Participant Research Complaints or Concerns		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-RE-330.3	Status: Final	Version Date: 02/11/2025 Effective Date: 03/14/2025

1. PURPOSE

The purpose of this Standard Operating Procedure is to establish the processes for addressing and responding to participant complaints related to research participation or research procedures.

2. REQUIREMENTS

Complaints and/or concerns related to research participation or research procedures that are received formally or informally from participants should be addressed in a timely and thorough manner per the IRB of record's policy and according to the requirements specified in the reliance agreement if IRB review has been ceded to an external IRB.

3. DEFINITIONS

N/A

4. PROCESS

A. All complaints should be taken seriously without consideration of potential severity.
   - All complaints and/or concerns should be addressed regardless of severity, in a timely manner, and with fairness, flexibility and thoroughness
   - Assure the participant that the study site is serious about handling all complaints and/or concerns and that there is a procedure in place to handle the complaint and/or concern.
   - The study site staff and clinical care personnel should try to resolve the complaint at the time it is received and inform the Principal Investigator about the complaint and/or concern in parallel.
     - If not able to be resolved by the study team, etc., the matter is to be addressed by the Integrity and Compliance Office.

   - The complaint and/or concern must be documented in the research file along with the measures taken to address the complaint and/or concern. Reporting of complaints and/or concerns should follow the IRB of record's policy about participant concerns/complaints..

5. REFERENCES

A. IRBs
- VCU HRPP Policies and Guidance - HRPP Toolkit
  - HRP–103 - Investigator Manual
  - HRP-103p - Investigator Manual p-site
- National Cancer Institute CIRB Policies
- WCG IRB Guide for Researchers
- Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsor's Representatives (See Reference Materials on CIRBI's platform; Login Required)
- Other external IRB Policies

B. VCUHS Policies (Policy Manager)
- Complaints and grievances from patients

Review/Revision History CR-RE-330

Version No.	Effective Date	Description
CR-RE-330.3	03-14-2025	• Clarified reporting complaints and concerns based on IRB of records policies • Biennial review performed • Minor formatting edits • Reference links updated • Updated to ICH E6(R3)
CR-RE-330.2a	07-01-2020	• Links updated
CR-RE-330.2	07-01-2020	• Biennial review performed • Minor formatting edits • Reference links updated
CR-RE-330.1	02-03-2018	• Original