NIH Clinical Trial Budgeting

February 15, 2024
Budgeting for Federal Clinical Trials

• Clinical Trial Budget Basics
• Workflow
• Budgeting for Scope of Work
• Tips & Tricks
• Resources & Contacts
• FYI: Just In Time Coverage Analysis
Clinical Research

The current NIH definition of clinical research is human subjects research that is:

1. **Patient-oriented research.** Research conducted with human subjects (or on material of human origin) for which an investigator directly interacts with human subjects. Excluded from this definition are in vitro studies that use human tissues that cannot be linked to a living individual.

2. **Epidemiologic and behavioral studies.**

3. **Outcomes research and health services research.**

Examples include:
- Registries
- Observational Studies
- Retrospective Chart Review
- Social/Behavioral Studies
- Clinical Trials

Clinical Trials

Clinical Trials are a subset of Clinical Research and defined by the NIH as: a research study in which **one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Trials can be:
- Investigator Initiated and:
  - Federally Funded
  - Industry Funded
  - Privately Funded (Internal Awards, Private Foundations)
- Single Site or Multi-site
- Industry Sponsored
  - Single Site or Multi-site
Two Types of Trial Budgets: Overall & Site

- Overall = you are the PI of a multi-site or single site trial and are responsible for all parts of the budget.
- Site Budget = you are the local site PI.
  - Site budget is fixed including overhead, and not negotiated at site level.
  - Site budget is negotiable; local site and Prime site negotiate start-up of trial/study, per patient enrollment, and closeout.

Guiding Principle:
Budget must reflect scope of work!
What do you think are the most common budget categories?
Major Clinical Trail Cost Categories

• Personnel Time – salary effort & per patient fees
  • Screen, enroll, measure outcomes
  • Follow subjects, data entry & analysis
  • Study management
• Procedures: Technology – can be completed through centralized services
  • Imaging & labs
• Procedures: Study-related Care & Intervention
  • Drugs & devices
• Protocol-Related Fees
  • Start-up, close-out, & institutional fees
• Other Expenses
  • Data Management
  • Travel & Meetings
  • Materials & Supplies

How we organize expenses
Cost Reimbursable, Per Patient & Patient Care

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directs</td>
<td>$7,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$27,000</td>
</tr>
<tr>
<td>IDC</td>
<td>$5,495</td>
<td>$3,925</td>
<td>$3,925</td>
<td>$3,925</td>
<td>$3,925</td>
<td>$21,195</td>
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<tr>
<td>78.50%</td>
<td>$12,495</td>
<td>$8,925</td>
<td>$8,925</td>
<td>$8,925</td>
<td>$8,925</td>
<td>$48,195</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Salary</td>
<td>$2,218</td>
<td>$2,218</td>
<td>$2,218</td>
<td>$2,218</td>
<td>$2,218</td>
<td>$11,090</td>
</tr>
<tr>
<td>PI (1% of Cap)</td>
<td>$1,896</td>
<td>$1,896</td>
<td>$1,896</td>
<td>$1,896</td>
<td>$1,896</td>
<td>$9,480</td>
</tr>
<tr>
<td>Fringe (17%)</td>
<td>$322</td>
<td>$322</td>
<td>$322</td>
<td>$322</td>
<td>$322</td>
<td>$1,610</td>
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<tr>
<td>Total - PI</td>
<td>$2,538</td>
<td>$2,527</td>
<td>$2,625</td>
<td>$2,603</td>
<td>$2,682</td>
<td>$12,947</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator</td>
<td>$2,097</td>
<td>$2,160</td>
<td>$2,225</td>
<td>$2,292</td>
<td>$2,292</td>
<td>$11,066</td>
</tr>
<tr>
<td>(5%) (includes 3% inflation vs 1-4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fringe (17%)</td>
<td>$356</td>
<td>$367</td>
<td>$378</td>
<td>$390</td>
<td>$390</td>
<td>$1,881</td>
</tr>
<tr>
<td>Total - Coordinator</td>
<td>$2,453</td>
<td>$2,527</td>
<td>$2,603</td>
<td>$2,682</td>
<td>$2,682</td>
<td>$12,947</td>
</tr>
<tr>
<td>Supplies</td>
<td>$2,329</td>
<td>$2,255</td>
<td>$179</td>
<td>$100</td>
<td>$100</td>
<td>$2,862</td>
</tr>
<tr>
<td>Total per Year</td>
<td>$7,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$26,900</td>
</tr>
</tbody>
</table>

