Clinical Research Support Office ("CRSO")
STANDARD OPERATING PROCEDURE

SOP NUMBER	**TITLE**
CFI-SOP-4003	**Amendments**
EFFECTIVE DATE	**WRITTEN BY**
08/15/2019 **Revised 12/21/21**	**Jessica Heskel**

APPROVAL

William W. Stoops
William W. Stoops (Jan 14, 2022 09:13 EST)

SIGNATURE

Jan 14, 2022

DATE

1. POLICY STATEMENT

Clinical trials undergo periodic amendments to approved protocols, budgets, and contractual terms for a variety of reasons. These amendments require timely review to determine the impact on approved protocol calendars, coverage analyses, budgets, and protocol information to ensure continuity of subject tracking, sponsor invoicing, and research billing processes in the Clinical Trial Management System ("CTMS").

2. PURPOSE

The purpose of this policy is to ensure that all applicable trials follow a standardized amendment process, including completing all data entry steps defined under the data required elements for the CTMS.

3. SCOPE

This policy is applicable to all clinical trials maintained within the CTMS that may be subject to an amendment.

4. RESPONSIBILITY

Regulatory Owner/Protocol Coordinator/Manager

- The Regulatory Owner/Protocol Coordinator/Manager is responsible for Institutional Review Board ("IRB") preparations and submissions related to the amendment;
- Updates IRB (and other committees, if applicable) submission and approval

information in the CTMS and uploads approved documents;
- Updates any protocol data fields in CTMS, if needed- referencing the PC Console Minimum Data Footprint Work Instructions;
- Confirms with the Investigator whether an amendment requires re-consent for participants
- Submits the amendment to the non-indemnification committee, if applicable;
- Updates information on ClinicalTrials.gov, if applicable.

Budget Owner
- The Budget Owner is responsible for the preparation and negotiation of the protocol budget amendment;
- Reviews the revised protocol and determines any impact to the budget in the executed clinical trial agreement(s);
- Issues and releases bill hold(s) as appropriate;
- Uploads Office of Sponsored Projects Administration ("OSPA") revised clinical trial agreement(s) amendments into the CTMS;
- Initiates the revised eIAF, if required by OSPA written guidance.

CRSO Clinical Research Administrative Support and Billing Integrity Team
- Reviews the amended protocol, ICF and other documents, identifies, and performs any changes to PC Console information, calendar and coverage analysis.
- Based on the amendment, the team may create a new version of the calendar and any other pertinent updates within the CTMS.
- The Coverage Analyst reviews any changes to the calendar or calendar items, and modifies and/or enters new justifications for billing designations, if needed.
- Provides study teams with an e-mail outlining any changes to the calendar and/or CA, and may make additional modifications, if requested by study teams.
- Completes the CA Sign-off within the CTMS Specifications.

CRSO Central Budget Analyst
- Reviews amendment document to determine if a budget revision is necessary
- Updates the finance console in OnCore to reflect the amended budget

Principal Investigator ("PI") or designee
- Submits an amendment request through the online Amendment Submission Form, for any amendment, including budget only amendments;
- Re-consents participants ,as necessary, per IRB policy, and updates consent information in the CTMS, if determined necessary by the Regulatory Owner;
- Reviews and accepts the terms of the coverage analysis and budget and contract amendments, if applicable;

- Updates subject calendar versions, if applicable.

5. PROCEDURE

1. PI or designee will submit the amendment request through the online Amendment Submission Form, indicating whether the amendment is substantial or administrative.
2. The PI or designee clearly identifies the changes to the protocol, ICF and any other applicable documents
3. The CTASBI team will perform changes to the calendar and/or CA, as needed, and will communicate any and all changes with the study team.
4. The CRSO Central Budget Associate will update the budget, as needed.
5. The PI or finance lead must approve all changes.
6. The CTASBI team performs the CA sign-off, if needed, and documents any or all changes.

6. ATTACHMENTS

None

7. REFERENCES

Office of Research Integrity: Modification - IRB Review of Changes [C2.0300]
Office of Research Integrity: Informed Consent [C3.0050]
Office of Sponsored Projects Administration: Clinical Trial Agreements
Office of Sponsored Projects Administration: Industry Sponsored Agreements
University Financial Services: Business Procedures Manual
Amendment Work Instructions
Protocol Entry Work Instructions

Amendments CFI-SOP-4003 V2 FINAL

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