

# Clinical Trial Budgets

## Clinical Research Finance and Administration

*Presentation created by: Kyle Jernigan  
Clinical Research Financial Analyst*



# RESEARCH

## REVIEW 8

### PROJECT INFORMATION:

<b>PROJECT TYPE</b>	<b>PROPOSAL TYPE</b>	<b>AWARD TYPE</b>
<input type="checkbox"/> Instruction <input type="checkbox"/> Research <input type="checkbox"/> Scholarship/Fellowship <input type="checkbox"/> Service <input type="checkbox"/> Other	<input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Renewal <input type="checkbox"/> Resubmission <input type="checkbox"/> Supplement <input type="checkbox"/> Transfer	<input type="checkbox"/> Contract <input type="checkbox"/> Coop A <input type="checkbox"/> Grant <input type="checkbox"/> Subcont

Project Title: \_\_\_\_\_  
 Existing Grant/Award #: \_\_\_\_\_

<input type="checkbox"/>	Basic
<input type="checkbox"/>	<u>Clinical Research</u>
<input checked="" type="checkbox"/>	<u>Clinical Trial</u>
<input type="checkbox"/>	N/A

### UTHEALTH INFORMATION:

PI Name/Degree: \_\_\_\_\_  
 Academic Position: \_\_\_\_\_  
 Email: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
 UThhealth salaried appointment for PI?  Yes  No (if not, attach a memo from Chair/Dean/Director authorizing submission.)

**Other Covered Individuals** \*List all covered individuals (as defined [here](#)) responsible for the design, conduct or reporting of the research. All persons listed below must complete a [Research Conflict of Interest \(RCOI\)](#) certification form (page 4 of this R&A). Additional forms can be found [here](#).

Do you have personnel from other UT Health schools or departments?

Yes  No (If yes, obtain other school/departmental signature on [The R&A Form Signature Addendum](#))

Name	Role	% Effort	Department	Faculty
_____	_____	_____	_____	<input type="checkbox"/> <input type="checkbox"/>
_____	_____	_____	_____	<input type="checkbox"/> <input type="checkbox"/>
_____	_____	_____	_____	<input type="checkbox"/> <input type="checkbox"/>
_____	_____	_____	_____	<input type="checkbox"/> <input type="checkbox"/>

\*Additional Covered Individual sheets can found [here](#).

### Department Administrative and Financial Contacts

Contact Person: \_\_\_\_\_ Phone: \_\_\_\_\_  
 Alternate Person: \_\_\_\_\_ Phone: \_\_\_\_\_

### SPONSOR INFORMATION:

Sponsor/Agency: \_\_\_\_\_ Prime (Funding Agency if Subcontracting): \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Contact Name: \_\_\_\_\_ Phone: \_\_\_\_\_ Email: \_\_\_\_\_  
 Due Date: \_\_\_\_\_  Receipt  Postmark Sub Due Date: \_\_\_\_\_  
 Funding Opportunity Number (FOA)/Announcement: \_\_\_\_\_  
 Link to Guidelines: \_\_\_\_\_

Electronic Submission Required?  Yes  No  
 Has this proposal been awarded?  Yes  No  
 If yes, attach Notice of Grant Award.  Yes  No  
 After the fact proposal?  Yes  No  
 (Has this proposal already been submitted to the agency?)  
 FOA Limited Submission?  Yes  No  
 (If yes, then include [permission to submit from FVP/ABA](#))  
 Continuous Submission?  Yes  No

# What is a Clinical Trial?

**A research study<sup>1</sup> in which one or more human subjects<sup>2</sup> are prospectively assigned<sup>3</sup> to one or more interventions<sup>4</sup> (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes<sup>5</sup>.**

<sup>1</sup> See Common Rule definition of “research” at [45 CFR 46.102\(d\)](#).

<sup>2</sup> See Common Rule definition of “human subject” at [45 CFR 46.102\(f\)](#).

