


Clinical Research Support Office (“CRSO”) STANDARD OPERATING PROCEDURE

SOP NUMBER CFI-SOP-4006	TITLE Budget Monitoring
EFFECTIVE DATE 03/08/2021	WRITTEN BY Jessica Heskell
REVIEW/REVISION HISTORY 3/17/21, 12/21/21	REVIEWED BY JESSICA HESKEL

APPROVAL	
 <small>William W. Stoops (Jan 14, 2022 09:12 EST)</small>	<p style="font-size: 24pt; margin: 0;">Jan 14, 2022</p>
SIGNATURE	DATE

1. POLICY STATEMENT

The CRSO Finance Team will review all industry sponsored Clinical Trial budgets for the UK College of Medicine to confirm that research-budgeted items are aligned with the coverage analysis (CA).

2. PURPOSE

The purpose of this SOP is to verify that all internal industry sponsored clinical trial budgets adhere to the CA as part of the billing integrity process.

3. SCOPE

This SOP covers all industry sponsored clinical trials with a PI whose primary appointment is in the College of Medicine.

4. RESPONSIBILITY

The CRSO finance team will review the budgets.

Sponsored Research Administrative Services (SRAS) will assist with identifying and referring studies that require review.

5. PROCEDURE

5.1 The Clinical Trials Administrative Support and Billing Integrity Team will share the Excel version of the billing grid or CA once finalized, which will serve as the template to develop the study budget.

5.2 Study teams will utilize this template as the foundation to develop the study

budget; including, but not limited to patient care costs, invoiceable research items, and time and effort, in accordance with the Uniform Grant Guidance and other applicable rules and regulations. Study teams will upload the finalized internal budget and sponsor budget to the eIAF, or e-mail the budget documents to the CRSO at CRSOFinance@uky.edu

5.3 The CRSO Finance Team will review the documents to confirm that the budget document includes the items outlined on the CA as Bill to Sponsor (R) and not items marked as Bill to Insurance (BILL)

5.3.1 The Finance Team will communicate with the study team regarding any discrepancies or other questions and work to resolve the issue

5.3.2 Finance Team will upload the budget documents and approval into OnCore after review

5.4 The CRSO Finance Team will respond with a verification email to [SRAS](#), the study team member who submitted the eIAF, and will upload the documents to the CTMS Finance Console to be accessed by other CRSO teams.

5.5 Email to SRAS will include the following

5.5.1 The PI and department or center in the subject line

5.5.2 Final budget

5.5.3 Body of the email will include protocol information and statement of the budget review

5.6 SRAS will not approve the eIAF until receiving confirmation that the budget was reviewed by the CRSO.

5.7 Any amendments that require a new eIAF will also require a second review by the CRSO Finance Team utilizing the amended CA and budget.

6. ATTACHMENTS

Example Budget Entry Form

7. REFERENCES

CFI-SOP-4005 Clinical Trial Budget Development SOP






Budget Review 4006 V2-FINAL

Final Audit Report

2022-01-14

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