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

Approval Date: **July 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:
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 that research or situations meeting one of the criteria below 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 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 Operations Review and Billing Guide.

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	Research Operations
Research Agreements and Contracts	SYS-ADMIN-RA-202.00	Research Operations
Research Site Responsibility for Identification of Non-Billable Items and Services	SYS-ADMIN-RA-203.00	Research Operations

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