Budget Development Guidance

There are many costs to consider when developing a budget for clinical research. The goal of budget development is to receive full reimbursement of costs associated with conducting a clinical research study. The information below includes some standard items to consider when developing a budget.

This is a guidance document. The examples given do not apply to every clinical research project, nor is the list entirely comprehensive. There may be other costs to be considered on a study-by-study basis.

Do's and Don'ts of Budget Development:

- **DO** create a project specific detailed budget that includes all protocol procedures and associated costs
- **DO** read the contract language related to budget and payment terms carefully
- **DON'T** give final approval of the budget without reviewing the final protocol
- **DON'T** execute an agreement until you have created a final budget and are confident that you have identified ALL study costs

Budget Types:

The steps involved in budget development may differ based on sponsor;

- Industry-sponsored study
- Investigator Initiated Trial (IIT)
- Federally sponsored study

The steps described are geared toward the process of developing and negotiating a budget with an industry sponsor, as negotiating with this sponsor type is often considered more comprehensive.

When developing a budget, consider the following steps:

Budget Development - Step 1: Identifying Costs and Determining Budget Feasibility

Budget Development - Step 2: Budget Negotiation

Budget Development - Step 3: Budget management after start-up

Other UW websites that may be of interest:

- UW SMPH Intranet - for Researchers - https://intranet.med.wisc.edu/
- Research and Sponsored Programs (RSP): Home Page: https://www.rsp.wisc.edu/
  - F & A and Fringe Benefit Rates: https://www.rsp.wisc.edu/rates/index.html
  - Budget Tools: https://www.rsp.wisc.edu/forms/budgettools.html
  - WISconsin Proposal & Electronic Routing (WISPER) System; https://www.rsp.wisc.edu/WISPER/index.html
  - Proposal Preparation & Submission: https://www.rsp.wisc.edu/proposalprep/

Step 1: Identifying Costs and Determining Budget Feasibility

The topics listed below can serve as guidance and questions to ask yourself when identifying the costs of a clinical research study.

1. Determine what you can do independently with research staff and which supplies or services must be purchased.

If services will be purchased, determine where the procedures will be performed (location) and the cost,

- Pharmaceutical Research Center (PRC)
- UWHC Clinical Core Lab or 3P Lab
- Clinical Research Unit (CRU)
- Wisconsin Institutes for Medical Research (WIMR) (Research Radiology)
- Other clinical departments (e.g. cardiology, physical therapy, etc.)
- The retail and research costs for a given procedure are determined by identifying the location (Cost Center) where the procedure will be performed or conducted using OnCore.
- Don't hesitate to reach out to the contact people with the various contacts involved in the [OnCore] Ancillary Service Review with questions.

If services performed by your staff, identify the value of the procedure using the University of Wisconsin Hospital and Clinics (UWHC)/University of Wisconsin Medical Foundation (UWMF) retail rate

- UWHC/UWMF retail rates are identified when developing a budget in OnCore .
- If not available, calculate costs of procedure based on staff time for preparation, conduct and evaluation, purchase of supplies and maintenance cost

ECG Example:

- Will ECG equipment be provided or will new equipment need to be purchased?
- Are there additional ECG supplies needed, such as leads, linens, gowns, etc.?
- What will be the cost of routine equipment maintenance, ongoing calibration, etc.?
- What is the estimated cost of staff training and ongoing staff effort to perform the ECG?
    - What is the cost of the use of the space/room where the ECG will be performed?

2. Include all procedures, (e.g. informed consent, medical history, vital sign measurement, lab processing, medication dispensing/accountability, etc.) identified as part of the protocol that will be performed or conducted as part of the study.

In the event that you are unable to find the procedure that you are looking for in the ICTR OnCore Charge Master, contact the support team (email: ICTROnCore@ictr.wisc.edu).

You may be asked to identify 3-4 patients that have had the procedure you are looking to identify all of the necessary items or components of the procedure in question.

3. Select the appropriate Research Rate or Rate Tier

All three UWHealth partners; University of Wisconsin Hospital and Clinics (UWHC), University of Wisconsin Medical Foundation (UWMF), and the UW-Madison School of Medicine and Public Health (SMPH) share a common mission:

Advancing health without compromise through:

- Service
- Scholarship
- Science
- Social Responsibility

To show its support of research, UWHealth offers discounted research rates for all types of sponsored research. Some funding sources receive a greater research discount than others.