**Per Patient Payment - $1700 per patient (No IDC) (PID#2)**

<table>
<thead>
<tr>
<th>Source of payment</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment, completed telephone encounter (medical CRF including)</td>
<td>$500.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed neurodevelopmental Questionnaires (BRIEF, VSCS, SRS, Sensory)</td>
<td>$150.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed parent well-being questionnaires, $150 (line 77)</td>
<td>$150.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gift Cards ($100) (line 78)</td>
<td>$100.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Breakdown of $1700**

These services do not have CPT codes but are part of the patient care. So patient care can have both billable and non-billable services.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Pro Fee</th>
<th>Tech Fee</th>
<th>From Charge Master</th>
<th>discount applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>70551</td>
<td>MRI, BRAIN WO CONTRAST (tech +pro)</td>
<td>$800.00</td>
<td>$237.00</td>
<td>$506.00</td>
<td>$800.00</td>
</tr>
</tbody>
</table>

How we bill for expenses
Research, Standard of Care & Non-Billable

**Research (R)**
Current Procedural Terminology (CPT) coded procedure with professional and/or technical fee associated.

Non-covered, non-routine charges.

Generally, patients would not be receiving this care. Patients should never bear the cost of the research related procedure.

Cost of care is billed to sponsor.

**Standard of Care (SOC)**
CPT coded procedure with professional and/or technical fee associated.

Routine care that patient would receive regardless of study participation.
Cost of care is billed to insurance.

**Non-Billable (NB)**
No CPT code is associated with the items/activity.

This is a per-patient personnel cost that is estimated by hour x frequency.
Federal Clinical Trial Workflow

Standard Proposal Process for Federal Clinical Trials / Clinical Research

- PI & study team works with research administrators to kick off submission
  - CRI BearGrants Intake Form supported by the Proposal Development Team
  - GW Research Admin Pod Notice of Intent
- Assigned administrator will provide details about necessary internal & sponsor requirements
- Draft budget is informed by PI & study team and developed/finalized by administrator
  - Typically, coverage analysis is not completed until the Just In Time stage.
- Final documents are submitted for review prior to submission
  - CRI Proposal Development Timeline
    - 7 business days for final docs to Proposal Dev;
    - 4 business days to Grants & Contracts
  - GW Proposal Development Timeline
    - 5-7 business days for budget, sub docs & cost share requests;
    - 2-3 business days to Office of Sponsored Programs
Budgeting for Scope of Work
Budgeting for Scope of Work

- What is the clinical question to answer?
- How many patients are needed to answer the question?
- How many sites are needed to recruit the patients over what period?
- What will be measured to determine safety and clinical outcomes?
- What are the per patient costs in terms of technology, treatments, and personnel time?
- Who is coordinating the trial and what is their level of effort and/or related costs?
- Who is providing data analysis and managing or monitoring data? What is their level of effort and/or related costs?
- What are the travel, communication, and training expenses for trial staff and sites?
- Are there ancillary costs for procedures or treatment?
- Are you using consultants or advisors?
Step 1: Identify Procedures & Schedule of Events

<table>
<thead>
<tr>
<th>Study Visits</th>
<th>Screening</th>
<th>Enrollment and Randomization</th>
<th>Baseline Visit</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Final Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIHSSS</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Laboratory assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum Chemistry/hematology</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Study drug or device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

PI & study team build schedule of events including the number of cycles required.
Step 2: Determine Per-Subject Procedural Costs

PI & study team work with the assigned SRA/PDS to calculate procedural costs.

- Procedures = based on Current Procedural Terminology (CPT) codes found in your respective institution’s Charge Master
- Charge Master is updated monthly
  - Includes professional and technical fees
  - A discount rate is applied based on procedure and sponsor type
Ancillary Departments & Associated Costs

Different departments within our institutions offer services with institutionally-approved fees. If procedures will be completed by these central units, a budget must be requested from the respective unit.

