Children's National

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

Children's National

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

Children's National

Cost Reimbursable, Per Patient & Patient Care

Cost Reimbursable (apply IDC) (PID#1)						
	Year 1	Year 2	Year 3	Year 4	Year 5	
Directs:	$ 7,000	$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 27,000.00
IDC:	$ 5,495	$ 3,925	$ 3,925	$ 3,925	$ 3,925	$ 21,195.00
78.50%	$ 12,495	$ 8,925	$ 8,925	$ 8,925	$ 8,925	$ 48,195.00

Salary	Year 1	Year 2	Year 3	Year 4	Year 5	
PI (1% of Cap)	$ 1,896	$ 1,896	$ 1,896	$ 1,896	$ 1,896	$ 9,480
Fringe (17%)	$ 322	$ 322	$ 322	$ 322	$ 322	$ 1,610
Total - PI	$ 2,218	$ 2,218	$ 2,218	$ 2,218	$ 2,218	$ 11,090
Coordinator (5%)(includes 3% inflation -yrs 1-4)	$ 2,097	$ 2,160	$ 2,225	$ 2,292	$ 2,292	$ 11,066
Fringe (17%)	$ 356	$ 367	$ 378	$ 390	$ 390	$ 1,881
Total - Coordinator	$ 2,453	$ 2,527	$ 2,603	$ 2,682	$ 2,682	$ 12,947
Supplies	$ 2,329	$ 255	$ 179	$ 100	$ 100	$ 2,862
Total per Year	$ 7,000	$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 26,900

Per Patient Payment - $1700 per patient (No IDC) (PID#2)						
12 subjects per year @ $1700 per subject. Max 48 subjects	$ 20,400.00	$ 20,400.00	$ 20,400.00	$ 20,400.00	$ 20,400.00	$ 102,000.00

Breakdown of $1700

Enrollment, completed telephone encounter(medical CRF including	$	500.00
Completed neurodevelopmenatal Questionnaires (BRIEF, VSCS, SRS, Sensory	$	150.00
Completed parent well-being questionaires; $150 (line 77)	$	150.00
Gift Cards ($100) (line 78)	$	100.00

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

CPT			Pro Fee	Tech Fee	
70551	MRI, BRAIN WO CONTRAST (tech +pro)	$ 800.00	$237.00	$506.00	From Charge Master (dicount applied)
		$ 800.00			

How we bill for expenses

Children's National

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

Study Visits	Screening	Enrollment and Randomization	Baseline Visit	Visit 2	Visit 3	Final Visit
Informed Consent	X					
Medical History	X					
Physical Exam	X					
NIHSSS		X		X	X	X
Vital Signs		X		X	X	X
Laboratory assessment -Serum Chemistry /hematology	X					X
Study drug or device Administration			X			
Adverse events			X	X	X	X

PI & study team build schedule of events including the number of cycles required.

Children's National

Step 2: Determine Per-Subject Procedural Costs

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

***CNH Technical CDM* - As Of** **2/1/2024**

This file does not contain CDM information for supplies. If there are any questions about supplies please contact the CDM Team <CDM_Team

This file does not contain BID Numbers (CDM Numbers) as these are specific to department workflow - If there are any questions regarding B

FROM CDM Audit File/Cerner Bill Item Audit

CPT/HCPCS	CDM_DESCRIPTION	REVENUE_COD	PRICE
97760	ORTHOTIC MGMT AND TRAINING	420	$ 276.00
97761	PROSTHETIC TRAINING	420	$ 314.00
97763	ORTHC/PROSTC MGMT SBSQ ENC	420	$ 305.00
97802	MEDICAL NUTRITION INDIV IN	942	$ 109.00
97803	MED NUTRITION INDIV SUBSEQ	942	$ 114.00
97804	MEDICAL NUTRITION GROUP	942	$ 258.00
97810	ACUPUNCT W/O STIMUL 15 MIN	940	$ 170.00
97813	ACUPUNCT W/STIMUL 15 MIN	940	$ 170.00
98975	REM THER MNTR 1ST SETUP and EDU	761	$ 320.00
98976	REM THER MNTR DEV SPLY RESP	761	$ 101.00
98977	REM THER MNTR DV SPLY MSCSKL	761	$ 101.00
99001	MICRO COURIER FEE LOCAL	300	$ 491.00
99024	POSTOPERATIVE FOLLOW-UP VISIT, INCLUDED IN GLOBAL SERVICE	515	$ 170.00

