CLINICAL TRIALS – NON-PROFIT PATIENT CARE EXPENSES

Revised December 12, 2024

OVERVIEW – CLINICAL TRIAL NON-PROFIT PATIENT CARE EXPENSES

Research Administrators and other assigned administrative contacts can request an estimate for patient care for clinical trials. Non-profit patient care expenses are crucial because they represent a category of essential costs needed to run a clinical trial effectively.

If the study team confirms the study is a non-profit clinical trial, the next steps in creating the patient care estimate are necessary to complete the submission.

- **Timeline:** The budgeting process for a non-profit is **Time Sensitive** depending on the submission deadline for the grant.
  - ***Tip:*** Allow at least 10-15 business days before the internal due date of submission to ensure there is enough time for all stakeholders to thoroughly review the protocol and capture all related costs in the estimate. Submit requests for patient care build as early as possible.

HOW TO REQUEST A PATIENT CARE BUDGET

1. Submit an application to the Department of Medicine Clinical Trial Program (DOMCTP) Service Application Form to request to create a patient care budget.

HOW THE PATIENT CARE BUDGET IS CREATED

a. DOMCTP will work with the Research Administrator (RA) and Principal Investigator (PI) to complete the estimate, asking protocol related questions pertaining to patient care.
b. The estimate is established by reviewing and understanding the protocol schedule of events and the operations in the clinic and/or ancillaries in which the PI sees patients.
c. This estimate will provide you with the amount to insert into the patient care category of the overall budget.

2. **Budgeting for Start-Up:**
   a. Common Ancillaries for Clinical Trials:
      i. IRB
      ii. Other Ancillaries - Clinical Research Financial Pulse
   b. *Ancillaries may provide a reduced rate or waiver for non-profit sponsored studies upon request via email submission.
      i. Email request example for non-profit funded grants:
         a) *Greetings, This study is funded by (NIH/agency) and has limited funds budgeted for this project. The budget did supply (minimal or no) funds for (ancillary name) startup/maintenance/closure. This PI along with other PIs from the Department of Medicine utilize (ancillary name) for many for profit studies, and we gladly are able to pay for such set up fee. Unfortunately for (NIH/agency) funded studies, we don't have that wiggle room. We appreciate anything you can do to assist us in moving forward with this project at UCLA and any reconsideration for the request of these fees to be waived.*
   c. How are Ancillary/Department Costs determined?
      i. A cross-functional team of stakeholders, comprised of representatives from several departments, determine costs for items and present proposed rates to the

Pricing Committee for review and approval. Procurement teams must adopt a detailed approach while estimating the cost per service.

ii. UCLA Clinical Research Charge Review – Standard Operating Procedures define key roles and responsibilities in facilitating the accurate review and adjudication of clinical research charges across UCLA Health.

iii. There may be costly items in which the PI may have questions on the rate provided. For these special occurrences, PI may request a procedure price reduction. These requests should not be requested arbitrarily. High ticket items $500.00+ are typically the ones questioned.

1. To request any reductions, send email to CDM Attn: Tymaine Clay / Ronnie Diep
    a. They will have to be in agreement and supportive before escalating to the Pricing Committee.
    b. Include number of services
        i. Name of procedure
        ii. CPT #s / Multi-code breakdown
    c. Location of procedure
    d. Current Rate and Inflationary Rate (you may obtain from DOMCTP)
    e. Example of previous patient care expenses for same procedure
    f. Reason why you believe reduction should be considered
2. CRBP is assigned the coding, we must ensure the codes are accurate.
    a. MRNs for patient care expenses
3. CDM may escalate to Pricing Committee.

3. **Budgeting for Procedures:**
    a. Non-profit rates are established by referencing Current Procedural Terminology (CPT) codes and using UCLA's Charge Master Rates
        i. The Department of Medicine has developed an internal Cost List that contains common clinical trial procedures used in DOM clinical trials. The Charge Master rates are referenced when updating the DOM Cost List. It is an easier method to identify common items used in clinical trial budgets. The DOM Cost List is updated annually, every March (after Medicare rates are released every February). For access to the DOM Cost List rates, please contact Department of Medicine Clinical Trial Program at DOMCTP@mednet.ucla.edu.
    b. CPT Codes
        i. CPT Codes are used to:
            a) Improve collection and revenue and to meet budget projections
            b) Prevent mischarging of procedures to the subject's insurance or to the clinical trial
            c) Authorize procedures for each subject based on the study they are enrolled on
            d) Provide a template of procedures, which is generated for each patient enrolled
            e) Confirm what should be billed to the account for pre-invoicing
        ii. Some common research-related examples of CPT codes:
            a) **CPT 99201-99215** Physical Exam / Office Visit
            b) **CPT 36415** Venipuncture/Blood Draw/Specimen Collection

4. **Overhead Costs**

a. All rates for funded clinical trials, regardless of protocol authorship, are subject to Facilities and Administrative Costs (F&A)
    i. Current F&A Rates
b. How to determine which items are patient care related and which items do not require the overhead: Select sponsors may utilize a Modified Total Direct Cost base (MTDC) for indirect cost calculations. When preparing a budget for a sponsor who utilizes MTDC calculations, refer to the Sponsor's Guidance to determine how patient care and patient-related expenses must factor in for the indirect cost calculation.
    i.