Children’s Hospital
- Clinical Research Unit (PCI/CRU)
- Investigational Drug Service (IDS/Pharmacy)
- Core Service Centers
  - Cell Therapy Lab
  - Biostatistical Core
  - Genomics & Gene Editing Core
  - Cell & Tissue Microscopy
  - & more!
Research Patient Care Costs

Research patient care costs do not include:

• personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments of individuals

• costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service

• recruitment or retention fees or,

• the data management or statistical analysis of clinical research results.
Step 3: Determine Personnel Costs by Study Complexity

PI & study team work with the assigned SRA/PDS to determine:

- Personnel Effort (FTE) / Salary & Benefits – for individuals supporting study's infrastructure
- Per Subject Fees – time to do a procedure/task
  - Hourly rate multiplied by number of hours to complete task each visit.
  - Informed by PI/Study Team

<table>
<thead>
<tr>
<th>STUDY COMPLEXITY</th>
<th>LOW</th>
<th>MEDIUM</th>
<th>HIGH</th>
<th>EXCEPTIONALLY HIGH</th>
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</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>0.5</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Inclusion/Exclusion Criteria</td>
<td>0.25</td>
<td>0.5</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>Screening Eligibility</td>
<td>0.25</td>
<td>0.5</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Medical History/Demography</td>
<td>0.5</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Vitals</td>
<td>0.25</td>
<td>0.25</td>
<td>0.25</td>
<td>0.25</td>
</tr>
<tr>
<td>AE Reporting</td>
<td>0.25</td>
<td>0.5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>SAE Reporting</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Step 4: Protocol-Related Expenses

- Can be one-time or recurring fees depending on expense type/event.
  - Administrative start-up & close-out
  - Feasibility fee, coverage analysis, PowerTrials, and OnCore build & maintenance
  - Pharmacy fees: start-up, yearly maintenance, and close-out
  - IRB fees (dependent on type of study, single site, local, etc.): start up, annual, continuing review, amendment review, and review of reportable events

- **Not included on NIH/Federal studies because of negotiated F&A rate agreement.**

Step 5: Other Expenses

- Investigator meetings, training & travel
- Participant incentives
- Materials & supplies (printing costs, etc.)
- Data management
- Dissemination of findings
CRI Division Approval Form

When coverage analysis is not completed prior to submission, a Division Approval form must be signed and submitted internally.

Why is it required?
• If items are not billed to insurance or paid by the sponsor, the subject/Department gets billed. CNH loses money — There is no free lunch.
• Coverage Analysis ensures all procedures and associated costs are included at the correct time points; ancillary charges are captured; & proper CPT codes are present.
Tips & Tricks
Budget Tips & Tricks

- Every task and data point = $$ expense
  - Minimize data points; what is truly needed?
  - Imaging is expensive; choose imaging that is part of standard of care (SOC) unless critical to study
  - Inpatient vs outpatient and associated costs (room & board, sedation, etc.)
- Never underestimate time & number of sites needed to recruit
  - Underestimating time to complete study means you will exceed budgeted infrastructure costs (coordinating center, data management, etc.) which are typically budgeted as personnel effort; meanwhile, your per patient costs will remain static.
- Pay for time to do task rather than effort
  - Keep FTE to PI, key personnel, study manager, data manager and statistical analysis
  - If you pay 0.5 FTE for coordinator but have 2/3 enrollment as expected after 5 years, you will no salary remaining for coordinator work to complete trial and stay within budget.
What budget items do you think investigators underestimate or forget to include?
Hidden Costs

Items not addressed in the schedule of events in the protocol that are also billable to the sponsor. Must be built into budget during build/negotiation or the sponsor will not reimburse for them.