- **Retail Rate:** this rate is the UWHealth Fair Market Value of the procedure to be performed. Retail rates may differ slightly based on the location (Cost Center) where the procedure is being conducted or performed.
    - On April 18, 2003, the Office of Inspector General (OIG) in the US Department of Health and Human Services has issued a regulation titled “Compliance Program Guidance for Pharmaceutical Manufacturers” that affects the process of clinical trial budgeting. The regulation states that “payments for research services should be fair market value for legitimate, reasonable, and necessary services”. UW uses standardized rates, with ‘retail’ as the ‘fair market value’ determination.
    - Retail Rates are the rate that research staff should aim toward when negotiating budgets with non-federal sponsors.
- **Research Rate:** this is the discounted rate that will be *charged to your research account* when this procedure is performed by UWHC/UWMF staff and/or using UWHC/UWMF facilities or services.
    - When negotiating budgets with *non-federal sponsors*, research staff should negotiate a rate ABOVE the research rate. We encourage research staff to start with the Retail Rate and negotiate lower settling on a rate above the Research Rate (e.g. the window of negotiation is between the Retail and Research Rates).
    - Tier 1 Research Rate (for Industry Sponsored research) this tier of the discounted research rates should be selected for all studies that are fully, or mostly, sponsored by pharmaceutical/industry
    - Tier 2 Research Rate (for Investigator-Initiated research) this tier of the discounted research rates should be selected for studies that are initiated by the investigator.

These are studies that are primarily funded by associations, foundation, or non-profit organizations. An Investigator Initiated Protocol that receive funding from an industry sponsor are also considered Tier 2.

- Tier 3 Research Rate (for Federally Funded research) this tier of the discounted research rates should be selected for all studies that are sponsored by a federal agency (e.g. NIH) or the federal government (VA, Dept. of Defense, etc.). The Tier 3 Research Rates are the least amount that can be charged for a given item or procedure as Tier 3 Rates are the Medicare Rates.
- *NOTE: Tier 3 should ALWAYS be selected for federally funded research project, as it is not considered acceptable to charge the federal government (e.g, grant) more than the federal rates.*

4. Know the Facilities & Administration (F&A) rate, also known as 'Indirect Cost rate' that will be applied

Indirect Costs are defined by the June 19, 1998 Notice 98-4 issued by the University of Wisconsin-Madison, Office of Research and Sponsored Programs (RSP) as 'Indirect costs are real costs that provide reimbursement for actual institutional expenses that support extramural activities but cannot be directly charged to a grant or contract. The costs result from shared services such as libraries, physical plant operation and maintenance, utility costs, general, departmental and sponsored projects administrative expenses, and depreciation or use allowance for buildings and equipment.

Indirect cost rates for all Federal grants and contracts are computed on the basis of actual costs incurred and regulations from the U.S. Office of Management and Budget that define the cost categories that are eligible for reimbursement. Indirect cost reimbursement rates are periodically negotiated with our cognizant Federal audit agency, the Department of Health and Human Services (DHHS). A signed agreement, that establishes the allowable rates of reimbursement, is entered into between the University and the Government. These Federally audited and approved rates are also applied to some categories of Nonfederal awards as explained in each section.

- Refer to the RSP 'F&A and Fringe Benefit Rate's website for the current rates: http://www.rsp.wisc.edu/rates/index.html
- Remember to add indirect rates to all applicable study related costs. It is assumed that final rates you negotiate include indirect costs and will be deducted upon receipt of the reimbursement payment. If the final rates that were negotiated did not include the Indirect rates, the amount that will be deposited will be less than anticipated.

5. Know if there will be a percent withheld from expected payments.

It is common for sponsors to withhold a percentage of all subject related costs until study completion.

6. Is there an annual cost adjustment allowed? (e.g. to account for inflation if study timeline is lengthy)

UWHC/UWMF have agreed to lock the research rates that you will be charged for the conduct of UWHC/UWMF procedures for up to 3 fiscal years based on how close to the February 1 budget fiscal

year you begin the budget development process. For example, if you begin the budget development process for a given study on February 1, your rates will be locked for 3 years. If you begin the budget development process on January 31, your rates will only be locked for 2 years.

