



Children's National

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**SUBJECT:** ClinicalTrials.gov Registration and Results Reporting

**POLICY/PROCEDURE:** RA:02

**DATE EFFECTIVE:** September 9, 2019

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## **I. POLICY STATEMENT**

This policy reflects current federal and ancillary regulations regarding the registration and results information submission requirements for ClinicalTrials.gov. Children's National Medical Center (Children's National) is committed to transparency and research integrity in its research activities. Children's National requires that all investigators comply with the requirements of Health and Human Services (HHS) regulations (42 CFR 11) (FDAAA 801), "Clinical Trials Registration and Results Information Submission," and the "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information."

The HHS regulations mandate registration and results reporting for applicable clinical trials (ACTs) regardless of funding type. ACTs generally include interventional studies of drugs, biological products, or devices that are subject to FDA regulation. (More details at <https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>.)

The NIH policy mandates registration and results reporting for clinical trials that are funded in whole or in part by NIH, even if they are not ACTs. NIH defines a clinical trial (NIH-CT) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (More details at <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>.)

In addition, this policy recognizes International Committee of Medical Journal Editors (ICMJE) recommendations to register clinical trials and Centers for Medicare and Medicaid (CMS) policy to require a ClinicalTrials.gov study identification number (NCT#) when billing for routine care associated with applicable clinical trials.

It is the policy of Children's National that registration of trials meeting any of the criteria outlined in this policy **must be submitted to ClinicalTrials.gov concurrently with initial IRB submission**. If the trial has not been registered at that time, the PI may indicate the National Clinical Trial (NCT) number is "pending" and report the NCT number immediately after obtaining from ClinicalTrials.gov. It is the responsibility of the Children's National PI to notify the IRB as soon as the NCT number has been obtained by entering it in the electronic IRB platform. The Children's National PI will also be reminded at the time of the continuing review application to indicate the NCT number.

## II. PROCEDURE

It is the responsibility of the Principal Investigator to ensure registration and results reporting are completed and updated, and in the timeframes required, by FDAAA, NIH, CMS and/or ICMJE.

### A. DEFINITIONS

#### **Clinical Trial:**

- **Applicable Clinical Trial, or ACT (FDAAA)**: Includes interventional studies (with one or more arms) of FDA-regulated drugs, biological products or devices that meet one of the following conditions: (a) the trial has one or more sites in the U.S.; (b) the trial is conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE); or the trial involves a drug, biologic or device that is manufactured in the U.S. or its territories and is exported for research. There are two types of FDAAA-defined applicable clinical trials which must be registered and results reported:
  - o **Applicable Clinical Drug Trial**: A controlled clinical investigation, other than a Phase I clinical investigation, of a drug or biological product subject to FDA regulation; and
  - o **Applicable Clinical Device Trial**: A controlled trial with health outcomes of devices subject to FDA regulation, other than small feasibility studies or pediatric post-market surveillance required by FDA.

Registration is required for applicable clinical trials (ACT) initiated after September 27, 2007, or ongoing as of December 26, 2007.

- **Clinical Trial (NIH)**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
  - o NIH requires registration and results reporting for all NIH-supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA.
- **Qualifying Trial (CMS)**: The activity must be a clinical trial that qualifies for coverage (as specified in CMS Section 310.1 of the Medicare National Coverage Determination Manual) and the purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' services, durable medical equipment, diagnostic test, etc.). The trial must have therapeutic intent and must enroll patients with diagnosed disease, not only healthy volunteers.
- **Clinical Trial (ICMJE)**: A clinical trial is a research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes—includes drugs, biologics, devices, surgical procedures, and behavioral treatments (see The Uniform Requirements for Manuscripts Submitted to Biomedical Journals). This definition includes Phase I studies.

## B. REGISTRATION

1. Unless the clinical trial has already been registered by the sponsor or other responsible party, Principal Investigators are responsible for registering clinical trials at *ClinicalTrials.gov*, reviewing the content of the information uploaded to the registry to verify completeness and accuracy, and ensuring all data-entry activities **upon IRB approval**. This standard meets the required time frames, as follows:
  - a. **FDAAA:** The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website ***no later than 21 days after enrollment of the first participant*** (<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa>).
  - b. **NIH:** The Principal Investigator must register and input required clinical trial information at the ClinicalTrials.gov website ***no later than 21 days after enrollment of the first participant*** (<https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>).
  - c. **CMS:** The Principal Investigator must register and input required clinical trial information and obtain a NCT# at the ClinicalTrials.gov website ***before submitting claims for such services to CMS***.
  - d. **ICMJE:** The Principal Investigator must register with an ICMJE qualified publicly-accessible registry ***at or before the first patient is enrolled in the study*** as a condition for publication in a participating journal (<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration>).
2. Children's National Medical Center (Children's National) applicable clinical trials must be registered on ClinicalTrials.gov through the Children's National organizational account at the website, unless the clinical trial has already been registered by the sponsor or other responsible party.
3. The Institution will assign an IRB Protocol Number at the time the IRB application is created in the electronic IRB system. The Principal Investigator should initiate study registration once the IRB Protocol Number is assigned.
4. Principal Investigators should use the *Update ClinicalTrials.Gov Nbr* activity on the study workspace to add the NCT# to the electronic IRB system.
5. The Informed Consent document of applicable clinical trials will include the following exact statement:

"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

### C. UPDATING RECORDS

Principal Investigators are responsible for updating clinical trial records registered at ClinicalTrials.gov, reviewing the record for accuracy and verifying that data-entry occurs within the required time frames, as follows:

FDAAA, NIH, CMS and ICMJE require the following:

- a. Registration information must be updated *no less than once every six months*;
- b. Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input *within 30 days of any change*;
- c. Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input *within 30 days of trial closure*.

