Allina Health

System-wide Policy:

Use of the Excellian (Epic) Research Functionality

Reference #: SYS-ADMIN-RA-001

Origination Date: December 2015
Next Review Date: May 2022
Effective Date: May 2019

Approval Date: **May 2019**
Approved By: **Research Oversight Committee**

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

Stakeholder Groups
Human Research Protections Program (HRPP)
Compliance / Privacy Office
Research Oversight Committee
Health Information Management (HIM)
Health Information Privacy & Security (HIPS) Committee
Research Directors Roundtable
Research Operations
Clinical Research Informatics and Analytics

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital, Unity Hospital, WestHealth Inc., Orthopedic Institute Surgery Center, Allina Health Group, Allina Health Home Care Services, All other patient care business units, System Office	All departments, divisions, and operational areas	Any person or entity, internal or external, involved in the conduct of research at an Allina facility.

POLICY STATEMENT:

All interventional studies or studies where Allina Health services are received and those services are billed to sponsors or grants, are required to have a research study record created in Excellian. These studies will utilize the Excellian (Epic) research functionality. For the remainder of this policy, these studies are referred to as: "ERF Applicable Studies".

ERF Applicable Studies are entered into Excellian per the Excellian RSH Study Record Build Process

Patients are scheduled at Allina Health per normal scheduling processes within each Allina Health facility.

For all ERF Applicable Studies, Allina Health will associate enrolled subjects to research study record in Excellian.

Relevant Stakeholders must follow the appropriate Research Linking, Billing Review and Charge Correction Workflows.

Exclusions: The following study types are not required to use the research functionality: Studies that have been granted a full waiver of consent by an Institutional Review Board ("IRB"), i.e., no consent is obtained from the subject for participation in the study;

Opt Out Options or Modification(s) to study information:

In some circumstances, ERF Applicable Studies may use a modified study description or Principal Investigator (PI) may petition for opt out of using the ERF.

These circumstances include:

1. If the PI believes use of the research functionality it is not appropriate.
2. If a study involves sensitive and confidential information, (e.g. AIDS/HIV, reproductive health, mental health, or genetic testing).
3. If the study is operating under a Certificate of Confidentiality, generic language must be used in the study description or the PI may petition to opt-out of using the research functionality.

Researchers seeking an Opt Out or Modification must contact Allina Human Research Protections Program ("HRPP") and Office of Sponsored Programs ("OSP") on whether opting out is appropriate.

Opt In Option: If a study does not meet the above criteria for use of the ERF, but the PI believes the study would benefit from its use, the PI may petition to opt in to use the ERF.

The Allina HRPP and OSP has final authority for determining whether the use of the research functionality is required or excluded.

Adding Required Language to Informed Consent:

For studies where Allina Health is engaged in the research and that meet the criteria for use the research functionality, the following language must be included in the confidentiality section of the Research Informed Consent Form (ICF):

> *"Your participation in this study will be documented in Allina Health's electronic medical record system. This documentation provides health care providers with basic information about the study and information so that they can contact the study team to learn more, if important for your care. It can also be used by the study team and Allina Health Research Administration to assist with administrative processes such as tracking enrollment and participation in the study.*

For research where Allina is not engaged, the IRB of record has final approval authority over the ICF language.

Research where Allina is engaged, Allina HRPP have final approval authority over the ICF language.

DEFINITIONS: Privacy & Security Glossary of Terms

Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive health-related research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Electronic health record (EHR) refers to Excellian which is Allina Health's brand name for the Epic electronic medical record system.

Engaged in research - In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the

informed consent of human subjects for the research. (from OHRP Guidance on Engagement of Institutions in Human Subjects Research)

Epic research functionality ("ERF") refers to EHR tools that provide the ability to have an individual research study built into the EHR and allows the researcher to link patients, encounters, and orders to that study. Once a patient is linked and active in the study, a banner will appear in the patient's chart header alerting providers that the patient is participating in a research study. The research functionality facilitates reporting and billing processes.

Interventional Study - A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. (from ClinicalTrials.gov)

Intervention/treatment - A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise. (from ClinicalTrials.gov)

PROCEDURES:

Excellian RSH Study Record Build Process

Opt Out and Opt In Petition Process:

1. Investigator or designee should email the Research Operations (add email address) and irb@allina.com with the eProtocol study # (if available), IRBNet #, full study title, PI name, and a description of the basis for requesting an opt out or opt in.

2. The petition will be reviewed and a determination made by HRPP and OSP in consultation with others as needed.

3. For guidance regarding whether a study should be considered sensitive or confidential and/or whether a petition for opting out should be submitted, please email your questions to Allina Human Research Protections Program via irb@allina.com.

FORMS: Not applicable.

ADDENDUM:

Excellian Functionality for Research Studies - e-Learning & Reference Guide

PROTOCOL: Not applicable.

ALGORITHM: Not applicable.

FAQs: Not applicable.

FAQs: Not applicable.

REFERENCES:

Related Regulation and Laws: N/A

Alternate Search Terms: N/A

RELATED POLICIES:

Name of Policy	Content ID	Business Unit where Originated
Research Billing Compliance	SYS-ADMIN-RA-200.00	Research Operations
Research Site Responsibility for Identification of Non-Billable Items and Services	SYS-ADMIN-RA-203.00	Research Operations
Allina Health Research Pricing	SYS-FIN-FCouncil—01-19	Research Administration

POLICIES REPLACING:

Name of Policy	Content ID	Business Unit where Originated
N/A		