7. Protocol-Related Budget: Identify startup and maintenance costs

Many start-up costs are incurred before subject enrollment, thus it is encouraged that these costs be negotiated as nonrefundable.

a. Protocol-Related/Start-Up fees to consider;

- IRB Review fees (initial, continuing, and changes to be identified separately)
- IRB application preparation/submission fees (initial, continuing, and changes to be identified separately)
- If study takes place on the CRU and the study is sponsored by industry, CRU initial review, amendment, and rush implementation fees
- VA Research Services review fees, if applicable
- PRC Review and Setup Fee and ongoing maintenance fee (billed quarterly beginning month 4)
    - Send budget request form to PRC with protocol and Investigational Drug Brochure (IDB), if applicable, as soon as the study is considered feasible to allow PRC time to develop an accurate budget.
- Contract/Budget negotiation fee
- Administrative fees (office supplies, pager, voicemail, computers, printing of records for subject charts or regulatory binder, file/cart setup, locked filing cabinets, etc.)
    - Telephone charges: will there be a significant amount of long distance calls anticipated? (e.g. teleconferences, subject visit reminders, IVRS, etc.)
    - Determine need for postal charges (important if recruitment letters or flyers, or visit reminder letters will be mailed)
    - Development of study tools, visit calendars, intake forms, screening materials, etc.
    - Ongoing invoicing and budget/billing reconciliation
- Site Initiation Visit
- Recruitment/Advertising Costs
    - Potential subject identification and pre-screening (i.e. chart reviews, database searches, clinic schedule review, etc.)
    - What type of recruitment activities and/or advertising will be used?
    - Will the sponsor be providing any materials or must they all be created by the research team?

- Study teleconferences
- Training/In-services (study specific and ongoing continuing education)
- Development of study documents (e.g. source templates, checklists, recruitment materials, mailings, etc.)
- Supplies and equipment specific to study (e.g. office supplies, lab/shipping supplies, dry ice, equipment service contracts, etc.)
- Storage and Archiving fees
- Study close-out
- Change in monitor fee

8. Subject-related Budget Items

a. Compare schedule of events from the protocol to the text descriptions in the protocol, and the study budget template for completeness

- Sponsor budget is a template that is to be used by every site, yet every site has slightly different needs, and costs for initiation, implementation, and study conduct.
- Sponsor budget may not identify all of the costs of the trial
- Sponsor budget may not reflect institution-specific charges/fees

b. Build protocol calendar/specifications in OnCore

c. Determine if procedures will be covered as Standard of Care (SOC) vs. billed to the research account by reviewing with PI and other clinicians (mid-level, clinic nurses, etc.)

- *Reminder: the study cannot bill insurance for any item or procedure that will be reimbursed by the sponsor*
- The Research Billing Compliance Committee has determined that the Clinical Trial Billing Checklist must be completed for every study. This is a necessary step for all clinical trial budgets, even if there are no procedures planned to be billed to a provider. Refer to the following KB document for more information: Clinical Trial Billing Checklist
- If a third party will be providing coverage, complete the CMS Checklist and determine if prior authorization will be necessary before procedures are completed. Clinical research often takes place in conjunction with routine clinical care of patients. It is very important to ensure that routine/standard of care services and non-routine/research services are billed to the appropriate payer and in compliance with statutory requirements.

d. Clinic Visits:

- Do you have a clinical research exam room that could be used for some or all visits?

- If not, you must determine visit level (minimum of level 2) and if professional fees can be and/or will be waived by clinicians

e. Blood collection and labs:

- Study schematics taken from the protocol should include the visit-specific laboratory tests to be performed, but often DON'T include the venipuncture/blood draw as a separate reimbursable procedure

f. Research Sample Processing:

- Will any or all of the samples be analyzed locally shipped to a central lab?
- How many samples/tubes will be processed?
- How will samples need to be stored?
- Will the samples be immediately shipped or shipped in batches at regular intervals (e.g. quarterly, every 6 months, etc)
- Will the samples all be shipped to the same lab, or will they go to different labs? (e.g. safety labs to a central clinical lab, and genetics tests to a different lab)
- Specimen shipping: Are the cost(s) of dry ice, shipping boxes, and shipping costs included? (ask for sponsor billing number)

NOTE: The Lab Manual most often contains the answers to the questions above, but often times it is not provided up front, but rather must be requested.

g. Subject Compensation:

- Does the subject compensation adequately address the amount of time and level of procedure invasiveness?
- Is there a need for retention gifts? If so, will these be provided by the sponsor?
- How long will subject participation last? 6 months or 2 years?
- How many visits are involved? 5 or 25?
- Is transportation and/or hotel accommodations provided or reimbursed?

h. Is this a Device Trial?

