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: June 2027
Effective Date: June 2024

Approval Date: 6/10/2024
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:
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 facility

POLICY STATEMENT:
It is the policy of Allina Health that any research effort or events meeting one of the following criteria must be submitted to Research Operations for review and approval in advance:

- An Allina entity providing items or services related to a research project;
- Research conducted by an Allina employee or department for which there is a contract/agreement with a study sponsor;
- Use of an investigational drug or medical device within an Allina facility;
- Research with an FDA approved medical device that is new within Allina. "New" means any product that has not been approved for use at Allina Health by its Non-Labor Supply Committee, including new generations of products;
- 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.

Notes:
This policy is not related to the Allina Health HRPP/IRB Standard Operating Procedure https://akn.allinahealth.org/integrityandcompliance/HRPP%20and%20IRB%20Documents/Allina%20Health%20HRPP%20IRB%20SOPs.pdf#search
This process 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 including but not limited to: eProtocol submission and review, billing compliance review, research pricing review, IDE review and set-up, coordination with Allina Health Lab and Pharmacy review, research billing reviews and payments.
3. Complete the review and decision for approval.

Contact: OSPBilling@allina.com

Research Sites are responsible for:
1. Submission to Research Operations through the eProtocol system. Reference: eProtocol User Guide, and Use of Excellian Functionality for Research.
2. Secure Research Operations approval prior to implementation of the research-related effort. Reference: Research Linking and Billing Workflows, and other Research Operations Procedures for researchers.

DEFINITIONS:
Research Site: Allina Health business unit or external entity responsible for 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