


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

<b>SOP NUMBER</b> CFI-SOP-4003	<b>TITLE</b> Amendments
<b>EFFECTIVE DATE</b> 08/15/2019	<b>WRITTEN BY</b> CRSO Director

<b>APPROVAL</b>	
	<b>August 9, 2019</b>
<hr style="width: 50%; margin: 0 auto;"/> <b>SIGNATURE</b>	<hr style="width: 50%; margin: 0 auto;"/> <b>DATE</b>

1. POLICY STATEMENT

Clinical trials may 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, and budgets 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 go through a standardized amendment process and the responsible parties complete all appropriate steps for studies built in the CTMS.

3. SCOPE

This policy is applicable for all clinical trials being tracked in the CTMS subject to an amendment.

4. RESPONSIBILITY

Regulatory Owner

- The Regulatory Owner 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 Protocol

Entry Work Instructions;

- Confirms with the Investigator if re-consent for participants impacted by the amendment is required
- Submits the amendment to the non-indemnification committee if applicable;
- Updates information on CT.gov if applicable.

Budget Owner

- The Budget Owner is responsible for preparation and negotiation of the protocol budget amendment;
- Reviews the revised protocol and determines the 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 Billing Integrity Manager

- Releases a new version of the CTMS study calendar or budget

CRSO Coverage Analyst

- Reviews the revised protocol and determines if changes alter approved coverage analysis or modify qualifying clinical trial (“QCT”) determinations;
- Updates the CTMS coverage analysis to reflect changes.

CRSO CTMS Specialist

- Initiates the amendment task list;
- Reviews amendment for protocol calendar changes;
- If applicable, initiates new version of specification and updates arms, procedures and calendar events in the CTMS to reflect protocol changes.

Principal Investigator (“PI”) or designee

- Submits amendment request through the online [Amendment Submission Form](#);
- Re-consents participants as necessary per IRB policy and updates consent information in the CTMS as determined necessary by the Regulatory Owner;
- Reviews and accepts terms of coverage analysis, 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](#).
2. The CTMS Specialist determines the nature of the protocol amendment, initiates the amendment task list, and makes any protocol calendar changes as needed.
3. The amendment will undergo one of three workflows based on the changes required and the timing of the events:
  - 3.1. An **administrative amendment** is a protocol amendment that does not require a change to the CTMS calendar, coverage analysis or budget.
  - 3.2. A **comprehensive amendment** is a protocol amendment that requires changes to the CTMS calendar, coverage analysis and/or budget.
  - 3.3. A **split amendment** is a protocol amendment that requires changes to the CTMS calendar or coverage analysis that need to be released before a budget or contract amendment is finalized.

#### **Administrative Amendment**

1. The Regulatory Owner will:
  - 1.1. Enter IRB submission information into the CTMS;
  - 1.2. Update any relevant CTMS tracking fields;
  - 1.3. Enter IRB approval information and upload approved documents;
  - 1.4. Update amendment task list.
2. The CTMS Specialist will internally document the version review and no changes are required.
3. The Coverage Analyst will document to the study team no changes to the CA are required.

#### **Comprehensive Amendment**

1. The Regulatory Owner will perform tasks as outlined in Administrative Amendment procedure above.
2. CTMS Specialist reviews the protocol and makes required updates to the protocol arm/levels in the CTMS.
3. The CTMS Specialist creates a new version of the protocol calendar and makes necessary updates.
4. The Coverage Analyst is notified when the calendar is complete, reviews and modifies the coverage analysis, updates the CTMS and amendment task list as needed.
5. The Budget Owner is notified once coverage analysis is complete, reviews and modifies the budget, and updates CTMS and the amendment task list as needed.
6. Following study team acceptance of calendar and coverage analysis changes (if applicable), billing integrity review and IRB approval, the Billing Integrity Manager releases the new version of the specification.
7. OSPA will email the final version of the clinical trial agreement(s) to the budget

owner when executed.

8. The Budget Owner uploads the latest version of the clinical trial agreement(s), if applicable and finalizes the CTMS amendment task list.

8.1 If applicable, the Budget Owner will initiate the revised eIAF if required by OSPA written guidance.

### **Split Amendment**

1. The Regulatory Owner will perform tasks listed in Administrative Amendment procedure above.
2. The CTMS Specialist will perform Comprehensive Amendment steps 2 and 3 above.
3. The Coverage Analyst will perform Comprehensive Amendment step 4 above.
4. The Budget Owner may initiate the bill hold per the Amendment Work Instructions document and negotiate the budget changes with the sponsor as necessary
5. Following the execution of the revised clinical trial agreement(s), the Budget Owner will:
  - 5.1. Initiate the revised eIAF if required by OSPA written guidance;
  - 5.2. Upload revised clinical trial agreement(s) to the financials tab in the CTMS;
  - 5.3. Initiate a budget amendment in the CTMS;
  - 5.4. Enter the budget effective date and release the new budget version;
  - 5.5. Remove the bill hold, if applicable.
  - 5.6. Update the amendment task list

### 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