Pro CDM | Tech CDM

CMS Ln #	CMS Ln Descr	Federal/ Non-Federal Proposed	Federal Discount
50	OPERATING ROOM	27.09%	72.91%
51	RECOVERY ROOM POST-ANESTHESIA CARE UNIT (PACU)	25.71%	74.29%
53	ANESTHESIOLOGY *(falls under CMS 50: Operating Room)*	27.09%	72.91%
54	RADIOLOGY-DIAGNOSTIC INTERVENTIONAL RADIOLOGY ULTRASOUND NUCLEAR MEDICINE PET SCAN X-RAY	15.30%	84.70%

Children's National

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

RESEARCH COORDINATOR/RESEARCH NURSE				
STUDY COMPLEXITY	**LOW**	**MEDIUM**	**HIGH**	**EXCEPTIONALLY HIGH**
	Hour increments			
Informed Consent	0.5	1	2	3
Inclusion/Exclusion Criteria	0.25	0.5	1	1.5
Screening Eligibility	0.25	0.5	1.5	1.5
Medical History/Demography	0.5	1	2	3
Vitals	0.25	0.25	0.25	0.25
AE Reporting	0.25	0.5	1	2
SAE Reporting	1	2	3	4

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

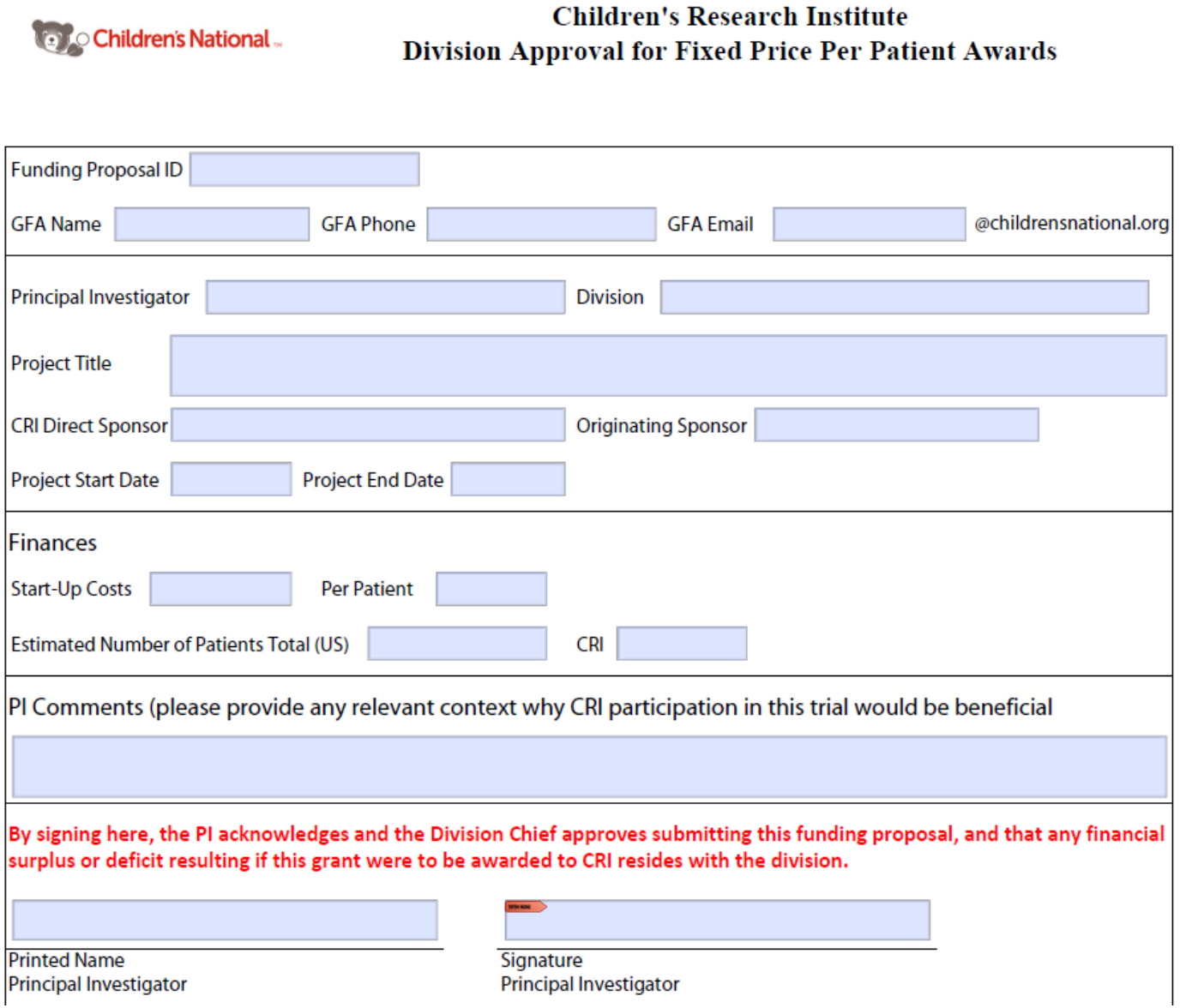
- Investigator meetings, training & travel
- Participant incentives
- Materials & supplies (printing costs, etc.)
- Data management
- Dissemination of findings

