University of Colorado Hospital Policy

National Clinical Trial Number requirement

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<th>Effective Date:</th>
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Introduction:
This policy describes the requirement for University of Colorado Health to include National Clinical Trial (NCT) numbers on invoices for applicable research activities.

The purpose of this policy is to comply with Centers for Medicare & Medicaid Services (CMS) Transmittal 2955, which requires facilities engaged in research to report a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. (“Transmittal 2955”, 2014)

Scope:
UCHealth is responsible for requiring the inclusion of an NCT number, and the line-item services for which the NCT number needs to be included, on the invoice to CMS and other 3rd party payers who align their policies with CMS.

The Investigator is responsible for obtaining an NCT number from ClinicalTrials.gov for all applicable trials, as discussed below. The Investigator or his/her designee is responsible for identifying all tests & procedures used for research purposes, ensuring that the proper documentation is provided to UCHealth Research Administration so that research charges are billed to the correct grant number and that documentation of all research visits are documented in the patient’s medical record.

Research Support Services is accountable for determining if a proposed study requires an NCT number and to be include the NCT number on applicable invoices for applicable trials.

Definitions:
A. The Investigator (or Primary Investigator (PI)) is the lead researcher for a research study.
B. The Study Team is the group of people engaged by the PI by employment, affiliation or as a volunteer to assist with study responsibilities.
C. A Clinical Trial (or qualifying clinical trial or applicable trial) could be either an Applicable Drug Clinical Trial or an Applicable Device Clinical Trial, defined separately below.
D. Applicable Drug Clinical Trial: Consistent with FDAAA, UCHealth defines this term as “a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject
E. **Applicable Device Clinical Trial:** UCHealth adopts the definition of this term as provided in FDAAA and defines the term as “(1) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subject if it meets four criteria: (1) it is prospective clinical study of health outcomes; (2) it compares an intervention with a device against a control in human subjects; (3) the studied device is subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (FDC Act); and (4) it is other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes. ("Elaborations of Definitions", 2009)

**Policies and Procedures:**

University of Colorado Health will comply with CMS Transmittal 2805:

1. It will be mandatory to report an NCT number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008 - the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials data base.

2. UCHealth will use professional judgment in applying the NCT requirement for all studies.

3. Limitations:
   a. This policy requiring an NCT number applies to all Clinical Trials, as well as registries as determined by their IRB of record to be Human Subject Research.
   b. **Retrospective, observational only and other types of studies that do not direct treatment activities are not required to obtain an NCT number for UCHealth billing purposes.** (“Mandatory Reporting,” 2014)

4. RSS will include the NCT number for applicable trials along with other federally regulated coding on all line items for related claims.

5. RSS will not activate newly submitted applicable trials until an NCT number has been provided.

6. RSS Billing will direct any invoices for claims related to applicable trials that have not provided an NCT number into a claim edit queue and will contact the PI/study team to resolve the need for an NCT number.

**References:**

University of Colorado Hospital
Review and Approval of Research Activities
