Brief CT.gov Registration Highlights

Each of the 4 rule bodies with bearing on trial registration: ICMJE, NIH, CFRs, and CMS should be assessed independently to determine the need to register and to recognize if an additional requirement to report results exists. See also Registering an Investigator-Initiated Clinical Trial in a Public Registry and Trial Registration Highlights in the ClinicalTrials.gov section of the Office of Clinical Trials' website.

International Committee of Medical Journal Editors (ICMJE)

To be eligible for publication consideration by journals following the International Committee of Medical Journal Editors' (ICMJE) guidelines, prospective trial registration is required (*prior to 1st participant's signing of informed consent*). Most journals follow ICMJE standards whether they are actual ICMJE members or not.

Official study registration is marked by NCT number assignment. The NCT assignment occurs upon completion of ClinicalTrials.gov's QC review process which is initiated following protocol record creation, completion, and subsequent release.

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 consent. See also: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html.

National Institutes of Health (NIH)

Trials receiving NIH funding either in whole or in part (including, for example, any NIH division or center, training grant, and/or Clinical and Translational Science Award (CTSA) such as grants awarded by NC TraCS) and meeting the NIH 'clinical trial' definition must be registered (within 21 days of the 1st participants enrollment*) and report results in the ClinicalTrials.gov registry (by no later than 1 year of collection of the last primary outcome-related data). The NIH 'clinical trial' definition , decision tree , and NIH Case Study examples can be used to help with this determination.

*While NIH requires registration within 21 days, for those studies seeking to publish, the ICMJE requires completion of registration before the start of enrollment (see ICMJE section above).

Note that the NIH 'clinical trial' definition can include social-behavioral research.

Applicable Clinical Trial (ACT)

Section 801 of the Code of Federal Regulations (CFR) defines Applicable Clinical Trials (ACTs). Trials meeting this definition require both registration (within 21 days of 1st participant's enrollment) and results reporting in ClinicalTrials.gov (by no later than 1 year of collection of the last primary outcome-related data). A clinical investigation of an FDA-regulated intervention outside the use of a marketed product in the course of medical practice should be evaluated in light of the ACT rules. ACT rules apply to interventions which are unapproved as well as those already approved/cleared for marketing by the U.S. Food and Drug Administration.

Centers for Medicare and Medicaid Services (CMS)

To avoid payment denial, CMS requires entry of the National Clinical Trial (NCT) number on all study-related claims submitted. NCT numbers are available only through registration at ClinicalTrials.gov.