

Developing Budgets for Research Projects Session Focus: Clinical Trials

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MEDICINE *of* THE HIGHEST ORDER



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Today's Topics

- **Core components for an internal (UR) clinical research trial (CRT) budget** – *What costs need to be included ?*
- **Resources available for determining cost** – *How do I figure out the costs for study items?*
- **Elements of the UR Budgeting workbook** – *How does the Sponsor/NIH budget get translated into ORPA workbook – or vice versa?*

Types of Clinical Trials

Funding Source

- NIH, FDA or other federal funding
 - Student/Fellow/Faculty Investigator
- Industry Sponsored
 - Pharma (drugs)
 - Medical device company
- Unfunded: Student/Fellow/Faculty

TIP:

Federally funded studies have special pricing and overhead. Let your Vendors/Fee for Service providers know as you explore pricing and request quotes.

New Study Process, Budget Prep

Content

- Clinical Research Trial (CRT) = intervention
 - ✓ *ORPA Budgeting workbook needs to be completed and sent to Mike Ritz for review if study involves:*

AT LEAST ONE TEST/PROCEDURE That Has A BILLABLE CODE.

- *Studies with only questionnaires or chart review are EXEMPT from ORPA Workbook requirement.*

Steps in New Study Process

1. Initial Contact
2. Feasibility Assessment "Lite"
3. Obtain/Return Confidential Disclosure Agreement (CDA)
 - a) Send to your Materials Transfer Administrator at ORPA (<http://www.rochester.edu/ORPA/>), along with a CDA checklist (on ORPA page under "FORMS" – "CDA/Confidential Disclosure/NDA Checklist")
 - b) ORPA returns CDA to sponsor – you get Protocol
4. Obtain Protocol and Sponsor Budget

Steps in New Study Process, cont.

5. Obtain CRT Protocol and budget and share with Dept. Research Administrator (RA).

Do I have an administrator?

6. Prepare your Budget & UR Budget Workbook <http://www.rochester.edu/ORPA/>

- Workbook Template:
<https://orpa.ur.rochester.edu//CTP/default.aspx> – choose ‘Shared documents’, ‘Budgeting forms, Practice Aids, Templates’

Establishing a Budget

The Three P's:

- ***Place (Where?)***
- ***Procedures (What?)***
- ***People (Who?)***

Answers are Protocol driven

Establishing a Budget

P1 = PLACE

Where will Study Activities take place?

- Where will subject be seen/treated?
- Who do I need permission from to use it?
- How much will it cost to use that space?

Establishing a Budget

P1 = Place

1. Out-Patient Study Costs:

- a) Dept clinic at Strong, Strong Ambulatory Care Facility (ACF) or off-site - *CRT use fee? Per visit ?*

- a) Home/School/Hospice/Workplace Visits

- b) Standard of care visit coupled with study task?
 - i. Split out study vs. SOC (Std of Care)

Establishing a Budget

P1 = Other location-related costs

- Transportation costs/parking (SC, Subject, Family)
- Subject and Caregiver stipends
- Meals/Snacks included?
- Overnight stays for early, late visits?
- Follow-up visits if patient is discharged before study visits completed – *how will those be different?*
- Cost to recruit/conduct in the community?

Establishing a Budget

P1: Transportation Cost Resources

- Fed gov't(IRS) reimbursement for medical mileage: <https://currentmileagerate.com/>
- RTS pass/card: <https://www.myrts.com/Buy-Passes>
- Taxi: Marketplace Transportation: email Tina Anderson at mktpltrans@gmail.com and arrange a flat fee per study subject; they will pick up and drop off at pre-specified times
- UR Garage Parking pass: 312 Requisition to UR Parking office; single or bulk (e.g., 30 at a time)

