Agreements for Externally-Sponsored Clinical Research		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-210.3	Status: Final	Version Date: 10/11/2024 Effective Date: 10/18/2024

1. PURPOSE

This SOP outlines processes and procedures relating to agreements for sponsored research executed by VCU. This SOP applies to employees who submit, review, approve, or sign (execute) agreements necessary to conduct sponsored clinical research.

2. REQUIREMENTS

The Division of Sponsored Programs (DSP) is Virginia Commonwealth University's central office authorized to submit extramural proposals and receive awards from all funding sources on behalf of the University. DSP is also the official contact for the University on administrative award-related matters. Agreements also encompass contracts.

All research agreements involving VCU, VCU Health, research affiliates, and participating sites will be drafted, reviewed, and finalized in accordance with all such applicable regulations, laws, human subject requirements and policies and procedures as carried out by the VCU Division of Sponsored Programs (DSP) within the VCU Office of the Vice President for Research and Innovation (OVPRI).

Agreements for sponsored clinical research will comply with applicable legal, regulatory, ethical, VCU, and VCU Health standards.

Submission of documents to the VCU DSP is supported by the Research Administration Management System - Sponsored Programs Online Tracking (RAMS SPOT) system. In support of efficient contract review and accurate cycle timelines, submission of agreements should occur promptly following determination that the study is feasible.

3. DEFINITIONS

Master Agreement- An agreement in which the parties agree to most of the terms that will govern future transactions and/or agreements.

4. PROCESS

A. All agreements for sponsored research will be negotiated and administered by the DSP in the VCU OVPRI. The designated signatory for sponsored research agreements is held within DSP. The individual agreements reviewer that is asssigned by DSP is responsible for obtaining the appropriate authorized signatory, in accordance with the applicable policies.

B. Upon being contacted by a sponsor interested in contracting with VCU to conduct a research protocol, a signed confidentiality agreement will be required before protocol specific documents are released from the sponsor to VCU. The investigator or their designee must utilize the "Submit Document for Review" section of RAMS - SPOT system for electronic submission of the Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) to the Red Team in DSP for review, negotiation, as appropriate, and execution. A fully executed copy of the CDA/NDA will be uploaded in the RAMS-SPOT system.

C. Investigators should notify their coordinators and regulatory personnel of a potential study, provide relevant contact information for the sponsor/contract research organization (CRO), and provide the approximate date material is expected from the sponsor/CRO.

D. Upon receipt of the study material, study feasibility is assessed per school, department, or center requirements.

E. Once the decision to move forward with the study has been made, the budget should be drafted, the draft consent form should be uploaded into OnCore in accordance with DSP subject injury review procedures and the draft contract should be submitted through "Submit Document for Review" section in RAMS-SPOT to the VCU DSP for review. Funding proposals containing the approved Sponsor and internal budget information are submitted through RAMS-SPOT to DSP for compliance review and incorporation into the contract.

F. Use of an existing Master Agreement is preferred due to the efficiencies that this provides. Investigator or their designee should coordinate with DSP as necessary to confirm whether a master agreement is active for the sponsor/CRO or if there are any questions about which contract is appropriate.

G. Acquire signatures from the institutional authority, principal investigator, and sponsor for the final budget and contract.

H. Upon contract execution, DSP will upload a copy in the RAMS-SPOT system. Study coordinators may also need to file a copy in their study binder in accordance with Sponsor guidelines and provide a copy to their Department/School financial team, as appropriate.

I. In the event that the contract is not executed prior to the sponsor closing to enrollment, or the Sponsor decides not to pursue VCU as a site, the Study Team should work with their budget team and DSP contacts to pursue payment of start-up costs from the Sponsor/CRO.

5. REFERENCES

A. Code of Federal Regulations

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B. Good Clinical Practice

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) March 2018 ○ Section 5.1.4 Quality Assurance/Quality Control

C. VCU Policy

- VCU Policy - Corporate Research Agreements
- VCU Policy - Office of Sponsored Programs Responsibilities
- VCU Policy - Delegation of Signatory Authority

D. VCU Research Compliance Notices

- 15-004 Full Cost Recovery Guidelines for Clinical Research Initiated and Sponsored by Industry
- 20.007 Subject Injury Language Requirement and Review for Industry-Sponsored Human Subjects Research

E. VCU Resources

- VCU Sponsored Project Navigator
- VCU Division of Sponsored Programs
- DSP Subject Injury Review Process Guidelines
- VCU RAMS SPOT Login
- HRPP Policies and Guidance, HRPP Toolkit
    - HRP-309 - Ancillary Review Matrix

Review/Revision History CR-ST-210		
Version No.	**Effective Date**	**Description**
CR-ST-210.3		● Clarified clinical investigator definition ● Clarified who is responsible for forwarding the management plan to the external IRB ● Updated references ● Links updated ● Biennial review
CR-ST-210.2a	06-01-2020	● Links updated
CR-ST-210.2	06-01-2020	● Biennial review performed ● Reference links updated
CR-ST-210.1	08-27-2017	● Original