will not have a significant economic impact on a substantial number of small entities.

#### Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written statement, to include an assessment of anticipated costs and benefits, before proposing any rule that includes a Federal mandate that may result in the expenditure by State, local and Tribal governments or more, in the aggregate or by the private sector, of \$100,000,000 [adjusted annually for inflation (with base year 1995)] in any 1 year. The current inflation-adjusted statutory threshold as of January 2024 is approximately \$183 million based on the Bureau of Labor Statistics inflation calculator. The Secretary, HHS, certifies that that this rule does not mandate any spending by State, local, or Tribal government in the aggregate or by the private sector.

#### Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) is not applicable, because this rule does not contain any new information collection or record keeping requirements that require the approval of the Office of Management and Budget, and this rule does not impact information collection and recordkeeping requirements in part 11 that are already approved under OMB Control Number 0925–0586.

#### Congressional Review Act

The Secretary, HHS, has determined this rule is a non-major rule under the Congressional Review Act (5 U.S.C. chapter 8) and has provided a report thereon to the Senate, House of Representatives and General Accounting Office in accordance with that law.

#### List of Subjects in 42 CFR Part 11

Biologics, Drugs, Human research subjects, Information, Laboratories, Medical devices, Medical research, Reporting and recordkeeping requirements.

Accordingly, under the authority of 42 U.S.C. 216, the Department of Health and Human Services amends 42 CFR part 11 by making the following technical amendment:

#### PART 11—CLINICAL TRIALS REGISTRATION AND RESULTS INFORMATION SUBMISSION

■ 1. The authority citation for part 11 continues to read as follows:

**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).

#### §§ 11.4, 11.8, 11.44, 11.48, 11.54, and 11.64 [Amended]

■ 2. Amend §§ 11.4, 11.8, 11.44, 11.48, 11.54, and 11.64 by removing the URL “<https://prsinfo.clinicaltrials.gov>” wherever it appears, and adding, in its place, the text “<https://clinicaltrials.gov> or successor site”.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

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#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 90

[WP Docket No. 07–100; FCC 23–3; FR ID 261942]

#### Improving Public Safety Communications in the 4.9 GHz Band

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule, announcement of compliance date.

**SUMMARY:** In this document, the Federal Communications Commission (FCC) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collections associated with certain rules adopted in the Seventh Report and Order, in WP Docket No. 07–100; FCC 23–3. This document is consistent with the Seventh Report and Order, which directs the Public Safety and Homeland Security Bureau and the Wireless Telecommunications Bureau to publish a document in the **Federal Register** announcing a compliance date for the rule section and revise the rule accordingly.

#### DATES:

*Effective Date:* December 9, 2024.

*Compliance Date:* Compliance with 47 CFR 90.1207(e) and (f) published at 88 FR 12565 on February 28, 2023, is required as of December 9, 2024.

**ADDRESSES:** Federal Communications Commission, 45 L St. NE, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Brian Marengo of the Public Safety and