Establishing a Budget

P1= PLACE

2. In-patient study

- Clinical Research Center – *Ann Miller, RN, CCRC*
contact at (585) 275-2907 or
- www.urmc.rochester.edu/clinical-translational-science-institute/resources/clinical-research-center
- Emergency Department - [EMResearch](http://www.urmc.rochester.edu/emergency-medicine/research.aspx)
<https://www.urmc.rochester.edu/emergency-medicine/research.aspx>
- Neonatal ICU – Dr. Timothy Stevens, Medical Director
- Peds ICU (PICU) – Dr. Louis (Gene) Daugherty, Director;
Tanisha Lewis, Nurse Manager
- Neuro ICU – Dr. Debra Roberts, Acting Director;
Jamie Fodness, Nurse Manager

Establishing a Budget

P1= PLACE

- Other Nursing Unit(s) – *Medical Director or Nurse Manager, or Dr. Mary G. Carey, Director of Nursing Research, SON*

TIP:

Contact Dr. Mary G. Carey anytime you are considering a study on an in-patient unit.

Dr. Carey needs to be included in the feasibility assessment with regard to nursing staff involvement.

(See global, or contact her Administrator, Brandon Qualls, to set up a meeting.)

Establishing a Budget

P2 = Procedures (What)

Protocol Driven: What is being done?

Go through Visit Task chart: typical costs include:

Drug(s)	Physical exam	EKGs
Device	Assessments	Biopsy
Labs	Questionnaires	Imaging
X-ray	Lumbar Puncture	PK samples

Establishing a Budget

P2 = Investigational Product (IP)

- ❑ Contact the Investigational Drug Service (IDS):
 - Send Protocol, Investigational Brochure & Pharmacy Manual to Steve Bean (& cc: Carol Cole) via email ASAP
 - Request a study-specific quote, includes:
 - Start-Up fee: \$1,800
 - Per delivery fee: \$75 per subject/Pyxis delivery
 - Annual maintenance fee: \$1,500
 - Close out fee: \$1000

TIP: IP order might also require a build in eRecord, so give IDS time for that to be done

Establishing a Budget

P2=Drug Study: IP costs

Other questions to ask re: IP costs:

- How is IP delivered? Part of a study visit? Shipped to/from subject? *Include pre-paid shippers*
- Is 'Local' storage a cost? (E.g., *Drug Cabinet needed in CRC for rescue med/controlled substance. Built into budget and paid for by sponsor.*)
- Pyxis or local storage: temperature logs required by sponsor/FDA? *Include a portable temperature data logger in budget.*
- Cost to return used containers or unused meds?

Establishing a Budget

P2 = Procedures

Device study: Special Requirements Upfront

- 1) Device must have a Category B designation from FDA,
- 2) CMS approval obtained for the device/device study for billing purposes, and
- 3) Pre-approval already obtained from any commercial insurers. This is explained in the ORPA SOP on devices:
<http://www.rochester.edu/ORPA/>

Other Considerations:

- Is Sponsor providing device?
- Updates/battery changes/removal costs?
- Shipping or repair costs?
- Surgical implant or other special fee for service needed? *Sort out SOC vs. Study costs*

Establishing a Budget

P2 = Procedures

Labs/specimens – blood, urine, sputum (etc.) samples:

Central or Local?

- Central – ICON, ACM, Quest – sponsor sets up
- Local/Central – URMCLabs : [URMC Central Lab Services](https://www.urmc.rochester.edu/pathology-labs/clinical.aspx) provides clinical laboratory assays and support for researcher studies.
(<https://www.urmc.rochester.edu/pathology-labs/clinical.aspx>) – study specific test request, separate out Study vs SOC tests
- Will URMCLabs also draw blood?
- Will subjects go to a satellite lab site?