Examples include:

- Serious adverse events
- Unscheduled visits
- Reconsent of participants
- Monitor visits/ agency visits
- Shipment cost
Common Tests with Coverage Limitations

- Lipid testing
- HIV and hepatitis screening
- Pregnancy testing
- ECGs
- Complete blood counts (CBC)
- Thyroid testing

When a coverage limitation exists and a procedure will be billed to insurance, documentation of test’s medical necessity is critical.
NIH Specific Considerations

• < $500,000 Direct Costs per year do not need pre-approval
• > $500,000 Direct Costs per year need prior approval from Institute
• NIH salary cap is $221,900; greater salaries require cost-share.
• Be sure that personnel costs are allocated to **either personnel effort OR per-patient**. You cannot have PI time as both salary & per-patient.
• NIH trials are milestone based and study will be stopped if recruitment doesn’t meet targets.
• Children’s MDTC indirect rate of 82% is applicable. Excludes patient care (cpt-coded procedures).
Resources & Contacts

• NIH Clinical Trials & You: The Basics; For Researchers & Trial Sites
• NIH Clinical Trial Requirements for Grants & Contracts
  • Clinical Trial-Specific Funding Opportunities
  • Human Subjects and Clinical Trials Information Form
  • Division of Human Subjects Research (DHSR) Resources on Human Subjects, Clinical Trials, and Inclusion
• NIH Grants Policy Statement
  • Research Patient Care Costs: Policy & Allowable Costs

Children’s Research Institute
• Clinical Trial Support Services through CTSI (CRI & GW)
• Mehzabin Khan, Clinical Trial Office Manager (industry-sponsored clinical trials)
• Caroline Wellington, Proposal Development Manager (all other clinical trials)

George Washington University
• Research Administration Pod 3 serving Faculty in the SMHS, SON, MFA, & SEAS
• Office of Sponsored Projects & Office of Clinical Research Fed/Fdn CTs Start Up
JIT Coverage Analysis
Just In Time Coverage Analysis

What is coverage analysis?
An independent review of study procedures to determine what procedures can be billed to insurance and what needs to be paid by the sponsor based on Medicare rules.

Why is it required?
• Required under the Federal Clinical Trials Policy
• Helps to comply with the False Claims Act
• Ensures the trial meets the federal definition of Qualifying Trial which means insurance may be billed for standard of care items.

Required Documents
• DRAFT Informed Consent Form
• DRAFT Budget
• DRAFT CTA, NOGA or JIT
• FINAL Protocol
• Children’s Logistic Review Form

How are Coverage Analyses initiated?

1. JIT request received
2. PI/Study team provides required docs.
3. PDS submits DR to CTO
4. CTO assigns coverage analyst
5. Budget updated based on CA
<table>
<thead>
<tr>
<th>Protocol Related Items and Services</th>
<th>Location in Protocol</th>
<th>CPT / HCPCS Codes</th>
<th>QL / Q1 (as needed)</th>
<th>Visit Schedule</th>
<th>Coverage Determination Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should Dx Code 200.5 / V70.7 (and Condition Code 30, where applicable) appear on the claim?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Is this an Outpatient (OP) or Inpatient (IP) visit?</td>
<td>OP</td>
<td>OP</td>
<td>OP</td>
<td>OP</td>
<td>OP</td>
</tr>
</tbody>
</table>

| Informed consent | p. 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Eligibility criteria | p. 45 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Archival tumor tissue (FFPE or fresh frozen) | p. 59, 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA |

| Pathology tissue preparation fee | p. 59, 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Optional tissue collection | p. 90 | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB |

| Procedural sedation (for biopsies, scans) | p. 90 | 99151 or 99155 (<5 yo), 99152 or 99156 (5-9 yo), 99153 (each added 14 min, <5 yo), 99157 (each added 14 min, 5-10 yo) | Q1 | R/S | R/S | S | Fresh tissue needed for screening if archival tissue is not available—sponser paying costs of research fresh tumor biopsy, which should include sedation fee. Per UpToDate, “MRI is not as fast as ultrasonography or CT, and image quality is compromised easily by motion. Thus, sedation or anesthesia is required in most infants and younger children and occasionally in older patients, especially those with cognitive impairments”. If a subject requires sedation for subsequent standard of care biopsies and scans, costs should be billed to insurance and is supported by NCD 310.1. |

| DAY 101 530mg/m², oral, once weekly | p. 3 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| DAY 101 dispensing/return | p. 90 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Drug diary review | p. 45, 65, 91 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NB |


| Neurology exam | p. 59, 60, 87 | 92020-92205 (new pt), 92241-99246 (consultation) | Q1 | R | R | R | R | R | R | R | R | R | R | R |

| Per ICF p. 4, the neurologic exam is for research. Budget paying for neurologic exam. |

