



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: July 2021
Effective Date: **July 2018**

Approval Date: July 10, 2018
Approved By: Research Oversight Committee (ROC)

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

Stakeholder Groups
Research Administration
Integrity & Compliance Department
Research Site Directors/Managers

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to (MD, NP, Administration, Contractors etc.)
System Wide	Research Operations and research sites	Any person or entity, internal or external, intending to conduct research within an Allina facility

POLICY STATEMENT:

It is the policy of Allina to establish responsibilities for the identification and removal of items and services from Allina research participant visit accounts that are non-billable to Medicare, Medicaid, or other governmental 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 Detail Charge Report – report generated from Allina’s billing system detailing all patient visit items and services charged to the patient’s account.

Research Vendor Account – vendor account assigned to the research site where all research charges and research discounts are applied and balance is payable by research site.

PROCEDURES:

As part of the project submission to Research Operations, research sites or delegate identify non-billable items and services in eProtocol and in accordance with applicable billing regulations.

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

Allina 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

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