Material and information from 2016 SCORE seminar on URMCLabs at [URMC Labs handouts and displayed materials](#) – forms for ordering lab tests; other useful links

Establishing a Budget

Lab Costs: other considerations

- Supplies provided or not? *Contact URMCLab Services if URMCLab is doing phlebotomy; if not, order from central stores or Medline: <http://www.medline.com/home.jsp>*
- Processing: equipment considerations:
Centrifuge? Refrigerated or Rm Temp? Dry ice for shipping? Freezer storage? -20, -70 or -80?
 - *See Cold Storage Slide below*
- SCORE Resources:
 - ResearchHelp@URMC.Rochester.edu
 - SCORE Chat distribution list (*Sign-Up today!*)

Establishing a Budget

Lab Costs: other considerations

- Point of Care (POC) Testing: Lab tests done on site with rapid results.
 - [click here](#) for information on POCT on the URMIC intranet .
Contact number: 275-0229.

- Processing of biological samples, biopsies, nucleic acid testing?
 - Obtain outside lab quote or URMIC Clinical Trials Processing Lab (URMIC-CPTL) - cost per subject or per test; cost to ship; what is NOT SOC is added to budget

 - Christopher Lane, Laboratory Director
Phone: (585) 276-5574
christopher_lane@urmc.rochester.edu

Introduction

The University of Rochester Clinical Trials Processing Laboratory is a fee-for-service resource that supports clinical trials and basic science research. The laboratory is located in the Division of Infectious Diseases in the Department of Medicine, but can assist with any clinical trial conducted at the URM. The laboratory provides technical services including processing of blood and tissue samples for PI-initiated, pharmaceutical and NIH-funded clinical trials, as well as shipment of specimens according to study protocols. The laboratory follows Good Clinical Laboratory Practices (GCLP), and is externally monitored for GCLP compliance. The laboratory is staffed by 4 full-time trained technicians and part-time support staff.

Facilities

- (5) Biological safety cabinet /centrifuge work stations (BSL-2/BSL-2+)
- (6) -80°C storage freezers
- (4) Liquid nitrogen storage tanks
(total capacity > 60,000 vials)
- The hours of operation are from 8:30 am to 9:00 pm, Monday-Friday.
- Access to tube station
- Automated cell counters

Processing

Laboratory staff are proficient in preparing a variety of specimen derivatives such as:

- Blood:
 - Peripheral blood mononuclear cells (PBMC)
 - Serum Plasma
- Compartmental Specimens:
 - Nasal (swabs, wicks)
 - Saliva
 - Semen
 - Urine
 - Rectal
 - Cervical (lavages, brushes)
 - Cerebral spinal fluid
- Tissue biopsies
 - Lymph nodes
 - Cervical
 - Liver
 - Endometrial
- Nucleic Acids: DNA extraction from blood or tissue

LDMS Database

All primary specimens and processed aliquots are entered into the Laboratory Data Management System (LDMS) for the purpose of

- Inventory control
- Barcode labeling
- Shipping manifest

Shipping

- IATA trained: All staff members are certified by the International Air Transportation Authority to ship diagnostic specimens.
- The lab is proficient in shipping domestically and internationally.
- The lab is experienced with most national testing labs, such as Covance, Quest, Esoterix, Labcorp, and PPD.
- The lab is experienced in shipping with ice packs, dry ice, or with nitrogen vapor phase dry shippers.
- We can ship using any carrier.

Laboratory Contacts

- Christopher Lane
Laboratory Director
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christopher_lane@urmc.rochester.edu

Laboratory Technologists

Diane Vosefski, Dan Krysinski, Cassandra Newkirk, Terry Shepard

Cold Storage Core: A University Resource for Investigators

Christopher Lane

Infectious Disease Division. University of Rochester School of Medicine and Dentistry. Rochester, NY

The Cold Storage Core (CSC) Facility is an alarmed and environmentally controlled area that provides a secure on-site environment for long-term storage of research materials at the main medical center campus. UR facilities also maintains four spare -80°C freezers in the CSC for emergency use by UR investigators.