<sup>3</sup> The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

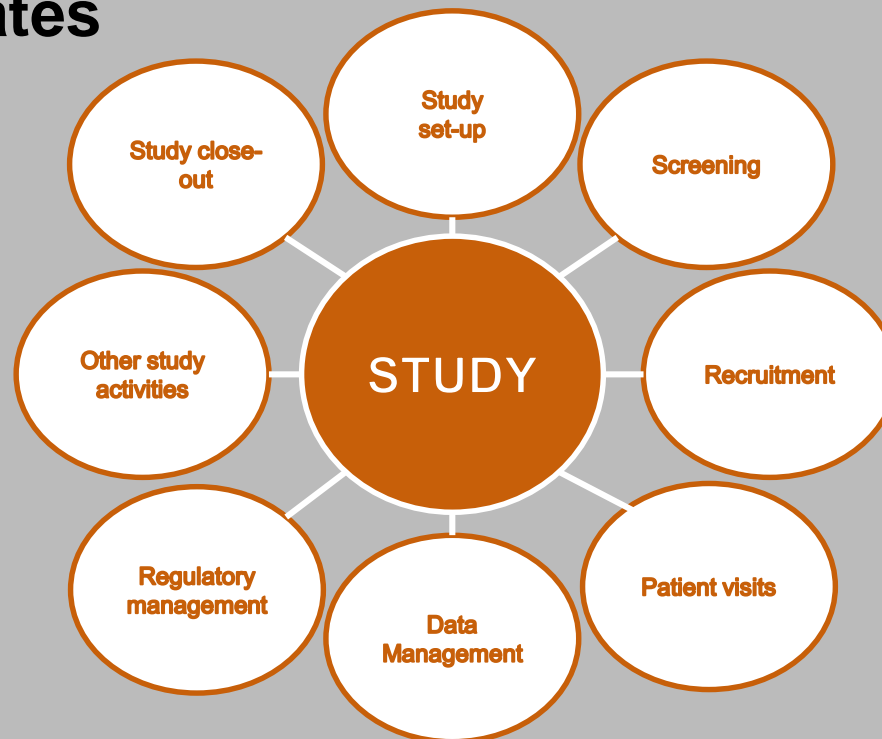
<sup>4</sup> An “intervention” is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

<sup>5</sup> A “health-related biomedical or behavioral outcome” is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

From: *Notice of Revised NIH Definition of “Clinical Trial”*, NOT-OD-15-015, October 23, 2014

# What is a Budget?

- ❖ **Telling the research story with dollars**
- ❖ **Monetary amount of committed research activities**



# What are the Objectives of a Budget?

- ❖ Identify and document *all research and routine care costs*
- ❖ Identify and document the *financial responsibility for all costs*
- ❖ **Recover all costs:** pre-study, project management, post-study

## Coverage Analysis

A systematic review of all study procedures to determine which ones are billable and who should be billed, i.e., Medicare/ insurance or the sponsor.

# What are Routine Costs?

CMS Manual System, Pub 100-03 Medicare National Coverage Determinations, September 7, 2007

- ❖ **Items or services that are typically provided absent a clinical trial**
- ❖ **Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications**
- ❖ **Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – NCD310.1**

# What are *Not* Routine Costs?

CMS Manual System, Pub 100-03 Medicare National Coverage Determinations, September 7, 2007

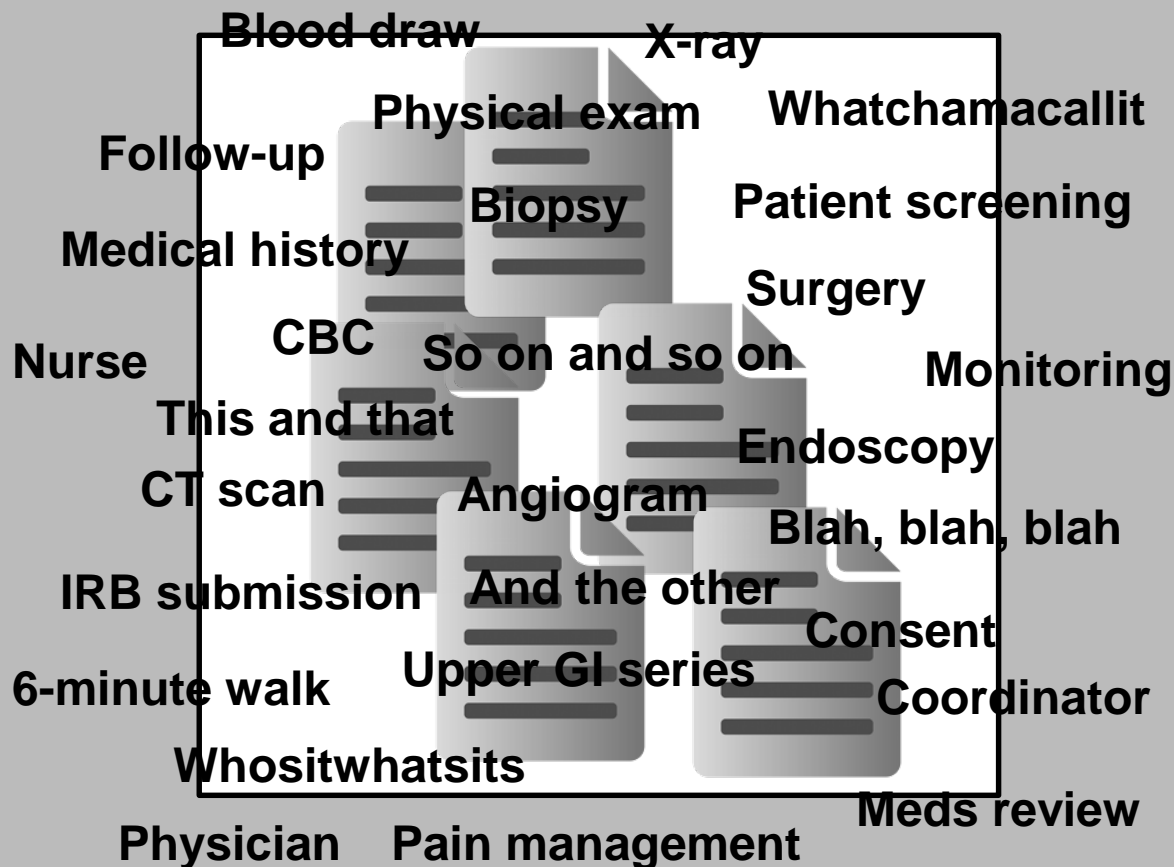
- ❖ **The investigational item or service itself, unless otherwise covered outside of the clinical trial**
- ❖ **Items or services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)**
- ❖ **Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial**

