System-wide Policy: Requirement for Complying with the Research Operations Review Process

Reference #: SYS-ADMIN-RA 201.00

Origination Date: September 11, 2001
Next Review Date: March 2024
Effective Date: March 2021

Approval Date: **March 24, 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:
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, Allina Health System Office; All other business units	All	Any person or entity, internal or external, intending to conduct research within an Allina facility

POLICY STATEMENT:
It is the policy of Allina Health that research or situations meeting one of the following criteria must be submitted to Research Operations for review:

- An Allina entity provides items or services related to a research project;
- Research conducted by an Allina employee or department and there is a contract/agreement with a study sponsor;
- Use of an investigational drug or medical device within an Allina facility;
- Research with an approved medical device that is new within Allina. "New" is defined as: any product that has not been used at the affected Allina facility, including new generations of products that *have* been used at an Allina facility;
- Use of a humanitarian use device;
- Use of a device or drug for compassionate or emergent use under FDA Expanded Access or;
- Research Operations determines the project must be submitted**.**

Note: This policy is not related to the Allina Internal Review Board (IRB) review policy and does not initiate IRB review.

PROCEDURES:
Research Operations will:

1. Develop and maintain the Research Operations review process
2. Provide guidance and support to the Research Operations review process and requirements

Research Sites are responsible for:

1. Submission to Research Operations through the eProtocol online submission system according to the eProtocol User Guide, and
2. Adhering to the Research Linking and Billing Workflows, Use of Excellian Functionality for Research, and other Research Operations Procedures for Researchers.

DEFINITIONS:
Research Site: Allina Health business unit or external entity responsible for the conduct of the research.

Humanitarian Use Device (HUD):Device approved for use by FDA via Humanitarian Use Exemption (HDE) per 21 CFR 814 Subpart H

Expanded Access (e.g., Compassionate or Emergency Use) Device:Meets criteria of FDA Expanded Access for Medical Devices

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
Research Billing Compliance	SYS-ADMIN-RA-200.00	System-wide
Research Agreements and Contracts	SYS-ADMIN-RA-202.00	System-wide
Research Site Responsibility for Identification of Non-Billable Items and Services	SYS-ADMIN-RA-203.00	System-wide

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
Requirement for Complying with Sponsored Projects Review Process	RES 300.00	Office of Sponsored Programs