Space for ~50 freezer units

❖ Key Card Entry Control

Preventive maintenance is performed on all units by University Facilities twice per year including:

1. Check alarm set points (high & low)
2. Check alarm operation with facilities customer support center (requires alarm point installation)
3. Check backup battery
4. Test temperature LED & chart recorder; calibrate if necessary
5. Inspect all gaskets and hinges
6. Check indicator lights for proper operation
7. Clean condenser
8. Check running load amps on 1st & 2nd stages
9. Inspect insulation
10. Check system for irregular noises
11. Check system for obvious leaks
12. Check thermistor temperatures 1-5
13. Check heat exchanger temperature

- A report of PM completion including unit status and maintenance recommendations will be sent to each user.

❖ 24 hour emergency alarm notification (requires alarm point installation). Alarm point tests are performed once per year on all units.

❖ Spare freezers are available to all URMCI investigators.

❖ Fees: PI-Owned Long Term Resident Users: ~\$55.00 per month
Emergency Spare Freezers: \$50 per week prorated by time
and by fractional volume of freezer space utilized

❖ Adding new freezers to the Core will occur on a first-come-first-serve basis

❖ Space is Currently Available

CONTACT:

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CSC Core Director

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Establishing a Budget

TIP: URM C Lab Documentation

- ✓ Lab Directors' CVs; CLIA, CAP certificates for all the lab sites, at:
<https://www.urmc.rochester.edu/pathology-labs/clinical/permits-certifications.aspx>
- ✓ Lab value Ranges: Documentation at:
https://www.testmenu.com/rochester?redir=www.stronghealth.com/services/pathologylabmed/tests_earch.cfm. You can locate the standard reference ranges in the right hand side column

Establishing a Budget

P2 = Visit Procedures

- What equipment is required?

Is it available and free as part of P1 or not?

E.g., Is portable ECG machine in clinic, or will you need to contract for it?

- What if a test is required that is standard elsewhere but not here?

Will sponsor supply the item, or do you need to find item, order and add cost to budget? (*E.g., nasal speculum*)

- What if it's a 'specialty' procedure? You have to involve other departments to conduct

Establishing a Budget

P2 = Imaging Procedures

- **MR/MRI, CT/CAT scans, Ultrasound, GI procedures, X-rays:**
 - ❖ The UR Department of Imaging Sciences: [Learn more about starting a clinical trial.](#)
 - ❖ JoAnne M. McNamara, RN, ANP, BC
JoAnne_McNamara@URMC.Rochester.edu
- **Specialty MRI: Rochester Brain Imaging (RCBI)**
 - ❖ Contact – Judy Ripton
jripton@rcbi.rochester.edu

Establishing a Budget

P2 = Other Medical Procedures

- Electrocardiogram (ECG/EKG)
 - ❖ Heart Station: Christine Izzo for logistics set up; Abbie Chizuk for billing set up; per EKG fee
- Electroencephalogram (EEGs):
 - ❖ Epilepsy Center – Steve Erickson, 5-8856
- Other Special Raters: cardiology, neuro, ophthalmology:
<https://sites.mc.rochester.edu/departments-intranet-sites>
- Assessments, Questionnaires
 - *Cost to obtain or get permission to use?*
 - *Is there a cost associated with training?*

Establishing a Budget

P3 = People = Time and Effort

Life-cycle of a CRT:

- Study start-up efforts
- Conducting Study Procedures
- Documentation
- Study Visit Follow-Up
- Close-Out



Establishing a Budget

P3 = People Costs ***Study Start Up Costs***

Preparation of regulatory documents/send to Sponsor

- 1572, CV's, licenses, HSPP/GCP Certificates
- Obtaining Approvals: RSRB/WIRB submission
- Pre-Site Selection, Site Initiation, Investigator Meetings
- Study team training & document preparation
- Any other special training needed? (e.g., IATA; study-specific assessments; phlebotomy)
- Electronic Data Capture & IVR/IWR training
- Budget preparation and negotiations/ORPA workbook

