Coverage Analysis

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-ST-215.3	Status: Final	Version Date: 10/11/2024 Effective Date: 10/18/2024

1. **PURPOSE**

The purpose of this SOP is to document the requirements and procedures related to a coverage analysis for all clinical research protocols at VCU/VCU Health.

2. **REQUIREMENTS**

The VCU/VCU Health Coverage Analysis process is required for all clinical research studies involving tests, procedures, or interventions associated with the clinical research study. Tests, procedures, or interventions include the administration of drugs, biologics, devices, procedures (to include venipunctures), or other services that have the potential of generating an invoice to a research participant or third party payer. The coverage analysis process:

- Must always be reviewed and approved by an *Institutionally-designated Coverage Analysis Specialist. Schools, centers, or institutes without an Institutionally-designated specialist must utilize the services of the School of Medicine for a fee.*
- Applies to all clinical research studies involving clinical services or items, regardless of funding source.
- Is based upon federal, state, and local policies, as the basis for determining coverage eligibility for clinical research study costs.

The coverage analysis process is a vital component of both the VCU and VCU Health research compliance program. A properly performed coverage analysis is necessary to protect the researchers and institution against violations of the False Claims Act and other federal regulations. Failure to comply with such regulations can lead to serious consequences for the investigator and the Institution, such as fines, loss of federal funding, loss of the ability to participate in clinical trials, accreditation issues, and potentially imprisonment.

3. **DEFINITIONS**

Clinical Research- Human subjects research that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. The definition includes:

- mechanisms of human disease
- therapeutic interventions
- clinical trials
- development of new technologies.

- Epidemiological and behavioral studies.

- Outcomes research and health services research.

4. **PROCESS**

- CMS National Coverage Decision 310.1 is the Centers for Medicare & Medicaid Services (CMS) National Coverage Decision for Routine Costs in Clinical Trials only allows for coverage of routine costs during a qualifying clinical trial. There is a set of criteria CMS requires which allows this qualifying status (refer to NCD 301.1). If the criterion is met, most routine care is usually billable to Medicare or a third party, if allowed by national and local coverage determinations.

  Medicare will not pay for:

  - Costs that are not considered routine care and therefore should be billed to the sponsor and paid for by the sponsor;
  - Items or services promised at no charge in the informed consent document;
  - Items or services not ordinarily covered by Medicare;
  - Items or services performed solely to determine trial eligibility; and
  - Items or services that are solely for data collection or analysis (serve no benefit to the participant).

  Routine Care includes:

  - Items or services that are typically provided absent a clinical trial (i.e Conventional Care)
  - Items or services required solely for the provision of the investigational item or service (i.e. administration of a non-covered chemotherapeutic agent)
  - Clinically appropriate monitoring of the effects of the item or service
  - Prevention of complications
  - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service

- Medicare Benefit Policy Manual (cms.gov) states Medicare may cover certain FDA-approved and Institutional Review Board (IRB) -approved investigational devices and services, such as:
  - Devices approved through the Pre-Market Approval (PMA) process;
  - Devices cleared through the 510(k) process;
  - Investigational Device Exemption (IDE) Category B devices; and
  - Hospital IRB-approved non-significant risk device

Medicare may also cover routine care items and services furnished in an FDA-approved Category A IDE study if certain IDE study criteria are met (refer to Medicare Benefit Policy Manual, chapter 14, section D).

- The VCU/ VCU Health Coverage Analysis process must be carried out and approved by the institution's *Coverage Analysis Specialists. Schools, centers, or institutes without an institutionally designated specialist must utilize the services of the School of Medicine for a fee.* A Coverage Analysis Billing Plan (plan for which payer is responsible for which clinical services over the lifetime of the study) will be developed by the Coverage Analysis Specialist with input from the study team, including the Principal Investigator, for the designation of "routine" or "research" for each assessment or procedure required for the study. The final billing plan is entered into OnCore (the VCU Clinical Research Management System). This electronic record becomes the official plan for ensuring billing compliance over the course of the study.
    - Any time a protocol is amended and changes are made to billable items or services, the Coverage Analysis will be reviewed, and the billing plan will be modified if necessary. Changes will be communicated to the study team, and the revised billing plan will be entered into OnCore.

5. **REFERENCES**

A. Centers for Medicare and Medicaid Services
- CMS Pub.100-03 Medicare National Coverage Determination Manual
- CMS Pub.100-02 Medicare Benefit Policy Manual
- The U.S. CMS National Coverage Determination for Routine Costs in Clinical Trials §310.1

B. US Federal Regulations
- The Patient Protection and Affordable Care Act (42 United States Code 300GG-8 – Coverage for Individuals Participating in Approved Clinical Trials);

C. The Code of Virginia
- §38.2-3418.8 – Coverage for Clinical Trials for Treatment Studies on Cancer ● §38.2-3453 – Clinical Trials.

D. VCU Research Compliance Notice
- 16-002 Clinical Research Coverage Analysis

E. IRB
- HRPP Policies and Guidance, HRPP Toolkit
    - HRP-309 - Ancillary Review Matrix

Review/Revision History CR-ST-215		
Version No.	**Effective Date**	**Description**
SOP No.: CR-ST-215.3	10/18/2024	● Updated the definition of Clinical research to align with VCU standard SOP definition ● Added what type of procedure Medicaid will and will not pay for ● Updated title to align with DSP wording ● Added additional references and edited existing references ● Reference links updated
CR-ST-215.2a	06-01-2020	● Links updated
CR-ST-215.2	06-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-ST-215.1	09-08-2017	● Original