



# Dartmouth

**CLINICAL TRIALS OFFICE**

## Mission of the Dartmouth Clinical Trials Office



**The Dartmouth Clinical Trials Office (CTO) is a centralized office established to enhance patient safety, promote high-quality research, ensure fiscal and regulatory compliance, and encourage clinical translation collaborations. The CTO provides financial management of clinical trials, as well as good clinical practice (GCP) consulting/monitoring services and educational programs for all levels of research staff.**

# Services



1. Medicare Coverage Analysis
2. Budget Negotiation
3. Contract Negotiation
4. Financial Management of Industry, Foundation, Unfunded/Departmental trials. Federal Studies still managed by Department Grant Managers w/OSP
5. Clinical Research Compliance
6. Regional Coordination
7. Fee for Service Research Support

# Glossary of Terms



**CTO = Dartmouth Clinical Trials Office**

**BOA = Business Operations Associate**

**IRB = Institutional Review Board**

**CPHS = Committee for the Protection of Human  
Subjects**

**MCA = Medicare Coverage Analysis**

**PI = Principal Investigator**

**CRC = Clinical Research Coordinator**

# CTO Study Registry



Clinical Trials Office has been charged with the study registry project which includes:

- Collecting documents for all CPHS review human subjects research (except for some DMS Arts & Sciences divisions)
- Entering studies into Velos (Clinical Trials Management System)
- Documenting and confirming if clinical research & if study involves billing
  
- ❖ Note the CTO is monitoring COEUS and will reach out to study team for information if we see a study has been submitted to the CPHS that is not entered into Velos.

# Submission to CTO



- Documents are submitted to CTO via online submission.
- CTO study intake link:

<https://dhmc.wufoo.com/forms/clinical-trials-study-intake-form/>

- CTO Business Ops Associate (BOA)
  - Read protocol
  - Review all documents
  - BOA draft MCA
  - Resource meeting scheduled

# Documents to include in submission



- **Protocol**
- **Model or Draft Informed Consent (ICF)**
- **Draft Clinical Trial Agreement (CTA) (Contract)**
- **IND or IDE letter, if applicable**
- **Sponsor contact information, if known**

# Timing for submitting Federal Studies



- No mandate for when a Federal study should be submitted to the CTO
- Two Scenarios:
  - 1) At proposal stage
  - 2) Prior to study activation, once research team knows a study will be awarded

## MCA-What is it?



- **Systematic review of all research-related documents to determine the Medicare qualifying status of the study itself and the Medicare billing status of the items and services**
- **Conducted prior to or in tandem with the budgeting process to ensure coverage for all items and services**
- **The MCA is the mechanism for compliance with the billing rules**

# Why do it?



- **Basis for billing for all patients**
- **Medicare rules tend to set the trend for the payor industry**
- **Almost every study has the potential to enroll for Medicare patients as participants**
- **Double billing or improper billing to Medicare can result in fines, sanctions, or suspension**

# Our Review



- **Reviewing all documents:**
  - Reading protocol in detail & not assuming all services are in protocol schema
  - Reviewing informed consent: particularly “What are the costs?” and “How is this different section?”
  - Sponsor agreement/contract and budget terms

**Objective: What has been promised “free” to patients.**

## Is it a Qualifying study?

**“Qualifying” studies must meet the following criteria:**

- 1.** The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category
- 2.** The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
- 3.** Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

## Is the study an investigation of a product/service that is covered by Medicare?



- **Is the study an investigation of a product/service that is covered by Medicare?**
  - **Very Broad Categories:**
    - ✦ **Drugs, Biologics and Therapeutics**
    - ✦ **Laboratory and Diagnostic Services**
    - ✦ **Medical and Surgical Procedures**
    - ✦ **Diagnostic Imaging**
    - ✦ **Medical Devices and Prosthetics**
    - ✦ **Durable Medical Equipment**

Not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

# Therapeutic Intent



- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent:
  - Overall Survival
  - Tumor Response
  - Efficacy
- Phase I Quandary:
  - Safety and Toxicity
  - Maximum Tolerated Dose

**Dartmouth policy: Therapeutic intent must be stated in any of the protocol objectives**

## Does the study enroll participants with a diagnosed disease?



- Review of the following items should provide answers to this question:
  - ✦ **The Study Inclusion/Exclusion Criteria**
  - ✦ **Informed Consent Form**

# Is the study “deemed”?



- **Deemed trials are:**
  - Trials funded by N IH, CDC, AHRQ, HCFA (CMS), DOD, and VA;
  - Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;
  - Trials conducted under an investigational new drug application (I N D) reviewed by the FDA; and
  - Drug trials that are exempt from having an I N D under 21 CFR 312.2(b)(1)

# Coverage Analysis



- If study meets all criteria, services can be listed on MCA as billable to insurance
- If study does not meet criteria, all services must be billed to study account



# Billing Acronyms



- **SOC = Billable to Medicare/Insurance**
- **STY = Billable to Study**
- **NB = Non-billable service (no charge run through DH Billing system)**

# Resource Meetings



- Meeting with research team (PI, CRC, RN, pharmacy, lab technicians, etc) to:
  - Review study protocol
  - BOA asks questions from Resource Meeting questionnaire & any other questions found when reading protocol
  - Answer questions about study that the team may have
  - Determine routine care vs. research
  - Evaluate resources needed for trial

# Updating MCA for IRB submission



**IRB requires an MCA as part of submission. After the resource meeting the BOA will:**

- Update MCA per Resource Meeting notes**
- Send to Research Team to review**
- Give five days for team to review and give comments**
- Save & return as PDF for IRB submission**

# Budgets for Federal Studies



- **Completed by the Department Grant Manager**
- **Routed to OSP**
- **CTO holds the chargemaster for DHMC and D-H Clinic patient services. Grant Manager can contact the CTO for help with pricing**
- **Caution: Good to have CTO review to confirm all patient care pricing is accurate**

# Before Federal study is activated



- **CTO as part of our process will:**
  - Conduct a consistency check of ICF, CTA, Budget, & MCA
  - Confirm all patient care costs were adequately budgeted
  - Help complete request for MHMH Account Number, if needed

# Updates-Unfunded Trials



- **Note effective July 1<sup>st</sup>, all “unfunded” (internal funded) clinical trials will have their own separate CTO account set up.**
  - If trial is funded by Dartmouth College or Hitchcock Foundation PI reserve account, processes have been set up to have checks cut from those reserve account to a CTO account based on amount of approved budget.
  - When study complete, any remaining funds will be returned to PI reserve.

# Communication is key!



- Important to work as a team in this process
- Communication vital re: Amendments, changes to ICF, protocol, etc
- Process for new study MCAs: resource meetings, MCA development before study activation



**QUESTIONS?**