

**DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH**

TITLE: Registration of Clinical Trials on ClinicalTrials.gov		
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1. POLICY STATEMENT:

DF/HCC Investigator-sponsored clinical trials applicable to one of the following policies must be registered and updated on ClinicalTrials.gov: the Food and Drug Administration Amendments Act (FDAAA) of 2007, the Health and Human Services Final Rule, or NIH Policy (2017) for clinical trials registration requirement.

DF/HCC Investigator-sponsored clinical trials that are not applicable to the above policies should be considered for registration to comply with the International Committee of Medical Journal Editors (ICMJE) requirements for publication.

For externally sponsored clinical trials, the regulatory sponsor is responsible for compliance with Clinicaltrials.gov registration requirements.

2. BACKGROUND:

Section 113 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 requires the registration of clinical trials that evaluate the efficacy of drugs for serious or life-threatening diseases that are conducted under an Investigational New Drug (IND) application. FDAAA, also known as [U.S. Public Law 110-85](#), expanded the scope of registration and results reporting of clinical trials at ClinicalTrials.gov.

The [Health and Human Services Final Rule and the NIH Policy](#), effective on January 18, 2017 further enhanced the clinical trials registration and results reporting requirement. FDAAA, HHS-Final Rule and or the NIH Policy require the reporting of aggregate results and summary adverse event information for certain applicable trials.

As of 2005, most medical journals, including [ICMJE member publications](#), required as a condition of consideration for publication, the prospective registration of certain clinical trials.

3. RESPONSIBLE PERSONNEL:

- 3.1. Principal Investigator (PI)
- 3.2. ODQ Program Manager, Clinical Trials Registry

4. DEFINITIONS:

- 4.1. **Applicable clinical trial definition (FDAAA-801):** Generally includes interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the United States, involves a drug, biologic, or device that is

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manufactured in the United States (or its territories), or is conducted under an IND or investigational device exemption (IDE). This excludes Phase I trials.

4.2. **Applicable Clinical Trial Definition (HHS Final Rule):** Applicable clinical trials of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. Does not apply to Phase I trials or small feasibility device studies.

4.2.1. Applicable clinical trials are (1) clinical trials of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations, of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA under the FD&C Act.”

4.3. **Applicable Clinical Trial Definition (NIH Policy):** “All clinical trials funded wholly or partially by NIH. This includes Phase I clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions.”

4.4. **Applicable Clinical trial definition (International Committee of Medical Journal Editors (ICMJE)):** “The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first patient enrollment, but best practice dictates registration by the time of first patient.”

4.5. **ClinicalTrials.gov:** A public database developed by the U.S. National Institutes of Health (NIH), provided through its National Library of Medicine

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(NLM), that meets FDAMA, FDAAA, HHS Final Rule, NIH Policy and ICMJE requirements.

4.6. **Responsible Party:** The sponsor of the clinical trial or the principal investigator of the trial if so designated by the sponsor, grantee, contractor, or awardee.

4.7. **Primary Completion Date:** The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies 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.

5. POLICY:

5.1. Clinical Trial Registration

5.1.1. All applicable clinical trials must comply with Clinicaltrials.gov registration requirements. For any DF/HCC-sponsored trial or externally sponsored protocol that will be registered on Clinicaltrials.gov, the NCT number must be assigned before opening to enrollment at DF/HCC.

5.1.1.1. For trials associated with an externally held IND or IDE (e.g., non-DF/HCC investigator, or industry), the IND/IDE holder is responsible for registration. However, for trials sponsored or funded wholly or in part by the NIH, Cancer Therapy Evaluation Program (CTEP) or National Cancer Institute (NCI), the core site PI should contact the sponsor or funding agency to determine registration responsibilities.

5.1.2. For DF/HCC-sponsored protocols, the Clinicaltrials.gov registration must be created in the institutional PRS account of the DF/HCC sponsor-investigator's home institution. Investigators must follow institutional policies and procedures regarding Clinicaltrials.gov registration.

5.1.2.1. For sponsor-investigators with a primary appointment at Dana Farber Cancer Institute (DFCI), the DF/HCC Office of Data Quality (ODQ) will create the initial registration in the DFCI PRS account, and no records should be created in the DFCI PRS account without approval from ODQ.

