Clinical Trial Budgets

Clinical Research Finance and Administration

Presentation created by: Kyle Jernigan
Clinical Research Financial Analysist

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RESEARCH

REVIEW 8

- [ ] Basic
- [ ] Clinical Research
- [x] Clinical Trial
- [ ] N/A

PROJECT INFORMATION:

PROJECT TYPE
- [ ] Instruction
- [ ] Research
- [ ] Scholarship/Fellowship
- [ ] Service
- [ ] Other

PROPOSAL TYPE
- [ ] New
- [ ] Continuation
- [ ] Renewal
- [ ] Resubmission
- [ ] Supplement
- [ ] Transfer

AWARD TYP
- [ ] Contrac
- [ ] Coop A
- [ ] Grant
- [ ] Subcon

Project Title: _____

Existing Grant/ Award # _____

UTHEALTH INFORMATION:

PI Name/Degree _____

Academic Position _____

Email _____ Phone Number _____

UTHealth 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 signatures on The R&A Form Signature Addendum.)

Name	Role	% Effort	Department	Faculty
				[ ]
				[ ]
				[ ]
				[ ]

*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.

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 EVP/ABA)

Continuous Submission? [ ] Yes [ ] No

What is a Clinical Trial?

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

[1] See Common Rule definition of "research" at 45 CFR 46.102(d).

[2] See Common Rule definition of "human subject" at 45 CFR 46.102(f).

[3] 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.

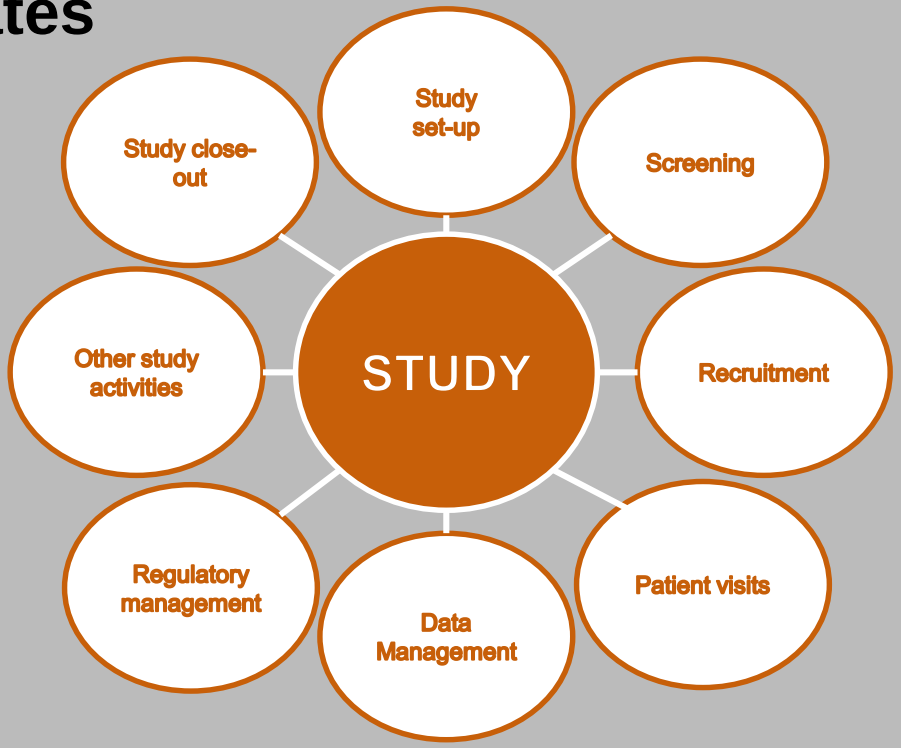
[4] An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); 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.

[5] 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 activates



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?

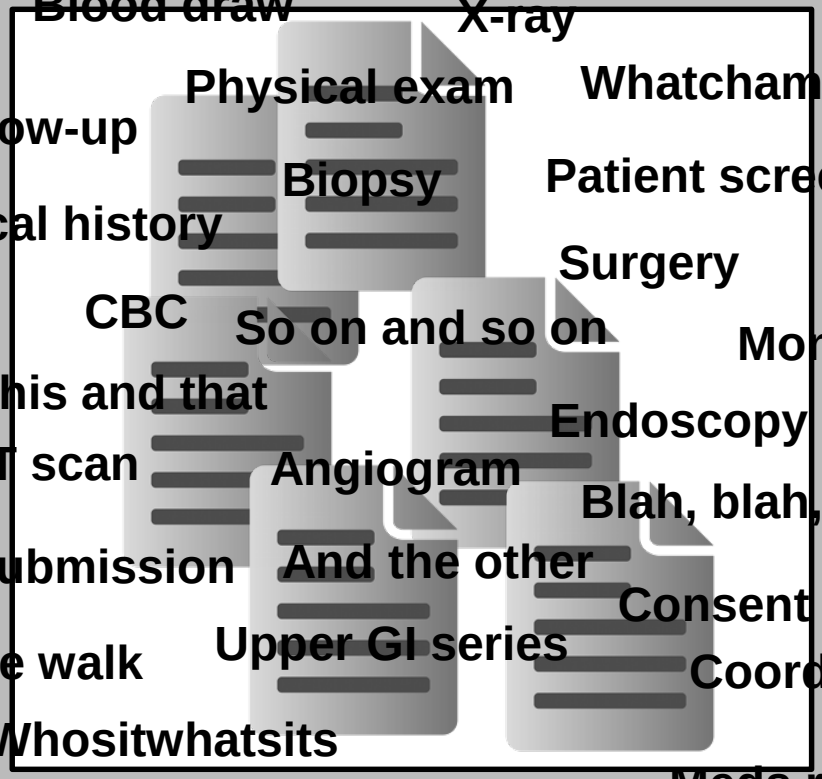
CMS Manual System, Pub 100-03 Medicare National Coverage Determinations, September 7, 2007

- 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?



Blood draw
X-ray
Physical exam
Whatchamacallit
Follow-up
Biopsy
Patient screening
Medical history
Surgery
CBC
So on and so on
Nurse
Monitoring
This and that
Endoscopy
CT scan
Angiogram
Blah, blah, blah
IRB submission
And the other
Consent
Upper GI series
6-minute walk
Coordinator
Whositwhatsits
Meds review
Physician
Pain management

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
- ✓ Stipends for initial enrollees
- ✓ Protocol submission preparation
- ✓ Consent development/translation
- ✓ Regulatory binder set-up (time!)
- ✓ Site initiation visit
- ✓ Site training (time!)
- ✓ Recruitment activities
- ✓ Administrative fee (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
- ✓ IRB amendments
- ✓ Other IRB submissions: SAEs, safety reports, patient materials
- ✓ Patient stipends/travel
- ✓ Consent changes/translation
- ✓ Freezer storage fees/dry ice
- ✓ Monitoring visits (time!)
- ✓ Screen failures
- ✓ Unscheduled visits
- ✓ Study close-out costs
- ✓ Record retention costs
- ✓ 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?

CRF@uth.tmc.edu

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