System-wide Policy: Research Agreements and Contracts

Reference #: SYS-ADMIN-RA-202.00

Origination Date: August 7, 2000

Next Review Date: June 2027
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Approval Date: June 10, 2024
Approved By: **Research Advisory Council (RAC)**

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

Stakeholder Groups
Research Administration
Legal and Risk Services
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 Health facility or using Allina Health patient data for research.

POLICY STATEMENT:

It is the policy of Allina Health to have a written agreement or contract for research activity requiring the use of Allina Health personnel, items, patient data, services, or space as outlined in this policy.

All research conducted within Allina Health must be submitted to Research Contracts for review in accordance with Research Operations Policy 201.00.

For research managed in whole or in part by Allina Health, where Allina Health is receiving or providing study personnel, items, patient data, services or space, any related agreements and contracts and any amendments must be submitted to Research Contracts for review and execution. See list of types of agreements involving research at the end of this policy.

Any agreement or amendment to an agreement that involves a Provider (as defined in Policy 100-1) will be negotiated, executed, managed and terminated consistent with Allina Health Provider Arrangements Policy 100-1.

DEFINITIONS:

Non-Allina Research: Research is conducted and managed wholly by a non-Allina Health entity.

- In general, if Allina Health personnel are only providing clinical trial-related medical services typical to those normally administered in the ordinary course of work (i.e. administer a radiology exam, draw blood sample, implant a medical device, etc.), then Allina Health is not considered part of the study conduct or management.

Allina Research: Research is conducted or managed in whole, or in part, by Allina Health personnel.

- For purposes of this policy, “conduct or managed” includes, but is not limited to: patient consenting, completing research case forms, administering research drugs or devices, receipt of industry or government awards through grant, contract or cooperative agreement.

PROCEDURE:

Required Agreement(s) for Non-Allina Health Research

Prior to the start of any services or use of facilities at Allina Health, the research site must have a fully executed:

- (MPSA) for Research and associated Work Order, or
- equivalent agreement approved by Research Contracts.

Required Agreement(s) for Allina Health Research

Allina Health Research – Industry or non-profit Funded

A clinical trial agreement or other similar type of agreement must be fully executed between Allina Health and the sponsor of the research project.

The sponsor's agreement must be submitted to Research Contracts for review in accordance with the *Research Operations Clinical Trial Agreement (CTA) Review Process*. The agreement terms will be negotiated in compliance with the *Allina Health Clinical Trial Agreement (CTA) Guidelines*.

Allina Health Research – Government Funded

Allina may need to execute an agreement with a government entity (or a primary awardee) which may include a prime award or sub-award agreement.

The agreement must be reviewed according to the Research Operations Government Award policies and procedures.

Allina Health Research – Allina Health or Allina Foundation Funded

An agreement is required if either 1) the research requires the services of a non-Allina person or entity or 2) data will be shared with a non-Allina person or entity.

Research Contracts will assist researcher(s) in determining the appropriate agreement(s) upon review of the research study details.

Investigator-Initiated Research ("IIR") from External Principal Investigators

Research Contracts will assist researcher(s) in determining the appropriate agreement(s) upon review of the research study details.

Research Involving Data Sharing

If services or facilities are not being used and Allina Health is only sending or receiving Allina Health patient data, a data sharing agreement may be required.

See Related Policies for more information.

Research Involving Material Sharing

If services or facilities are not being used and Allina Health is only sending or receiving Allina Health patient biological materials, a material transfer agreement may be required.

Research Agreement Approval and Execution

Research Contract staff will facilitate and manage research agreement execution, unless otherwise delegated.

Signatures for research agreements are obtained in accordance with Allina Health Policies and Procedures.

Types of Agreements used for Research Engagements:

Business Associate Agreement (BAA): Agreement between Allina Health and its business associate which provides written assurances relating to the privacy and security of protected health information used, disclosed, or accessed by the business associate. A "business associate" is a person or entity that performs certain activities that involve the use or disclosure of protected health information on behalf of, or provides services to, Allina Health. Allina employees are not business associates.

