



System-wide Policy: Research Site Responsibility for Identification of Non-Billable Items and Services

Reference #: SYS-ADMIN-RA-203.00

Origination Date: February 26, 2004
 Next Review Date: November 2024
 Effective Date: **November 2021**

Approval Date: November 10, 2021
Approved By: Research Oversight Committee (ROC)

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, District One Hospital, 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 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 accounts that are 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 billable and non-billable services according to all applicable laws, regulations and contracts for the research being conducted.

DEFINITIONS:

Research Visit Charge Report – report generated from Allina Health billing system detailing all patient visit items and services charged to the patient’s account.

Research Study Account – Hospital (“HB”) or Professional (“PB”) account assigned to the research site by Study where all research charges are applied and balance is payable by research site.

PROCEDURES:

As part of the project submission to Research Operations, research sites or delegate identify billable and non-billable items and services per a comprehensive Coverage Analysis in accordance with Research Operations Review Process and applicable billing regulations.

When a research patient receives items or services at an Allina Health facility, any item or services identified on Research Visit Charge Report as research and non-billable is considered by Allina Health to be billable to research site or PI. Allina Health will remove the identified non-billable services from the patient account and transfer to a Research Study Account, billable to research site or PI.

Allina Health reserves the right to monitor or audit the research patient visits and the selection of billable and non-billable 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