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.



Children's National

Children's Research Institute
Division Approval for Fixed Price Per Patient Awards

Funding Proposal ID

GFA Name | GFA Phone | GFA Email | @childrensnational.org

Principal Investigator | Division

Project Title

CRI Direct Sponsor | Originating Sponsor

Project Start Date | Project End Date

Finances

Start-Up Costs | Per Patient

Estimated Number of Patients Total (US) | CRI

PI Comments (please provide any relevant context why CRI participation in this trial would be beneficial

By signing here, the PI acknowledges and the Division Chief approves submitting this funding proposal, and that any financial surplus or deficit resulting if this grant were to be awarded to CRI resides with the division.

Printed Name
Principal Investigator

Signature
Principal Investigator

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.

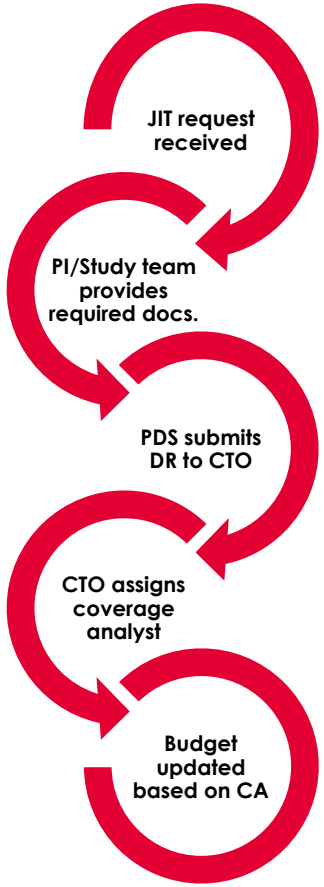
Why is it required?

- 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?



Children's National

Protocol Related Items and Services	Location in Protocol	CPT / HCPCS Codes	Q0 / Q1 Modifiers (as needed)	Visit Schedule								Coverage Determination Rationale	Communications:
					Post Enrollment								
				Screening (≤ 28 Days) [18]	Cycle 1				End of Treatment (Day 28 of final treatment cycle) (+/- 7 Days)	30-Day Post EoT Safety Follow-Up (+/- 14 Days) [26]	Long Term Follow-Up [11]		CTO Comments/Questions
					Day 1 [1]	Day 8 (+/- 3 Days)	Day 15 (+/- 3 Days)	Day 22 (+/- 3 Days)			Every 3 Months (+/- 1Mo)		
Should Dx Code Z00.6 / V70.7 (and Condition Code 30, where applicable) appear on the claim?				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/Phone	OP		
Informed consent	**p. 87**	NA	**NA**	**NB**								This is not a billable item or service.	
Eligibility criteria	**p. 45**	NA	**NA**	**NB**								This is not a billable item or service.	
Archival tumor tissue (FFPE or fresh frozen) [2]	**p. 59, 87**	NA	**NA**	**NB**								This is not a billable item or service. Sponsor paying costs to confirm tissue availability.	
Pathology tissue preparation fee [2]	**p. 59, 87**	NA	**NA**	**NB**								This is not a billable item or service.	Confirm with Sponsor if the $320 budget line item for "Shipping and process of sample collection-tumor tissue" applies to the archival tissue.
Optional tissue collection [9]	**p. 90**	NB	**NB**		**NB [9]**							This is not a billable item or service. Sponsor paying for optional tissue collection per budget.	
Procedural sedation (for biopsies, scans)	**p. 90**	99151 or 99155 (< 5 yo), 99152 or 99156 (5+yo), 99153 (each added 14 min, <5yo), 99157 (each added 14 min, 5+ yo)	**Q1**	**R/S**	**S**							Fresh tissue needed for screening if archival tissue is not available--sponsor 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/m^2, oral, once weekly	**p. 3**	NA	**NA**		**NB**	**NB**	**NB**	**NB**				Per protocol p. 48, "DAY101 for oral dosing is provided..." This is not a billable item or service.	
DAY 101 dispensing/return [16]	**p. 90**	NA	**NA**		**NB**	**NB**	**NB**	**NB**	**NB**			This is not a billable item or service.	
Drug diary review	**p. 49, 65, 91**	NA	**NA**		**NB**	**NB**	**NB**	**NB**	**NB**			This is not a billable item or service. Sponsor paying for diary collection and review per budget.	
Physical exam [20]	**p. 59, 60, 87**	99202-99205 (new pt), 99212-99215 (estab pt)	**Q1**	**B**	**B [20]**		**B [20]**		**B [20]**	**B [20]**		Although coverage to establish a baseline and monitor for side effects listed in the ICF is supported by NCD 310.1, the budget is paying for PE and VS.	
Neurology exam	**p. 59, 60, 87**	99202-99205 (new pt), 99241-99245 (consultation)	**Q1**	**R**	**R**		**R**		**R**	**R**		Per ICF p. 4, the neurologic exam is for research. Budget paying for neurologic exam.	Asked if PI or neuro would do exam