Establishing a Budget

P3 = People Costs

Study Start-Up Costs = SC (& PI) Time

- Contacting and meeting with stake-holders, services, internal and external
 - Investigational Drug Service (IDS): meeting with Steve Bean and Carol Cole
 - Medical Directors and Nurse Managers; Clinical Research Center (CRC), “P1” contact folks
 - Conversations and forms to get labs, imaging, etc. set-up
 - **TRAINING STUDY TEAM** – creating documents, setting up meetings, doing training

Establishing a Budget

P3 = People Costs

Ask for Study Start-Up Costs

- Estimate time & effort required to progress from Initial Contact to Site Initiation Visit (or Enrollment?)
- Time & Effort not otherwise captured in study budget
- Depending on complexity of the study, a one time non-refundable start-up cost may range from \$3,000 to \$10,000 may be reasonable.

Establishing a Budget

P3 = People Costs

Conducting Study Procedures

Typically underpaid for:

- Medical History – *How far back; Do you need to request records?*
- Inclusion/Exclusion Eligibility Requirements – *How many? How complicated to assess?*
- Informed Consent
 - *Simple or Complex study?*
 - *Setting: Outpatient clinic; ED or ICU*
 - *Patient, Parent or LAR?*

Sponsor may give you a dollar amount for these and other 'standard tasks'. Is it fair, accurate for time spent?

Establishing a Budget

P3 = People = Time & Effort

Conducting Study Procedures

- Protocol Driven – look to study task chart, per visit
- Lab tests: central or local – *who is doing sample collection; processing; order or pick-up dry ice; packing and shipping? Calculate SC, nurse or other investigator's effort per visit; transferring results to EDC*
- Vitals; physical/neurologic/dermatologic/eye exams; EKGs; biopsies; any special set up? *Who is allowed to conduct? PI/Sub-I/SC? How much time for ALL steps involved?*
- Special raters: cardiology, neuro, ophthalmology:

<https://sites.mc.rochester.edu/departments-intranet-sites>

Establishing a Budget

P3 = People Costs

Time and Effort *related* to P2 (Procedures):

- Drug: inventory control; ordering; pick-up/drop-off by IDS; infusion time; pill counts; IP accountability; train subject on compliance, re-train subject on compliance
- Imaging: SC time to schedule, walk-over, wait, document
- Time to train subject on and to review: Assessments; Questionnaires; Surveys; Diaries
- Travel time to visit site from your usual location

TIP: Go back over P2 items (procedures) and calculate REALISTIC time/effort per item, add to cost

Establishing a Budget

***P3 = People Costs - get the right rate
WHO?? For How Long??***

Time to complete Study visits:

Who does what & how long does it take?

- PI/Sub-I's
- Project/Study Coordinator
- Nursing – level of support?
- Patient (or other type) Technical help
- Overtime included for after hours, holiday or weekends?

TIP: Overtime for study team allowed IF sponsor pays, so include in budget, time + overhead

Establishing a Budget

P3 = People Costs

Study Visit Documentation & Follow-Up

- Creating/updating/completing source
- ECD/eCRF inputting
- Answering Queries
- AE and SAE process and follow-up
- Safety Report Documentation
- Monitor Visits – preparing and conducting
- Updating regulatory docs and IRB approvals

Establishing a Budget

P3 = People Costs & 'Other'

- Overhead: 30% for industry-sponsored
- For multiyear studies, include an inflationary percentage (3%)
- Biostatistician - *Brian Griebner 5-2407 or Susan Messing 5-0343 for consulting service, hourly billing*
- Cost of Advertising, Recruiting materials, paper, postage, other??

Translating the Budget into a UR Workbook

Using the simple study synopsis and task chart we have created, Beth will show how these costs go into a workbook and provide guidance on 'Participant grid' vs. Non-Participant grid; keeping SOC out of the study costs



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