<table>
<thead>
<tr>
<th>Communications</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTO Comments/Questions</td>
</tr>
</tbody>
</table>

| Should Dx Code 200.5 / V70.7 (and Condition Code 30, where applicable) appear on the claim? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | N/A |
| Is this an Outpatient (OP) or Inpatient (IP) visit? | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP | OP |
| Informed consent | p. 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Eligibility criteria | p. 45 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Archival tumor tissue (FFPE or fresh frozen) | p. 59, 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

| Pathology tissue preparation fee | p. 59, 87 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Optional tissue collection | p. 90 | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB | NB |

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| DAY 101 dispensing/return | p. 90 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Drug diary review | p. 45, 65, 91 | NA | NA | NA | NB | NA | NA | NA | NA | NA | NA | NA | NA | NA | NB |


| Neurology exam | p. 59, 60, 87 | 92020-92205 (new pt), 92241-99246 (consultation) | Q1 | R | R | R | R | R | R | R | R | R | R | R | R |

| Per ICF p. 4, the neurologic exam is for research. Budget paying for neurologic exam. |
BUDGETING FOR CLINICAL TRIALS & OCR ROLES

GW Office of Clinical Research

Eric Cannon, Sr. Contracting Officer
India Johnson, Sr. Finance Analyst
OCR Review Timeline

1. Receipt of Study Documentation from Sponsor
2. Packet submission to OCR
3. Negotiation period activities
4. Approvals & Signatures
5. Fully executed CTA, post-signature activities
Definitions

**CDA/NDA:** Confidential Disclosure Agmt/Non-Disclosure Agmt:
- Put in place to facilitate sharing of sponsor’s protocol in order to assess study feasibility

**CTA:** Clinical Trial Agmt

**ICF:** Informed Consent Form
- Signed by a prospective study subject prior to enrolling in the study; outlines known risks of drug/device, subject’s rights regarding PHI and compensation in the event of injury

**CRO:** Clinical Research Organization
- When involved, CRO performs study tasks on behalf of/in cooperation with sponsor (contracting, monitoring, for example) – can also impact timelines to study start-up
Coverage Analysis: analysis of study documentation and Medicare billing guidelines to determine what is deemed part of the clinical research study and what can be billed to insurance.

Calendar: schedule of protocol procedures according to study timeline.

Charge Master: comprehensive list of procedures, labs, and services; may include pricing information.
Receipt of Study Documentation from Sponsor

Typically sent via email by Sponsor following execution of a CDA
Study team (PI/study coordinator) should receive directly from Sponsor

- Should include:
  - Draft contract
  - Draft budget
  - Protocol
  - ICF
  - Investigator’s Brochure
  - Pharmacy manual
Packet Submission to OCR

Once documentation received from sponsor, study team submits to OCR inbox (researchcontracts@mfa.gwu.edu)

- Submission email should include:
  - All study documentation received from Sponsor
  - OCR Intake Form
  - COI forms for PI and any/all sub-l’s
  - Hospital Questions form
  - MFA Pharmacy Quote for drug trials (dmamuah@mfa.gwu.edu)
  - Establishment of OnCore ID
Contract Negotiation

CTA negotiation requires holistic review of all legal terms in the CTA to ensure minimal risk to GWU/MFA

• Negotiation involves review of legal terms and situating the terms to the study to be performed (i.e., Phase 1, Phase 2-3, post-market, registry)
• What internal parties are involved?
  • MFA (MFA PI, study activities taking place at MFA)
  • GWU (GWU PI, federal/foundation clinical research)
  • GW Hospital (if study activities taking place in Hospital facilities) – additional review/approvals required
• Sometimes all three!
OCR Contracting Officer reviews all legal language in the CTA, including:

- Publication
- Indemnification
- Insurance
- Subject Injury
- Subject Privacy
- Use of Study Data
- Confidentiality
- Intellectual Property
- Rights upon Termination/expiration
- Laws & Regulations (HIPAA, GCPs, etc)
- Governing Law
- Inspections, Study Monitoring
Budget Negotiation

What are the first steps?