### D. RESULTS REPORTING

1. Principal investigators are responsible for reporting results of clinical trials registered at ClinicalTrials.gov, reviewing the record for accuracy and ensuring data-entry occurs within required time frames, as follows:
  - a. **FDAAA:** Aggregate results and adverse event reporting on ClinicalTrials.gov must occur *within 12 months of the Primary (endpoint) Completion Date*;
  - b. **NIH:** Aggregate results and adverse event reporting on ClinicalTrials.gov must occur *within 12 months of the Primary (endpoint) Completion Date*;
  - c. **CMS:** If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur *within 12 months of the Primary (endpoint) Completion Date*. If the study does not qualify as a clinical trial under FDAAA or NIH, *results reporting is voluntary*.
  - d. **ICMJE:** If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur *within 12 months of the Primary (endpoint) Completion Date*. If the study does not qualify as a clinical trial under FDAAA or NIH, *results reporting is voluntary*.
2. If a clinical trial is subject to registration requirements by more than one entity—FDAAA, NIH, CMS or ICMJE--it need only be registered once at ClinicalTrials.gov. Registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.
3. Detailed instructions for submission of study results are found on the ClinicalTrials.gov website at <https://clinicaltrials.gov/ct2/manage-recs/how-report>.

## **E. OTHER CLINICALTRIALS.GOV SITE RESPONSIBILITIES**

The Principal Investigator is responsible to respond to registry reviewer requests for information or changes, as applicable, in a timely fashion.

## **F. TRANSFER OF PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES**

1. During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the Institution, the PI must work with the Department or Division Chief to ensure an orderly transition of his/her responsibilities to the new PI at the Institution or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.
2. If a clinical trial remains at the Institution and there are continuing registry reporting obligations without a named PI, then the Department or Division Chief must personally assume or appoint a PI to serve and assume any remaining reporting obligations.

## **G. SANCTIONS**

1. Principal Investigators that fail to comply with the ClinicalTrials.gov requirements may be subject to enforcement actions.
  - a. Failure to comply with FDAAA requirements may result in financial penalties, withholding of funds and sanctions imposed by the FDA.
  - b. Failure to comply with NIH may result in withholding of cash payments, disallowing cost for an activity, suspending or terminating either in part or whole the current award, withholding a future award and having a non-compliance notice publically available.
  - c. Failure to comply with ICMJE requirements may result in an inability to publish in an ICMJE affiliated journal.
  - d. Failure to comply with CMS requirements may result in a lack of payment for a qualified research billing service and a need to refile the qualified research billing claim.

## **H. INVESTIGATOR NON-COMPLIANCE AT CHILDREN'S NATIONAL**

Children's National reserves the right to impose discipline or sanctions for non-compliance. An investigator that does not respond to the ClinicalTrials.gov Navigator's request for compliance within 10 business days may incur one or more consequences. Consequences may include limitations on the ability to conduct research. Determinations regarding non-compliance with ClinicalTrials.gov requirements will be made jointly by the Children's National Offices of Corporate Compliance and Regulatory Affairs.

## I. SUPPORT FOR INVESTIGATORS

In partnership with the Clinical and Translational Science Institute at Children's National (CTSI-CN), Children's National offers the following support services to help investigators comply with these guidelines:

### 1. ClinicalTrials.gov Liaison

Providing investigator consultations and support for study registration, update of study records and data reporting into ClinicalTrials.gov within the federally required timeframes.

### 2. Biostatistician Support for Data Analysis and Result Reporting

The CTSI-CN has a **Biostatistics, Epidemiology, and Research Design (BERD)** module that provides statistical consultation, analysis and proposal development to investigators. Consulting services include biostatistical and epidemiologic consultative services in study design, statistical analysis, data management, and data dissemination.

To learn more about BERD please visit the CTSI-CN website at:  
<https://www.ctsicc.org/BiostatisticsServices>.

To request services, please arrange for a BERD consultation meeting via the SPARC Request portal at <https://www.ctsicc.org/sparc> or email [ctgov@cnmc.org](mailto:ctgov@cnmc.org) to contact our liaison.

## III. ACCOUNTABLE EXECUTIVE(S) AND REVIEWER(S)

A. **Accountable Executive:** Chief Academic Officer

B. **Department Responsible for Review:** Children's Research Institute, Compliance Department

C. **Committee Responsible for Review:** Research Compliance Work Group/Policy and Education Work Group

## IV. APPROVAL

Approved by:

Research and Compliance Workgroup/  
Policy and Education Workgroup

9/9/2019

Date



Mark L. Batshaw, M.D., Chief Academic Officer

10/30/19

Date

## V. APPLICABILITY

## VI. REVIEW OR REVISION DATE

Original: 9/9/2019

Revised:

## VII. REFERENCES

- FDAAA 801: <https://clinicaltrials.gov/ct2/manage-recs/FDAAA>
- Clinical Trials Registration and Results Information Submission (Final Rule): <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>
- NIH Elaboration Document of Responsible and Applicable Clinical Trial: <https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>
- NIH Policy & Compliance ClinicalTrials.gov and FDAAA: FAQs [https://grants.nih.gov/ClinicalTrials\\_fdaaa/faq.htm](https://grants.nih.gov/ClinicalTrials_fdaaa/faq.htm)
- ClinicalTrials.gov website: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- ICMJE FAQ: <http://icmje.org/about-icmje/faqs/>
- CMS Medicare Clinical Trial Policies <https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/ClinicalTrialPolicies>
- Center for Medicare and Medicaid Services (CMS):
  - o <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1344.pdf>
  - o [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1\\_part14.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part14.pdf)
- C-01P – Corrective Action Procedure: <http://intranet.childrensnational.org/policies-procedures/Documents/C-01P.pdf>

