

UWCCC Clinical Research Coordinating Office (CRCO) Standard Operating Procedure

Title	Clinical Trial Budget Preparation: Industry and IIT
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Introduction

Developing a budget for a clinical trial involves determining costs from participating shared services and collaborators, incorporating costs for clinical procedures that are performed specifically for research purposes, and determining the amount of research staff effort that will be required to conduct the study. Each DOWG has a designated person(s) who develops the budget on behalf of the PI and obtains necessary budgetary reviews and approvals. This SOP is intended to provide a general outline of the key steps in creating and finalizing a clinical trial budget.

I. Policy

When creating a budget for a clinical trial, all pertinent UW and UWCC policies and Medicare rules must be followed. The UWCCC Program Managers Committee has developed [Standard Budget Guidelines](#) that establish agreed-upon startup and invoiceable items to be included in each budget for sponsored studies. These Standard Budget Guidelines have been approved by the CRC and must be followed unless the research group identifies funds to subsidize study participation.

II. Procedure

A. Feasibility Assessment

The research team reviews the protocol and determines whether they wish to participate and determines whether necessary resources are available for study conduct. The following items are instrumental in evaluating the feasibility of conducting a study in accordance with the protocol:

1. Identify Participating Sites

Determine whether the study will be conducted only at UWCC or will involve external sites, including VA Hospital (VAH), UW Health Oncology at 1 South Park Street (1SP), UW Cancer Center at Johnson Creek (UWCC JC) and/or Wisconsin Oncology Network (WON). Budgetary considerations for external sites include:

- a. VA Hospital – Protocol review fees are assessed.
- b. 1SP, UWCC JC, and WON – Contact the CRCO's Outreach Specialist to identify elements for external sites' participation.

2. Protocol Procedures Review

The Principal Investigator (PI) reviews all protocol treatment(s) and assessments to determine those that are standard of care (SOC) in the study population and those procedures or treatments that are performed specifically for research (RES). Any discrepancies between the sponsor's and the PI's determinations of SOC vs. RES should be addressed with the sponsor early in the budget review process. The sponsor may request justification for local SOC practices in the study population.

- a. PI or PM denotes SOC and RES procedures on a copy of the study calendar (or equivalent written documentation of this determination.)
- b. PI signs and dates documentation of SOC versus RES procedures.

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Note: Written documentation of SOC and RES is required for UWCCC Budget Compliance Review (see section B below).

3. Medicare Compliance Review

The UW Health Research Billing Compliance Committee requires evaluation of all clinical trials using investigational devices and/or drugs for billing compliance with Centers for Medicare and Medicaid Services (CMS) policies. The PI should complete and sign the [Medicare Device and Clinical Trial Billing Checklist](#), which documents PI review and determination of Medicare billing eligibility for investigational drugs and/or devices. **Note: The signed checklist is required for UWCC Budget Compliance Review (see section B below).**

4. Identify Shared Services and/or Collaborators

Determine the location of study visits and treatment and identify the shared services and/or collaborators that will be utilized to conduct the study. In order to perform a comprehensive feasibility review and provide accurate budget information, the protocol, laboratory and/or imaging manuals, and Investigational Drug Brochure (IDB) may be required.

Send protocol and associated documents via e-mail to all shared services collaborators and any other entities involved in the trial and request their budgetary input. Refer to the UWCCC internet site for a [contact list for shared services](#) when making budget requests. Some commonly used shared services and/or collaborators include:

- a. Pharmaceutical Research Center (PRC) – Send protocol, IDB and pharmacy manual, if available, and note whether the VA, UWCC JC, WON or Affiliate Sites and/or 1SP will be participating. Treatment locations (i.e., outpatient oncology clinic vs. Clinical Research Unit) are also important information to provide.
- b. Clinics / Nursing Units
 - OPOC – Send protocol to OPOC Manager if there are questions over assessments to be done in OPOC, or to verify procedure codes for research-related items.
 - B6/6 or Infusion Center – Send protocol to unit contact if there are study treatments that must be administered in these units. Also email a copy of the protocol to the appropriate NP and outline any concerns regarding study conduct in these areas.
 - CRU – Complete a [CRU Consult request](#) on the ICTR website. Contact the CRU nurses to set up a meeting to review CRU requirements and identify CRU procedures and associated charges.
 - Contact other units as appropriate
- c. Radiology – Send protocol and central imaging manual to Dona Alberti for studies that have research-related imaging (e.g., Ultrasound or CT-guided biopsies), or for information regarding radiological procedures. For studies requiring central radiology review, send the protocol and central imaging manual to Mary Ametani.
- d. 3P Laboratory – Send protocol and laboratory manual to 3P Laboratory Program Manager if 3P services will be used for laboratory sample processing. Treatment locations (i.e., outpatient oncology clinic vs. Clinical Research Unit) are also important information to provide.

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- e. UWHC Clinical Labs – Send protocol and laboratory manual to Clinical Lab manager if the UWHC Core Lab will provide laboratory sample processing.

5. Identify Research Staff Effort

Staff effort should be calculated for all study visits. A useful tool to perform these calculations, the [Study Coordinator Effort Table](#), is available on the UWCCC internet site, as is the [Screening Effort Calculator](#), which can be used to calculate effort for screening-specific activities.

B. Budget Creation and Compliance Review

1. OnCore Financials Entry

Once the budget elements from the above steps have been compiled, the research group enters the Protocol Calendar and Budget Calendar into the OnCore Financials module to obtain UWHC procedure costs and UWMF professional fees. OnCore Financials Tutorials/Instructions are available on the [UWCCC intranet site](#).