- Complete the Clinical Trial Billing Checklist and submit the Medicare Approval letter.
- Work with the Research Billing Compliance Coordinator to determine the cost to the hospital
- Talk to the manager of the area where the service will be provided to start the process of determining cost to hospital and if that is acceptable.

- Review the device purchasing terms in the CTA – break out into separate purchasing agreement or include in subject-related budget item

i. Incorporate costs from ancillary services

- Radiology procedures
  - Refer to the UW Department of Radiology Research Application Instructions for more information: https://www.radiology.wisc.edu/research/scannerRequests/index.php
  - Consult with Radiology Research staff in the modality of interest to your study (CT, PET, US, MRI)
  - Identify procedures as SOC vs research and the locations in which they will be performed
  - Do images need to be interpreted with a formal report?
    - Determine if radiology professional services are required for your protocol (MD scan oversight, required reports, scan info and/or results data collection)
    - Are research scan over-reads required per protocol for disclosure of abnormal findings detected during a research scan?
  - Are copies/CDs of the radiology procedures needed?
- CRU procedures
  - Refer to CRU Charge Guidance (LINK) document for details.
  - Are the study visits outpatient or inpatient (visit > 10 hours or overnight)?
    - Inpatient – Will patients have a diagnosis/condition that results in a higher level room charge? Examples: subject is MRSA positive; subject needs protective isolation because of disease; subject has a high BMI that results in a bariatric add-on charge (regardless of diagnosis)
    - Outpatient – What level of clinic visit is needed (simple, intermediate, complex)? Does it differ by visit?
- PRC: drug preparation and dispensation fees
  - Will the sponsor be providing the study drugs, or will they need to be purchased using a different method?
  - Will PRC be preparing and dispensing study drug, or is subject responsible for obtaining medication from his/her own pharmacy?
  - Include an item of 'Drug Accountability' to reimburse study coordinator effort to assess ongoing study drug compliance.

j. Include reimbursement for screen failures

- Request an initial screen failure rate of a given number of subjects before agreeing to a ratio (e.g. reimbursement for first 4 screen failures, then reimbursement for 1 screen failure for every 3 randomized to treatment)

k. Include reimbursement for unscheduled/safety visits/procedures (per procedure performed)

l. Determine research staff effort – generally the most under estimated cost of a clinical research study budget – involve the study coordinator in your effort estimates

- How much time is required to complete each visit? What is the actual time anticipated to be spent with subjects at each corresponding visit?
- Request copies of CRFs and lab manuals to ensure appropriate estimates of time for data collection, data entry, lab processing, shipping, etc.
- Using salary and adjusting for inflation (including fringe) calculate coordinator hourly rate
- Estimate effort needed to conduct study visit procedures by identifying all tasks to be performed by research staff (e.g. informed consent, medical history, vital signs, etc.)
    - If subjects must be re-consented due to change in protocol or IDB, include this as a variable/pass-thru cost
    - If subjects must be contacted between study visits, include Telephone Contact as billable procedure
- Enter line item of 'Coordinator Time' costs to capture additional effort needed outside of conducting the study visits (e.g. screening, scheduling visits, study visit preparation (ordering labs, requesting study drug, scheduling visits, etc.) contacting subjects, data collection, CRF entry, query resolution, correspondence with sponsor/CRO, monitoring visits, routine conference calls, billing slip completion and reconciliation, ongoing subject follow-up between visits, SAE reporting, etc.)
    - Planning and conducting recruitment activities – include as additional cost in 'Coordinator Time' or separate Administrative/Protocol Related fee.
    - Pre-study subject identification activities (i.e. chart reviews)
    - Form Completion/Data Entry could be included in 'Coordinator Time' calculation, or listed as a separate Subject Related line item.
    - Include time to be spent with study monitors or auditors

- Enter line item of 'Investigator Time' costs to capture additional effort needed outside of conducting study visit procedures (reviewing subject records, signing source documents/CRFs, AE causality, etc.)
    - If associated with a procedure that usually carries a Medical Foundation charge, consider asking the physician(s) to waive the UWMF fees
    - Account for any time actually spent with subjects
    - Estimate a fee for assessment and follow-up of lab reports or tests, reviewing local AEs, sponsor generated reports, investigator meetings, etc. An average amount of time can be estimated as a per/subject/visit fee
    - Required on-line training by the sponsor

If investigator is compensated from the study budget, associated effort must be included, which requires department administrator approval.

