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
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
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.
“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?

- **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 NIH, 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 (IND) reviewed by the FDA; and
  - Drug trials that are exempt from having an IND 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
**MCA Billing Grid Template**

**PROTOCOLS**

| Item Number | Parameter | Item / Service Location in Protocol | Range of CPT/HCPCS/Code(s) | Range of CMG Codes | Research Health | Screening | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 | Comments |
|-------------|-----------|-------------------------------------|-----------------------------|--------------------|----------------|-----------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|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Billing Acronyms

- SOC = Billable to Medicare/Insurance
- STY = Billable to Study
- NB = Non-billable service (no charge run through DH Billing system)
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
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 1st, 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?