# What is the Budget Process?

- ❖ **Obtain study documents:** protocol, schedule of events, sponsor budget, consent form, anything else
- ❖ **Read**
- ❖ **Identify and list *all* study activities**
- ❖ **Ask questions:** PI, Research Nurse/Coordinator, Sponsor
- ❖ **Re-read**
- ❖ **Document**
- ❖ **Ask more questions**



# WHAT ARE YOU LOOKING FOR?



# Start-Up Costs

- ❖ Up-front costs needed to get the study started
  - ❖ Incurred whether or not a patient is enrolled
  - ❖ Paid upon execution of clinical trial agreement
  - ❖ Non-refundable
  - ❖ No monetary limit
  - ❖ Include F&A – ***30% non-negotiable!***
- |                                    |                                |
|------------------------------------|--------------------------------|
| ✓ IRB fee                          | ✓ Site initiation visit        |
| ✓ Stipends for initial enrollees   | ✓ Site training (time!)        |
| ✓ Protocol submission preparation  | ✓ Recruitment activities       |
| ✓ Consent development/translation  | ✓ Administrative fee (time!)   |
| ✓ Regulatory binder set-up (time!) | ✓ Anything else to get started |

# Invoiceable Costs

- ❖ Discrete items/events not assigned to each patient
  - ❖ May or may not be incurred
  - ❖ Frequency/quantity may vary
  - ❖ Invoiced and paid *after* they are incurred
  - ❖ Include F&A – **30% non-negotiable!**
- |  |                                 |
|--|---------------------------------|
| ✓ IRB annual review fees   | ✓ Monitoring visits (time!)     |
| ✓ IRB amendments   | ✓ Screen failures               |
| ✓ Other IRB submissions: SAEs, safety reports, patient materials | ✓ Unscheduled visits            |
| ✓ Patient stipends/travel  | ✓ Study close-out costs         |
| ✓ Consent changes/translation                                    | ✓ Record retention costs        |
| ✓ Freezer storage fees/dry ice                                   | ✓ Anything else that may happen |

# Expense-Based Costs

- ❖ Research and routine care costs
- ❖ UTP professional fees
- ❖ Match the protocol/schedule of events
- ❖ Account for price increases
- ❖ Include F&A – **30% non-negotiable!**
  - ✓ CBC
  - ✓ X-ray
  - ✓ Angiogram
  - ✓ Upper GI series
  - ✓ Biopsy
  - ✓ Surgery
  - ✓ Ultrasound
  - ✓ CT scan
  - ✓ PFT
  - ✓ 6-minute walk test

# Effort-Based Costs

- ❖ Time!
- ❖ PI, Nurse, Coordinator, Regulatory Specialist
- ❖ How much does it *really* cost to do the study?
  - ✓ Recruitment
  - ✓ Chart set-up
  - ✓ Patient screening
  - ✓ Informed consent
  - ✓ Medical history/meds review
  - ✓ Lab shipping/handling
  - ✓ Patient communication
  - ✓ Stipend/travel paperwork
  - ✓ CRF completion
  - ✓ Query resolution
  - ✓ Anything else that takes time
- ❖ Include as % effort or built into per patient costs
- ❖ Account for salary increases over course of study
- ❖ Include F&A – **30% non-negotiable!**

# Final Considerations

- ❖ Know your bottom line
- ❖ It's a negotiation
- ❖ Sponsors want sites that can produce...know what your site has to offer
- ❖ *You* should drive the budget process, not the sponsor
- ❖ Sponsors *should* pay for all work related to their study
- ❖ Sponsors will pay fair market value in your region... know and justify your costs
- ❖ Communication is key
- ❖ Own the process
- ❖ Review the contract
- ❖ Reconcile, reconcile, reconcile



# Questions?

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