Study Feasibility		
VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-AD-115.4	Status: Final	Version Date: 08/23/2024 Effective Date: 10/18/2024

1. PURPOSE

The purpose of this SOP is to define the policies and procedures for assessing study feasibility at VCU / VCU Health, i.e., the decision on whether study participation is feasible.

2. REQUIREMENTS

For any non-oncology study utilizing VCU Health facilities, data, and / or patients, Protocol Review Oversight Committee (PROC) review (clinical, operational and facility feasibility) and approval is required. Oncology-related studies must obtain approval from the Protocol Review and Monitoring Committee (PRMC). Additional feasibility information (e.g., financial) and assessment may be required by the VCU department, school, or center as specified.

While there are no VCU-specific institutional directives/guidelines concerning the feasibility assessment for clinical studies not utilizing VCU Health facilities and/or patients, departments, schools, and centers may have specific feasibility processes and standards that must be followed. These feasibility assessments may include the practical, operational, and financial merits of conducting a clinical research study.

An investigator should recognize that each study protocol is different from other protocols within a certain therapeutic area; inclusion/exclusion criteria affect the recruitment rate, treatment comparisons may not be suitable, local ethical concerns may be critical and certain clinical investigations may not be possible to offer. A proper study feasibility assessment is crucial to avoid involvement in studies that may consume time, effort and resources without a reasonable return of investment (ROI). VCU offers TriNetX and ACT Network as resources supporting the evaluation of study feasibility, particularly in determining cohort discovery.

3. DEFINITIONS

Principal Investigator

The Principal Investigator (PI) is the individual with overall responsibility for the scientific, technical, financial, and regulatory direction and success of a project. The PI ensures that a project is carried out in compliance with federal, state, and local regulations and policies.

The PI may delegate some duties to key research personnel; however, the ultimate responsibility for the management of the project rests with the PI.

Protocol Review Oversight Committee (PROC)

The purpose of PROC is to review and approve a clinical study ensuring that the study can be operationalized. The review includes assessment of VCU and VCU Health clinical, operational, and facility feasibility. Where IRB review focuses on protection of human subjects, PROC review focuses on the feasibility of the study within the Health System.

Protocol Review and Monitoring Committee (PRMC)

The Protocol Review and Monitoring Committee (PRMC) conducts independent peer reviews to assess the scientific merit and progress of all clinical cancer research studies conducted at Massey. Initially, the relevant Disease Working Groups evaluate the study's value, feasibility, and prioritization. The study is then submitted to the PRMC, which determines its overall scientific merit and whether it should proceed to activation.

Sub-Investigator

An individual who is a member of the study team designated and supervised by the PI to perform critical study-related procedures and/or to make important study-related decisions.

4. PROCESS

- Prior to IRB submission of any study utilizing VCU Health facilities, data, and/or patients, the Principal Investigator or their designee must submit the study to the appropriate PROC/PRMC for feasibility evaluation.
- Submission for PROC review is completed through the VCU OneTrac platform.
- Refer to the current PRMC process for PRMC review
- Following PROC/PRMC review and approval, the Principal Investigator or their designee will receive notification that PROC/PRMC approval has been obtained; this approval is required for IRB submission.
- Any VCU Department, School, and/or Center feasibility requirements must also be completed as specified.
- The following study feasibility questions assist with informing whether a clinical study is suitable and has a high potential for success:
    - Is this protocol scientifically, practically, technically, and ethically feasible?
        - Is the protocol scientifically sound?
        - Has it been approved by a third party?
        - Has the protocol been approved by other ethics committees (ECs)/institutional review boards (IRBs)?
        - Can the protocol be conducted in compliance with the local authorities and requirements?

- Is the protocol consistent with local/international ethical practices (e.g., placebo control group)?
- Is the comparative investigational product available and used in standard practice?
- Has the study been evaluated in relation to the number of site visits, number of hours per visit, additional clinical investigations, etc.
- What is the influence on upcoming holiday periods on the participant site visits?
- Has the study budget been assessed, and regarded as reasonable and acceptable?

○ Do we have the participant population required for this protocol?
- Are the subject eligibility criteria realistic and well defined?
- Do we have competing clinical studies?
- Utilize the cohort discovery resources (e.g. TriNetX or ACT Network) in support of available and sufficient potential participant population.

○ Does the investigator have sufficient time to:
- Meet the participants?
- Supervise the research team?
- Ensure accurate completion of case report forms (CRFs)?
- Interact with the sponsor/monitor?
- Oversee all regulatory and sponsor requirements?

○ Are there sufficient human resources within the research team?
- Can the investigator delegate some of the clinical duties to SubInvestigator(s)?
- Can the investigator delegate significant aspects of the study to the study coordinator(s) or other appropriate research staff?
- Will the investigator be able to rely on a sufficient number of qualified clinical research professionals for the anticipated duration of the study?
- Have these clinical research professionals required for the study been identified?

○ Do we have access to the necessary facilities and equipment, or do we need specific equipment?
- Is there adequate working space for study personnel?
- Is there adequate space for participant recruitment and follow-up?
- Is there adequate space to securely store study records and clinical study material?
- Are the necessary study materials and equipment available on site?
- Is there adequate space for storage of the investigational product?
- Are the local laboratory facilities and other clinical services appropriate to support the protocol?
- Have communications and/or written agreements with other service providers been verified?
- Has the space required for monitoring and auditing been evaluated?

5. REFERENCES

A. VCU OneTrac PROC submission platform

B. TriNetx and ACT Network: cohort discovery platforms in support of determination for sufficient and adequate study specified participant population.

C. Code of Federal Regulations
- 21 CFR 312.60 – General Responsibilities of Investigators
- 21 CFR 812.110 – Specific Responsibilities of Investigators

D. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) March 2018
- Section 4.1 – Investigator's Qualifications and Agreements
- Section 4.2 – Adequate Resources

Review/Revision History – CR-AD-115

Version No.	Effective Date	Description
CR-AD-115.4	10/18/2024	• Added PRMC references • Updated PI definition • Links Updated • Reference links updated
CR-AD-115.3	06-01-2023	• Triennial review performed • PROC process added and outlined • Minor grammatical corrections • Links Updated
CR-AD-115.2a	03-01-2020	• Links Updated
CR-AD-115.2	03-01-2020	• Biennial review performed • Reference links updated
CR-AD-115.1	08-12-2017	• Original