Clinical Trial Agreement (CTA): Agreement between a sponsor of a clinical trial, such as a drug or device manufacturer, and an institution like Allina Health.

Clinical Services for Research: Agreement between Allina Health and a provider for clinical services required under a research study which Allina Health cannot provide (e.g., radiology services). Allina Health pays the provider.

Confidentiality and/or Non-Disclosure Agreements: Agreement between Allina Health and the sponsor of a clinical trial that outlines the terms for disclosure of sponsor's confidential information. NOTE: Not required to be reviewed by Research Contracts, however will review if requested.

Data Sharing/Transfer/Use Agreements: Agreement between Allina Health and another entity for transfer or sharing of Allina Health patient data for research (classified as one of: a limited data set, identifiable, or de-identified). Agreement may be stand-alone or in combination with another research agreement (e.g., CTA).

External Access Agreement (EAA): Agreement between Allina Health and an external business user (EBU) granting EBU access to Allina Health information systems. An **Information Systems Access Agreement for Research** is an EAA used specifically for clinical trial sponsors to access Allina Health information systems (e.g., Epic) for the purpose of study monitoring done remotely.

Facilities Agreement: Agreement between Allina Health and research study sponsor where Allina Health is not participating in the research other than to provide access to facility for research services.

Government Award or Sub-Award Agreements: Agreement between Allina Health and a government entity/agency or a pass-through entity for a government award (e.g., University). Allina Health generally provides services for an established amount plus indirect costs.

Investigator Service Agreements (ISA): Agreement with a provider or provider group for principal investigator services related to research.

Material Transfer Agreement (MTA): Agreement that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for its own research purposes.

Non-clinical Services Agreements w/physician or physician owned entity (Independent Contractor): Agreement between Allina Health and a physician/provider entity for non-clinical services required under a research study (e.g., consulting services, research leadership agreement). Allina Health pays the contractor.

Non-clinical Services for Research with non-physician/non-provider (Independent Contractor): Agreement between Allina Health and a non-physician/non-provider entity for non-clinical services required under a research study which Allina cannot provide (e.g., consulting services). Allina Health pays the contractor.

Purchased Service Agreements (or Master Purchased Service Agreement): Agreement between Allina Health and an external research entity (may or may not be provider-owned) for Allina Health to provide clinical or other services required under a research study. External research entity pays Allina Health.

Research Membership Agreements: Agreement between Allina Health and a consortium or non-profit entity.

Software License/Use Agreement (SLA/SUA): Agreement between Allina Health and a software provider for Allina Health's license, use, and/or access to external company's software.

Subrecipient Services Agreement (SSA): Agreement between Allina Health and a contracting entity (may or may not be provider-owned) for services to be provided under the requirements of a government award. Allina Health is passing down some or all of the requirements of the award and compensation for the execution of specific services under the award to a contractor.

NOTE: If there is a research agreement that is not listed above, send to Allina Health Office of Sponsored Programs (Research Contracts) to determine if review is required.

RELATED POLICIES:

Name of Policy	Content ID	Business Unit where Originated
Requirement for Complying with the Research Operations Review Process	SYS-ADMIN-RA-201.00	System-wide
Provider Arrangements Policy	SYS-Admin-Legal-100.01	–System-wide

Use and Disclosure of Protected Health Information for Research	SYS-ADMIN-RA-005	System-wide
Procedure: De-Identification of Patient Health Information	SYS-PSC-705	Privacy Compliance
Procedure: Limited Data Sets: Patient Health Information	SYS-PSC-706	Privacy Compliance

POLICIES/DOCUMENTS REPLACING:

Name of Policy	**Content ID**	**Business Unit where Originated**
Written Agreements and Contracts for Research	RES 301.00	Office of Sponsored Programs