

System-wide Policy: Research Site Responsibility for Identification of Items and Services Paid by Research

Reference #: SYS-ADMIN-RA-203.00

Origination Date: February 26, 2004
 Next Review Date: November 2027
 Effective Date: **December 2024**

Approval Date: December 9, 2024
Approved By: Research Advisory Council (RAC)

System-wide Policy Ownership Group: Research Operations
System Policy Information Resource: Research Operations Manager

Stakeholder Groups
Research Administration
Research Integrity
Research Directors

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to (MD, NP, Administration, Contractors etc.)
System Wide; Allina Health Group; Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, Faribault Medical Center, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital; Allina Health Emergency Medical Services, Courage Kenny, West Health Rehabilitation Services; Allina Health System Office; All other business units	All	Any person or entity, internal or external, intending to conduct research within an Allina Health facility

POLICY STATEMENT:

It is the policy of Allina Health to establish responsibilities for the identification and removal of items and services from research visit Personal/Family (P/F) accounts that are research responsibility or otherwise non-billable to third party payers according to applicable laws, regulations, or contracts.

Research site and principal investigator (PI) have primary responsibility for the identification of services that are billable to patient/patient insurance as standard of care (SOC) and services that are research responsibility according to all applicable laws, regulations and contracts for the research being conducted.

DEFINITIONS:

Research Vendor Account - account assigned to the research site, by Study, where all research charges, hospital or professional, are applied, and balance is payable by research site.

Medicare Coverage Analysis ("MCA") - Allina Health documentation of billing or non-billing (not allowable) determination for clinical research services performed per research protocol(s) at Allina Health facilities. Includes a detailed review of all research study protocol events where all billable items and/or services that occur within the study protocol are either billable or non-billable using Medicare qualifying clinical trial criteria (CMS NCD 310.1), other, applicable CMS NCDs or LCDs, or standard clinical practice support. All protocol directed services identified in documentation as one of: standard of care ("S"), research ("R") or otherwise non-billable ("NB").

Schedule of Events ("SOE") - Alternate documentation to the MCA, accepted in certain study situations per Research Operations/OSP process. Similar to the MCA, at minimum, it documents in table form all billable, clinical items and services related to the study to be provided at Allina Health facilities, timeline of the services, and the research site/PI billing determinations. Unlike the MCA, it does not include Medicare or other payer coverage assessment for each line item. Required by OSP when MCA is not required, but there are still billable services related to the study.

PROCEDURES:

As part of the project submission to Research Operations, research sites or delegate identify each item or service, required by the Study protocol, as either billable to patient or patient insurance as standard of care or research responsibility per a Medicare Coverage Analysis (“MCA”) or if applicable, Research Operations approved Schedule of Events (“SOE”) and in accordance with [Research Billing SOP Manual](#), and applicable billing regulations.

All research-related visits at Allina Health are linked to the applicable Study by research site.

When a research patient receives items or services at an Allina Health facility, any item or services identified from the patient visit as research responsibility, per [Research Bill Review Process](#), will be removed from the P/F account and placed on the Research Vendor Account.

Allina Health reserves the right to monitor or audit the research patient visits and the selection of billable and research responsibility services at any time.

REFERENCES:

Related Regulation and Laws:

[Medicare Clinical Trial Policy](#)

[Medicare Benefit Policy Manual: Chapter 14 – Medical Devices](#)

RELATED POLICIES:

Name of Policy	Content ID	Business Unit where Originated
Research Billing Compliance	SYS-ADMIN-RA-200.00	Research Operations
Requirement for Complying with the Research Operations Review Process	SYS-ADMIN-RA 201.00	Research Operations
Research Agreements and Contracts	SYS-ADMIN-RA-202.00	Research Operations
Research Pricing Policy	SYS-FIN-101-19	Finance Council

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
Research Site Responsibility for Identification of Non-Billable Items and Services	RES 303.00	Office of Sponsored Programs