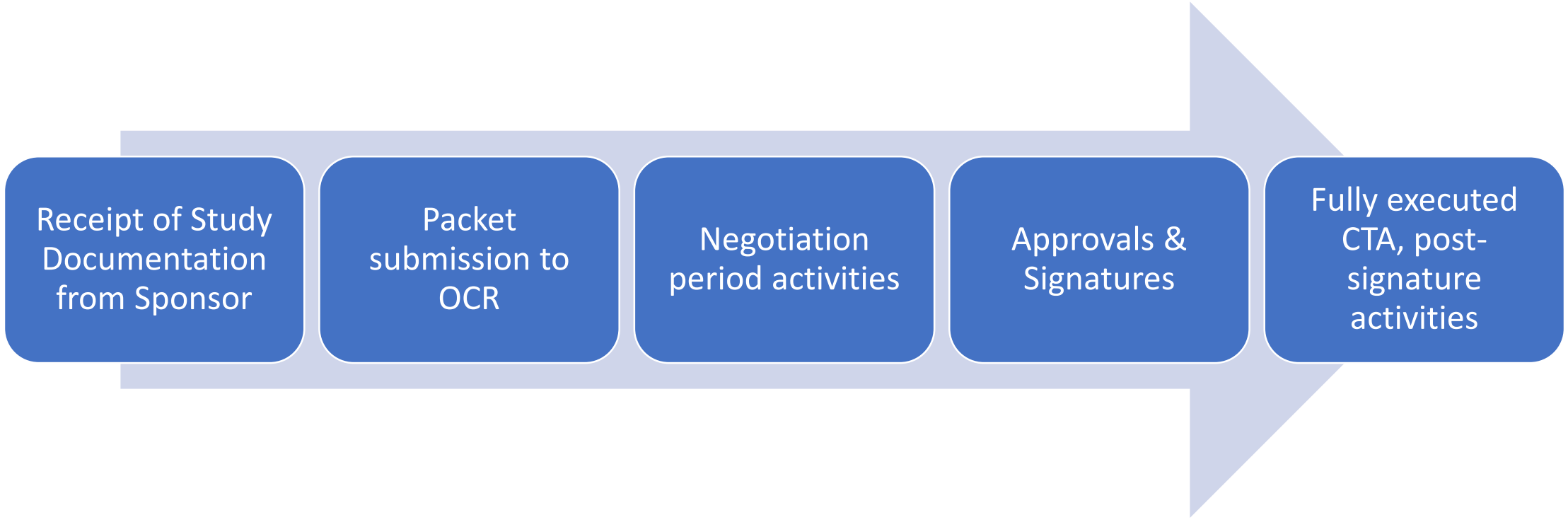
THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

BUDGETING FOR CLINICAL TRIALS & OCR ROLES

GW Office of Clinical Research

Eric Cannon, Sr. Contracting Officer
India Johnson, Sr. Finance Analyst

OCR Review Timeline



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

Definitions (cont'd)?

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-I'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!

Contract Negotiation (cont'd)

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).

Budget Negotiation (cont'd)

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

Approvals & Signatures (cont'd)

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)

Fully executed CTA, Post-signature Activities

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.