ROLE OF THE OFFICE OF CLINICAL RESEARCH

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to describe the comprehensive support services that the Office of Clinical Research (OCR) offers to investigators and research personnel conducting clinical trials at the Clinical Research Center (CRC).

SCOPE: This SOP applies to OCR personnel who facilitate non-federally sponsored clinical research projects from inception through completion.

RESPONSIBILITY: The OCR is responsible for managing non-federally sponsored clinical research studies for faculty in the USF Morsani College of Medicine. The OCR is comprised of three functional areas; clinical services, business operations and fiscal operations.

DEFINITIONS:

Clinical Trial Agreement (CTA): A contract between USF and the Sponsor of a clinical trial that defines the scope of work and formalizes the understandings between the parties and contains legal and financial terms related to the conduct of a clinical trial. The agreement is signed by the principal investigator, a USF Institutional Official (IO), and the sponsor.

Confidentiality Agreement (CDA): A legal agreement between at least two parties which outlines information the parties wish to share with one another for certain evaluation purposes, but wish to restrict from wider use and dissemination. The parties agree not to disclose the non-public information covered by the agreement. CDAs are commonly executed when two parties are considering pursing a relationship together and need to understand the other's processes, methods, or technology solely for the purpose of evaluating the potential for a future relationship. It is also referred to as a **Nondisclosure Agreement (NDA)**.

FAST: The Financial Administration Management System for financial transactions at the University of South Florida.

Internal Form: Form designed to streamline and improve the overall grant submission process; also referred to as **Electronic Proposal Authorization Form.**

Sponsor: The company, institution, individual donor, or organization responsible for the initiation, management or financing of a research study.

Sponsored research: Research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor. This includes clinical trials involving investigational drugs, devices or biologics.

PROCEDURE:

Pre-Award:

1. All CDA/NDAs received from sponsors/CROs must be submitted to OCR at OCR@health.usf.edu for timely processing.
2. OCR will route the CDA to USF Patents and Licensing (P&L) for negotiation and execution.
3. P&L will distribute the fully executed CDA to the site, the sponsor/ CRO and copy the OCR.
4. If PI decides to proceed with the new study, the PI or designee will submit the following four initial documents to the OCR:
    - Protocol
    - Draft consent form
    - Draft budget
    - Draft Clinical Trial Agreement (CTA)
5. Study staff should advise sponsor/CRO to send all contract, budget and protocol related correspondence to OCR@health.usf.edu
6. Upon receipt of the four essential documents, the contract and budget process will begin:
    - 6.1. An OCR business operations Contract and Budget Analyst (CBA) will open a study folder in the SharePoint PI Protocol eLibrary and add the study to Intake Tracking. The CBA will request additional documents if needed.
    - 6.2. The CBA will send the CTA to P&L for review, will insert USF required language, and will send the edited CTA to USF General Counsel (GC) for legal review. The OCR CBA will negotiate CTA language with the sponsor until the CTA contains language agreed upon by both parties.
    - 6.3. The CBA will send the Internal Form budget figures to the study team for initiation of the Internal Form.
    - 6.4. The CBA will review the protocol schedule of events and draft budget and will schedule a meeting with the study team to complete the New Study Questionnaire.
    - 6.5. The CBA will obtain vendor quotes and propose budget to the study team. The CBA will negotiate the budget with sponsor to agreed-upon terms.
    - 6.6. The CBA will review the IC document to ensure the compensation for subject injury language is in harmony with the CTA and the participant stipend amount is in agreement with the budget prior to the IC being submitted to sponsor by the study team pre-IRB submission.
    - 6.7. The CBA will initiate vendor contracts as needed.
    - 6.8. The CBA will combine the CTA and budget for an executable document. On receipt of final executable document from sponsor, the CBA will route to USF GC for legal stamp, then to PI, USF Sponsored Research (SR), and sponsor for signature.
7. The CBA prepares the GBR.
8. On receipt of both the fully executed CTA and IRB initial approval letter the CBA will send the Approval to Enroll (ATE) correspondence to the study team and affected departmental staff.
9. The CBA will enter the study in ClinCard Administrative portal, if applicable.

10. The CBA will send the project documents to SR to be set up in FAST and the CBA distributes the Research Award Notice (RAN) with the FAST chartfield string to the study team and affected departmental staff.
11. Study staff should advise sponsor/CRO to send any CTA or budget amendments to OCR@health.usf.edu

Post-Award:

12. The OCR fiscal operations staff will work with the PI and study teams as necessary regarding the fiscal aspects of the studies. They will ensure that study activity is being accurately entered into CTMS in real time or submitted monthly to OCRFM@health.usf.edu via study status logs (SSLs). CTMS data entry and OCR receipt of the SSLs trigger study related invoicing.
13. The fiscal staff will invoice sponsors for all aspects of industry sponsored clinical trial projects including study startup fees, IRB fees, and other study related costs when invoicing is required per the CTA/budget.
14. OCR fiscal staff will receive payments throughout the lifecycle of the study and post it to the project account.
15. OCR fiscal staff will track accounts receivable and follow up for outstanding payment.
16. ClinCard fiscal management will be handled by the OCR fiscal staff. This entails posting patient stipends and load and monthly service fees to the individual projects.
17. The OCR fiscal team will generate a monthly financial report and distribute to the PI,, affected staff within the department and to certain leadership positions within the Morsani College of Medicine.
18. OCR fiscal operations will be responsible for calculating and posting F&A (also known as indirects or overhead).
19. The OCR fiscal operations team is responsible for the closeout process for each study project.
    - To close out a project, OCR will ensure that all expenditures have posted and all earned revenue/payments have been received.
    - Residuals are rolled into the appropriate Research Initiative Account (RIA). Research Financial Management (RFM) does an analysis of all open projects that a PI has to ensure other projects are not in deficit prior to rolling residuals over to the appropriate RIA.
20. OCR fiscal staff will manage all the fiscal aspects of the OCR service fees including:
    - OCR's portion of the study startup fees
    - Nursing services fees
    - Regulatory support fees
    - Study coordinator support fees

REFERENCES:	ICH E6, 2.13 The Principles of ICH GCP ICH E6, 5.5 Trial Management, Data Handling and Record Keeping http://health.usf.edu/research/ocr/index.htm
RELATED	
APPENDICES:	Appendix F: Intake Flow; Appendix G: OCR Contract Process Flow;

REVISION HISTORY: Keep a running history of all revision dates.

Approval Date	Effective Date	Review/Revision Date
01/01/2015	**06/01/2015**	**06/15/2016**
05/10/2017	**05/10/2017**	**04/28/2017**