• Contractors from Advarra (formerly Forte) are engaged to provide Coverage Analysis and to build the protocol calendar in OnCore.

• In conjunction with this, the Financial Analyst will begin budget negotiations by requesting quotes from the hospital for procedures and evaluating the pharmacy budget information provided in the study intake documentation submitted to the OCR.

• Once budget has been redlined with any updates the PI and Study Team will review before submission to sponsor/CRO for negotiation (PI must approve the draft budget).
OCR Financial Analyst reviews all financial information including:

- Per patient costs
- Protocol and budget related items
- Stipends
- Payment terms

Once this information has been reviewed and updated a redlined budget is sent to the sponsor for approval or any counters they may have. Rounds of negotiations will continue until an amenable solution may be found for both parties.
How Do Sponsors React to Budget Items?

Every sponsor is different in what they will and will not pay for.

- Clarification from study team (and sponsor if necessary) on activities that will and will not take place for a particular study helps avoid some back and forth.

Items that may be contested:

- Storage/Archiving
- Dry Ice
- Audit Fees
- Document Request Fees
- Coordinator / PI Fees
  - Be able to provide expected hours and justification of time.
Amendments to Budgets

Study Team Will:
• Submit to OCR (clinicalresearch@mfa.gwu.edu) all related documentation and summary of changes.

Financial Analyst Will:
• Review original negotiated budget and submitted amendment.
• Negotiate with sponsor if needed.
• Request PI approval for finalization.
Factors impacting OCR timelines

- Who is sponsor?
  - Major pharma vs. startup company
- CRO involvement?
- Will study procedures take place in GW Hospital facilities?
  - Hospital quotes, CPT codes for incorporation into the budget
- Phase II/III trial vs. non-interventional study
- Timely receipt of study documentation from sponsor for OCR submission
- Are there any undisclosed study specific needs anticipated for inclusion in the budget? (e.g., patient stipend, additional PI or Coord. time, etc.)
Approvals & Signatures

Following conclusion of contract negotiations, sponsor will generate execution copy to route for signatures

- PI must sign CTA affirming s/he has read and acknowledges the terms applicable to PI
  - PI does not have signature authority to bind MFA/GW to the terms of the contract, signature is an acknowledgement only
- Following PI signature, agreement must be routed for Institutional signatures
Approvals & Signatures (cont’d)

Who needs to approve/sign?

• If MFA only (industry-sponsored study):
  • Routed to Vice Dean, SMHS for approval & then to MFA CEO for signature
• If MFA/GWU (industry-sponsored):
  • Routed to both Vice Dean, SMHS & MFA CEO for signatures
• If GWU (federal/foundation agreements)
  • Routed to Vice Dean, SMHS for approval & then to Assistant Vice Provost, Sponsored Projects (OSP) for signature
If GW Hospital is a party to the CTA:

- GW Hospital requires separate approvals
- CTA cannot be routed for GW Hospital approval until legal language is final (or nearly final)
  - GW Hospital Chief Medical Officer (Bruno Petinaux): reviewing for Hospital compliance, review of protocol & financials
  - UHS Deputy General Counsel (George Brunner): reviewing finalized (or near-final) contract language
- Separate Hospital signature required
  - GW Hospital CEO (Kim Russo)
Review of Informed Consent Form (ICF)
- OCR Contracting Officer review limited to Subject Injury & HIPAA language (all other revisions to ICF are performed by study team)
  - Ensuring congruence of the finalized CTA subject injury language to the language in the ICF

Sign-off on IRB submission
- WIRB submission form (typically the IRB of record) can only be signed off on by OCR Contracting Officer upon OCR Contracting Officer’s review of the ICF
  - Review of ICF cannot begin until CTA legal language is finalized (or nearly final)
Fully executed CTA, Post-signature Activities (cont’d)

Final Internal Activities:
• Submit to GCAS for cost centers

• Financial Build in OnCore
  • Parameters
  • Events
  • Configure budget terms

• Once complete, study coordinators can review the calendar and financials for approval.