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5.1.2.2. For sponsor-investigators with a primary appointment at Boston Children's Hospital (CHB), Beth Israel Deaconess Medical Center (BIDMC), or Massachusetts General Brigham (MGB) should contact their institutional PRS Administrator to establish new accounts, gain access to the ClinicalTrials.gov PRS site, or grant access to other members of the research team.

5.1.2.3. The sponsor-investigator is typically listed as the responsible party on each record and has overall responsibility for the accuracy and maintenance of the record.

5.1.3. The responsible party is required to update and release the registration record during the course of the trial in compliance with all applicable requirements. Generally speaking, the registration and update requirements include:

5.1.3.1. Initial registration of the trial on ClinicalTrials.gov.

5.1.3.2. Updates every 6 months for studies that are not yet completed, even if there were no changes to the record.

5.1.3.3. Updating the Primary Completion Date. For active studies, this means updating the Anticipated date of expected completion over the course of the study. Upon study completion, the Actual date should be entered.

5.1.3.4. Updates to the record within 30 days for Site Recruitment Status and Overall Recruitment Status Changes.

5.1.3.5. Other changes and updates to the record must be made at least every 12 months.

5.2. Transfer of Clinical Trial Records Between Institutions

5.2.1. PIs who change institutions must consult with their institutional PRS administrator to discuss the potential transfer of existing clinicaltrials.gov records to their new institution. Prior to the transfer of a clinical trial record from an external (non-DF/HCC institution) to a DF/HCC institution in clinicaltrials.gov, the following conditions must be met:

5.2.1.1. The protocol must be approved and activated at DF/HCC.

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5.2.1.2. The clinicaltrials.gov record must be error-free, up to date, and compliant prior to transfer.

5.2.1.3. The new Responsible Party within DF/HCC must accept responsibility for all future record maintenance, updates, and results reporting (when applicable).

5.2.1.3.1. This means the Responsible Party must ensure they have access to all clinical trial data and/or other information needed to fulfill these responsibilities.

5.3. Results and Adverse Event Reporting

5.3.1. The Responsible Party is responsible for submitting basic results and adverse event information for certain applicable clinical trials through the ClinicalTrials.gov Protocol Registration System (PRS) at <https://register.clinicaltrials.gov>.

5.3.2. For applicable clinical trials that are subject to 42 CFR 11.42, the standard submission deadline for results information is no later than 1 year after the study's Primary Completion Date, as described in 42 CFR 11.44(a) of the final rule.

5.3.3. The regulations provide for the delayed submission of results information under certain conditions (see 42 CFR 11.44(b)). This must be prospectively requested.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Subjects
Food and Drug Modernization Act (FDAMA) of 1997
FDA Amendments Act of 2007 (FDAAA or Public Law 110-85)
Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
ICMJE Web site <http://www.icmje.org>

7. RELATED REFERENCES:

DF/HCC ClinicalTrials.gov Registration Website –
<http://www.dfcc.harvard.edu/research/clinical-research-support/office-of-data-quality/services-support/clinicaltrials.gov-and-ctrp/>

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ClinicalTrials.gov Web site <http://clinicaltrials.gov>
FDAAA-801 Requirements <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>
Clinicaltrials.gov Protocol Registration Data Element Definitions
<http://prsinfo.clinicaltrials.gov/definitions.html>
Final Rule Information <https://prsinfo.clinicaltrials.gov/>
Summary of HHS/NIH Initiatives to Enhance Availability of Clinical Trial
Information <https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>
Summary Table of HHS/NIH Initiatives to Enhance Availability of Clinical Trial
Information
<https://www.nih.gov/news-events/summary-table-hhs-nih-initiatives-enhance-availability-clinical-trial-information>
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>
ClinicalTrials.gov User's Guide <https://clinicaltrials.gov/ct2/manage-recs>
Public Law 110-85 Information Page (<https://clinicaltrials.gov/ct2/manage-recs/fdaaa>
Data Elements for Results Reporting
(http://prsinfo.clinicaltrials.gov/results_definitions.html)
International Committee of Medical Journal Editors (<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration>)
ClinicalTrials.gov Training Materials
<https://clinicaltrials.gov/ct2/manage-recs/present>

8. RELATED RESOURCES:

DF/HCC Guidance on Common Mistakes with ClinicalTrials.gov Records
DF/HCC Guidance on Registering a Protocol on ClinicalTrials.gov
DF/HCC Guidance on Managing a ClinicalTrials.gov Record
DF/HCC List of Institutional PRS Administrators

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