	Baseline D1	D2	D3	D4	D5	D6	D7	D8-D28
Staff Cost								
Principal Investigator	X	X	X	X	X	X	X	X
Study Coordintor	X	X	X	X	X	X	X	X
Data Manager	X	X	X	X	X	X	X	X
Procedures/ Assessments								
Screening/Eligibility Assessment	X							
Informed Consent	X							
Office Visit/Physical Exam	$$	$$	$$	$$	$$	$$	$$	$$
Enrollment/Randomization	X							
Clinical Status Assessment[1]	X	X	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X	X	X
Concomitant Meds		X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X	X
Laboratory - Central								
Laboratory Specimen Collection/Draw - Central lab STAT	$$		$$				$$	
Laboratory Kit Processing & Handling - Central Simple STAT	$$		$$				$$	
Laboratory - Local								
Laboratory Specimen Collection/Draw - Local STAT	$$		$$		$$		$$	$$
Comprehensive Metabolic Panel	$$		$$		$$		$$	$$
CBC/Diff/Plt	$$		$$		$$		$$	$$
Direct Bilirubin (Conjugated)	$$		$$		$$		$$	$$
Study Drug /Device								
Pharmacy Dispensing Fee -IV (Investigational Agent)	$$	$$	$$	$$	$$	$$	$$	$$
Drug Accountability/ Administration - IV Non-Chemo First Hour (Investigational Agent Administration)	$$	$$	$$	$$	$$	$$	$$	$$
Drug Accountability/ Administration - Each Addt'l Hour IV Non-Chemo (Investigational Agent Administration)	$$	$$	$$	$$	$$	$$	$$	$$
Sub Total	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

Anticipated enrollment
X: Cost included in budget
* / INVBL: Invoice to sponsor
Q1 / RC1: ROUTINE CARE

c. **Unlike For-profit clinical trial budgets** where overhead is applicable to the entire budget, **Non-profit clinical trial budgets using the federal MTDC base method** must identify which costs will post to the General Ledger as bona-fide Patient Care Costs (will post via object code 3466) and be excluded from assessing overhead.
d. Common patient care items that exclude overhead:
    i. CTRC procedure charges
    ii. CPT coded procedures
    iii. Lab tests, if the labs are ordered and fulfilled via Epic

        *Note: If tests are not completed via Epic approvals, overhead applies.

e. Common patient-related costs that must include overhead:
    i. If the PI has their own laboratory/clinic and has a phlebotomist on payroll, this would be time and effort only and overhead applies.
    ii. Ancillary Start-up/Closing Fees
    iii. Patient Stipends (Cash incentives, meal reimbursements, travel and lodging, or similar cash-value payments made to or on behalf of an enrolled participant)
    iv. Patient Parking
    v. Supplies for clinical trials (chemicals, glassware or test kits needed to analyze samples collected post-procedure by the research team)
    vi. Outsourced testing and analysis (use of core services or outside labs)
    vii. Equipment
    viii. Freezer storage costs
    ix. Data management costs
f. Time and Effort outside patient care must include overhead:
    i. Both clinical trial and supportive grant responsibilities should be included in the efforts. This may include:

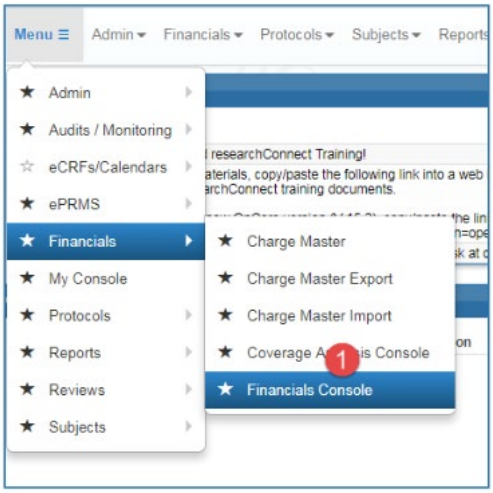
a) Salaries (PI, Clinical Research Coordinator, Data Manager, outside PI collaboration services)
b) Presentations
c) Meetings/Travel

5. After the patient care matrix is created based on protocol-required events and rates inserted, DOMCTP will send the draft patient care estimate via email to the requestor.