2. Budget Compliance Review

After all elements of the budget record have been entered into the Financials module, the budget must undergo a compliance review by the UWCCC Budget Compliance Specialist. The compliance review ensures that budget items have been correctly entered into Financials; that Medicare billing compliance issues have been addressed; and that SOC and RES procedures have been appropriately designated for the patient population. To request a budget compliance review, email the [Budgetary Compliance Specialist](#) with your request and upload the following documentation into OnCore:

- Financials Console>Attachments: **Protocol**
- Financials Console> Attachments: **PI-signed Medicare Device and Clinical Trial Billing Checklist**
- Financials Console>Attachments: **PI-signed documentation of SOC vs RES procedures**

The compliance review takes 2-3 business days and the research group will be notified of any changes that need to be made to the Protocol Calendar and budget elements in OnCore Financials .

3. Internal Budget Submission to SMPH

Upon compliance review and approval, the Budget Compliance Specialist submits budget through OnCore. This sends a notification to OCT to signoff on the Initial Version of the Protocol Calendar (and budget). OCT will send the record for Ancillary Services Review and release the budget in 3 business days. Upon OCT release of the record, the PM can then begin negotiations with sponsor. Negotiations should begin after Ancillary Services Review is complete in case changes need to be made in OnCore Financials. After negotiations, the PM creates a new version of the budget in OnCore Financials and updates the negotiated costs.

4. Create Draft Internal Budget

While OCT is reviewing the budget, the research group can begin drafting their study budget using the appropriate template.

- a. Choose a template – Sponsors may require the use of a company-provided budget template. If a sponsor-provided template is not available, the research team may use a generic [Industry-Sponsored Study Budget](#)

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[Template](#), available on the UWCCC internet site. The budget should include the following elements:

- Start Up Costs – These should include all applicable startup costs as outlined in the [UWCCC Standard Budget Guidelines](#)
 - Variable or Invoiceable Costs – These should include all clinical and non-clinical items not associated with specific subject visits
 - Study Procedures Costs – Procedure costs are available in Oncore Financials Console>Subject Related tab immediately after procedures are configured. Research groups should begin negotiations AFTER Ancillary Services Review in case changes need to be made. It is recommended that research groups attempt to negotiate with the sponsor to pay costs at the retail rate. However, in the event the sponsor is unable or unwilling to pay the retail rate for a procedure, the negotiated rate may be no lower than the research rate.
 - Research Staff Effort – For study coordinators, effort is often listed as a line item in the per- subject budget. The effort calculators noted previously are useful in determining study staff effort.
 - Shared Services/Collaborator Costs – These costs must be included in the budget in one of the above categories or as separate line items within the per-subject budget.
- b. Review with PI – After all costs have been incorporated into the draft budget, the research group should compare it to the sponsor’s proposed budget, as some adjustments may be needed. Moving costly or one-time costs out of the per-subject items into the variable or invoiceable costs section can make the overall budget more agreeable to sponsors.

5. Budget Negotiation & Completion

The research group provides the study budget to the sponsor along with justification documents (e.g., UWCCC Budget Guidelines, SC Effort Calculator, etc.) and commences with budget negotiation, if required. The budget may be revised through negotiations with the sponsor until both sponsor and research group come to agreement on the study costs. Once negotiations are finalized, PM enters negotiated costs into new version of budget in OnCore Financials and releases it (this cannot be completed until the budget has been released by OCT).

C. Budget Approval & Routing

After the budget has been finalized with the sponsor, the research group must incorporate the final version into the pre-reviewed CTA. The CTA is then uploaded into WISPER, and internal approvals must be obtained prior to routing the WISPER record to the SMPH and RSP for contract execution.

1. Verify Status of CTA Review

If RSP has not already finalized the CTA, notify RSP that the budget is complete and CTA language needs to be finalized in order to proceed with contract execution.

2. Obtain WISPER Approvals and Route Record

After RSP has finalized the terms and conditions in the CTA with the sponsor, RSP will notify the research group that the CTA is ready for signature and routing.

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- a. Upload the per-patient budget, final sponsor budget and the OnCore Ancillary Services Report into WISPER in the Attachments tab. This report can be found in Reports>Financials>Ancillary Services Report.
- b. Complete all required tabs of the WISPER entry if not yet completed.
- c. Send PI signature request from main page of WISPER record.
- d. After PI has signed the WISPER record, send **approval** request to administering department:
 - UWCCC: Department Chair designee, Marilyn Larson
 - DOM / Other Department: Section Administrator or Department Administrator
- e. After Chair or Administrator approval, **route** the WISPER record to the division: SMPH / Division Code 53. The SMPH will review the budget and WISPER record for completeness and will subsequently route the record to RSP for completion.

3. Obtain PI Signature on Original (Paper) CTA/Budget

If an original paper copy of the CTA/Budget must be signed by the PI, the research group prints a copy of the CTA/Budget and sends it to the PI for signature, as per the sponsor requirements (note: some sponsors may require multiple original documents). The original CTA/Budget is then sent via ID mail to RSP with a copy of the main page of the WISPER record and a pre-paid shipping label. The research group should check the box next to "Paper Copy to UW SPO" in the Submission Instructions section of the general tab in WISPER prior to routing the record.

D. Fully-Executed CTA/Budget Available in WISPER

After the original agreement has been fully-executed, RSP will upload the agreement in the Attachments tab in WISPER and the research group can download a copy for their records.

III. Related Documents and Websites

[UWCCC Standard Budget Guidelines](#)
[Medicare Device and Clinical Trial Billing Checklist and Rules](#)
[Budget Compliance Review Flowchart](#)
[Budget Compliance Review Process](#)

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