9. Determine if the Budget is Feasible

- Double check that you have identified all study procedures
    - Conduct a detailed review of the protocol, informed consent template, budget template, clinical trial agreement draft/template, laboratory manual and CRFs
- Determine if you have the estimated research staff effort available
- Does this study support the goals/objectives of your research program?
- What is your past experience with this sponsor?
- Does the budget support the cost needed to conduct the study?

10. Finalize budget draft

- If you determine that the study budget is feasible, finalize the Financial Console > Protocol and Subject Related Budget Items in OnCore, then click the "Complete" button on the Protocol Specifications to start the OnCore: Clinical Trial Billing Checklist process.

Step 2: Budget Negotiation

The text below can serve as guidance and questions to ask yourself when negotiating a clinical research budget.

Upon receipt of the Ancillary Services Review sign-off notification, you are ready to begin Budget Negotiations

1. Modify and submit sponsor template (if provided)

2. Negotiate with sponsor

- **ALWAYS** negotiate with the sponsor. Sponsors start with an amount that they know is below what they should expect to pay as a starting point to allow room for negotiation.
- Use *retail rates* when *starting* the negotiation process to allow room for negotiation. Your window for negotiations is between the Retail Rate and the Research Rate. The Research Rate is what your account will be charged for the procedure, thus, do not negotiate below the Research Rate.
- Compare your budget with that provided by sponsor – know where there are differences
- Always remain calm and exercise patience
- Get to know the budget/contract specialist with the CRO/Sponsor
    - They may, or may not, have a clinical background or be very knowledgeable about the protocol in question
    - They may receive financial incentive to keep site budgets low
    - They may expect antagonistic encounters with sites
- Don't provide rate justifications unless asked
    - There are some standard language memos that can be proactively shared with the sponsor, such as the Heath Sciences IRB memo and Pharmaceutical Research Center (PRC) standard language regarding fees
- Reach out to UW-Madison resources and colleagues with questions or if looking for advice. Don't ever be afraid to ask for help.
- If you are unable to negotiate a budget that is financially feasible, let the sponsor/CRO know that you will happily reconsider participation if the sponsor determines at some time in the future that they are willing to re-open the budget negotiations.

3. Finalize budget and initiate contract execution (contract language to be negotiated by RSP)

- Modify body of CTA payment terms if necessary
    - Include all Milestones,
    - Include all invoiceable items/Pass-thru procedures
    - Ensure correct name and address where checks will be sent

- UW investigators, faculty and/or staff cannot sign clinical research contracts or agreements. All contracts and agreements must be routed through the WISconsin Proposal & Electronic Routing system (WISPER): (https://www.rsp.wisc.edu/WISPER) with the Office of Research and Sponsored Programs (RSP) as the final signature authority.
- Refer to the Contract Signature Authority Memo for more information or the UW System Extramural Support Administration webpage for more information

Step 3: Budget management after start-up

The text below can serve as guidance and questions to ask yourself when managing a clinical research study after start-up.

1. Create face sheet with specifics about invoicing/reimbursement schedule, sponsor contacts, etc.

- Know the payment triggers, for example;
    - Receipt of start-up payment with execution of contract/agreement
    - Enrollment of first subject
    - When the study data is entered or completed in the sponsor database
    - When monitor reviews visit data

2. A Fund Account number will be created upon receipt of a fully signed award document or first check/payment.

- In some cases, an account number can be created in advance using the WISconsin Proposal & Electronic Routing (WISPER) system. Refer to the WISPER home page for more information :http://www.rsp.wisc.edu/WISPER/index.html

3. Invoice quarterly at a minimum (e.g. IRB submission related, PRC fees, and other variable/pass-thru items

4. Reconcile incoming checks as they arrive

- Request check statement of all items/procedures reimbursed as part of the payment

5. Reconcile expenses (statements from UWHC/UWMF patient billing, IRB fee invoices, etc.)

6. Provide Monitoring/Oversight of Grant/Contract Accounts:

Grant and Contract Accounts at the UW-Madison are monitored by a combination of the Principal Investigator, the departmental or lab administrator, the Dean's office (often both pre-award and post-award), and the Office of Research and Sponsored Programs (RSP).

Refer to RSP webpages for more information:

- Monitoring/Oversight of Grant/Contract Accounts: https://www.rsp.wisc.edu/awardmgt/oversight.cfm
- Grants and Contracts Management: Staff Roles and Responsibilities: https://www.rsp.wisc.edu/policies/staffroles.cfm