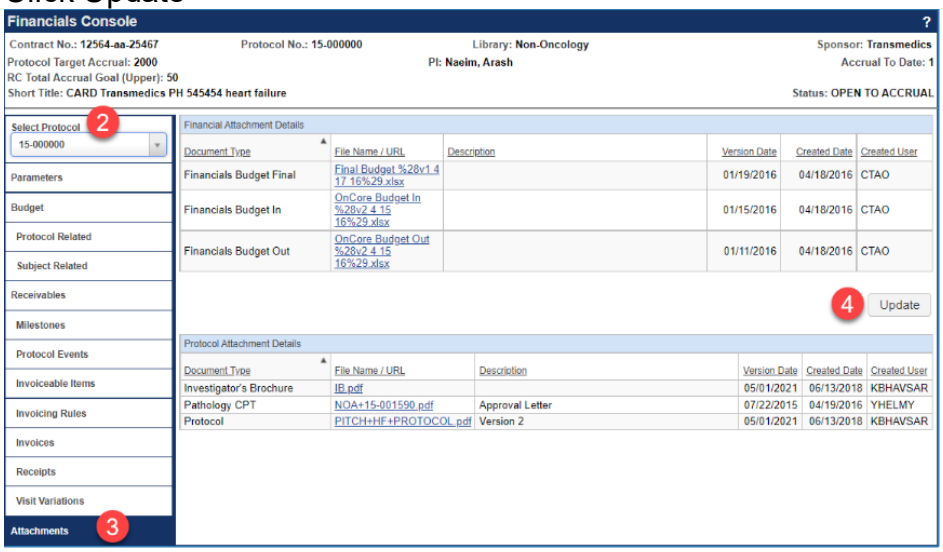
6. After funding is awarded, if your Regulatory marked yes in the BRUINIRB submission inquiry of Clinical Research Management System, please follow the next steps.

   a. In OnCore enter FAU. Budget draft costs for subject related, protocol related, and budget procedures that were documented on the Excel provided by DOMCTP will need to be uploaded to OnCore as the final draft Budget as Budget In, thus triggering a notification to the Clinical Research Finance (CRF) - Quality Assurance team. This step is necessary so that OCGA may receive the budget certification from CRF.

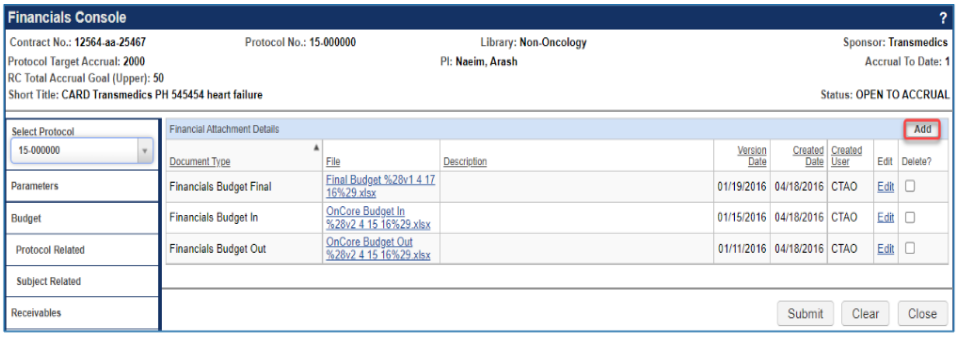
      1. Navigate to Menu > Financials > **Financials Console**



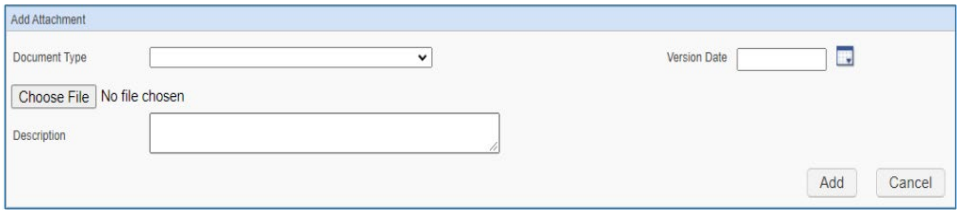
      2. Enter a protocol number in the Select Protocol field
      3. Navigate to the Attachments tab
         a) Click any of the File Name/URL hyperlinks to download a file.
      4. Click Update



      5. Click **Add**



6. Select the Document Type of Financials – Budget In
   *Uploading the "Financials - Budget In" in OnCore triggers a notification to Clinical Research Finance
7. Finance Quality Assurance team to review the Negotiated Budget (Budget In).
8. Enter the Version Date
9. Click Choose File to search for and select the File
10. Enter Description - information may be found in budget (Funding Agency, protocol #, protocol version, date)
11. Click Add



WHY SOME COSTS ARE SIGNIFICANTLY MORE THAN OTHERS

Due to specific procedural requirements and the complexity of each trial, it is possible that physicians perform specialized tests for particular disease indications along with regular physical examinations of patients. This may require more physician time that results in higher costs.

CONTACT/RESOURCES

- UCLA DOMCTP: DOMCTP@mednet.ucla.edu