

## System-wide Policy: Research Agreements and Contracts

### Reference #: SYS-ADMIN-RA-202.00

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**Approval Date:** July 2018  
**Approved By:** Research Oversight Committee (ROC)

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

Stakeholder Groups
Research Administration
Legal and Risk Services
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 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 when research conducted within Allina Health utilizes Allina Health personnel, items, services, and/or space as outlined in this policy.

All research conducted within Allina Health must be submitted to the Research Operations 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, data, services or space, any related agreements and contracts and any amendments must be submitted to Research Operations 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 physicians or staff are only providing clinical trial-related medical services typical to those normally administered in 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 physicians and/or staff.

For purposes of this policy, “conduct or managed” include, but is not limited to: patient consenting, completion of research case forms, administration of research drug or device intervention, receipt of government award through grant, contract or cooperative agreement.

## PROCEDURE

### Required Agreement(s) for Non-Allina Research

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

- Master Purchase Service Agreement (MPSA) and associated Work Order, or
- equivalent agreement approved by Research Operations and Legal,

and signed by the appropriate parties.

### Required Agreement(s) for Allina Research

#### Industry or non-profit Funded

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

The sponsor's agreement must be submitted to Research Operations 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 Research – Government Funded

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

Agreement will be reviewed according to the Research Operations Government Award policies and procedures.

#### Allina Research – Allina 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 Operations 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 is instead only providing data for research purposes, a data sharing agreement may be required.

See [Related Policies](#) for more information.



## **Research Agreement Approval and Execution**

Unless delegated by Research Operations contract staff, Research Operations will facilitate research agreement execution.

Allina Health authorized signatures for research agreements are obtained in accordance with Related Policies, procedures and processes.



## Types of Agreements Involving Research:

**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.

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

**Clinical Services for Research** – agreement between Allina Health (dba business unit) and a provider of clinical services for services required under a research study for which Allina cannot provide (i.e., radiology services agreement). Allina Health pays the provider.

**Confidentiality and/or Non-Disclosure Agreements** – between Allina Health and the sponsor of a clinical trial that outlines the requirements for sharing and disclosure of sponsor's confidential information. NOTE: Not required to be submitted to or reviewed by Research Operations.

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

**External Access Agreement (EAA)** – between Allina Health and external business user (EBU) for terms of EBU access to Allina information systems.

**Government Award or Sub-Award Agreements** – between Allina Health and a government entity/agency or an entity that is pass-through for government award (i.e., university). Allina Health will provide services for an established amount of awarded funding.

**Independent Contractor Clinical or Non-clinical Services Agreements w/physician or physician owned entity\*** - agreement between Allina (dba business unit) and a physician/provider entity for non-clinical services required under a research study for which Allina cannot provide (i.e., consulting services, research leadership agreement). Allina Health pays the contractor.

\*Exception: If managed through Division of Applied Research (DAR), does not require Research Operations review.

**Independent Contractor Clinical or Non-clinical Services for Research with non-physician/non-provider** - agreement between Allina (dba business unit) and a non-physician/non-provider entity for non-clinical services required under a research study for which Allina cannot provide (i.e., consulting services ). Allina Health pays the contractor.

**Investigator Service Agreements (ISA)** – agreement with a provider or provider group for principal investigator services related to research.



**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 services required under a research study. External research entity pays Allina Health.

**Research membership agreements** – between Allina Health and a consortium or non-profit entity

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

**Subrecipient Services Agreement (SSA)** – 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 Operations) 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	Research Operations
<a href="#">Provider Arrangements Policy</a>	SYS-Admin-Legal-100.01	System Office - Legal
<a href="#">Use and Disclosure of Protected Health Information for Research</a>	SYS-ADMIN-RA-005	Research Administration
Procedure: <a href="#">De-Identification of Patient Health Information</a>	304-P-13	Privacy Compliance
Procedure: <a href="#">Limited Data Sets: Patient Health Information</a>	304-P-14	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