Conducting Research at Allina Health:

A Handbook for Researchers

Allina Health

Advancing health outcomes through research

January 2025

Purpose & Goals

This handbook is designed to guide researchers and provide resources related to conducting research at Allina Health with the following goals:

- To provide guidance for researchers in the development, administration, and oversight of projects,
- To inform Principal Investigators of their role and responsibilities in project administration and research compliance, and
- To organize information and available resources pertinent to project administration and enhance the accessibility of this information.

Getting Started with Allina Health Research

The list of steps below does not represent a linear process for conducting research at Allina Health but a general timeline for making connections, the demonstration of available services and resources, and getting started with processes required for research at Allina Health. Several of these steps may be initiated concurrently following this general order. Reach out to any department with questions on their processes, timelines, and requirements for your specific research project. General questions and comments about this handbook can be directed to the IRB Office (irb@allina.com).

- Connect with a Research House or Research Council
- Review and Request Services from Clinical Research Informatics and Analytics (CRIA)
- Reach out to Research Grants & Finance for Sponsored Projects
- Contact Research Contracts to Review any Research Contracts and Agreements
- Work with Research Integrity for IRB Approval, Conflicts of Interest, and Human Research Protection
- Submit Interventional Studies and/or Studies with Billable Services to the Office of Sponsored Programs – Research Billing

Research Houses and Scientific Review Councils

Essential Information

Research at Allina Health is organized into clinically focused research houses. This structure aligns with and supports the strategic mission of Allina Health Research Clinical Service Lines.

The research houses at Allina Health have established councils that review and authorize research taking place under the purview of their research house and associated Clinical Service Line. Research councils certify that there is appropriate support for a proposed project, the scientific and ethical oversight of the project will be adequate, and that the project features sound research design that may yield the expected knowledge.

The established research councils and houses below have contact information for a person who can provide information and guidance for conducting research within a research house or submitting research to a council for review.

Allina Health also has a Multidisciplinary Research Council (MDRC) for Allina Health researchers from various departments that may not have a research house. Establishing connection with a research house or council is a preliminary step for conducting research at Allina Health.

Contact Information for the Allina Health Research Councils

AHCI Scientific Protocol Review and Management Committee	Sarah Pederson
MHIF Research & Data Committee	Lisa Tindell
Critical Care, Hospitalist & Medical Education Research Council	Summer Martins
Mother Baby Research Council	Abbey Sidebottom
Emergency Medical Services (EMS) Research Council	Lori Boland
Neuroscience, Spine, and Pain Institute Research Council	Marie Meyer
Mental Health and Addiction Services	Marie Meyer
Nursing Clinical Inquiry and Research Council (NCIR)	Stephanie Edmonds
Orthopedics Institute Research Council	Ned Tervola
Courage Kenny Research Council	Katy O'Brien
Multidisciplinary Research Council (MDRC)	Summer Martins

Clinical Research Informatics and Analytics (CRIA)

Essential Information

Contact: ResearchAnalytics@allina.com

The mission of the CRIA team is to apply the science of information management to enable the effective and efficient execution of clinical research, including clinical trials, observational studies, and outcomes research. CRIA analysts assist researchers with data requirements, perform queries for feasibility and preparatory to research (prep to research) activities, and provide data for clinical research studies and projects, mostly extracted from the electronic medical record. CRIA also has statisticians who can consult and collaborate with researchers regarding statistical design and analysis, as well as interpretation of results and writing.

CRIA also manages two large federally sponsored research programs. The national Patient-Centered Outcomes Research Institute (PCORI) supported Great Plains Collaborative Clinical Research Network (GPC) provides access to broad databases and research opportunities for our provider-scientists to analyze current Allina Health common data modules or expand their research scope by partnering with other GPC members. We are also members of the Minnesota Electronic Health Records Consortium (MNEHRC) which provides data to the Minnesota Department of Health in support of resource allocation statewide and provides opportunities for researchers to participate in state and federal sponsored research efforts.

CRIA Services

CRIA provides various support services to researchers from the development and feasibility stage to data collection and the interpretation of results.

Budget Estimates for CRIA Services

CRIA can provide completion time estimates and cost estimates to assist with budgeting and seeking grants for researchers using CRIA services.

Prep to Research

When Principal Investigators (PIs) are trying to determine if they should participate in or originate a study, a prep to research request can help determine if Allina Health has a certain population base for a study, determine eligibility of patients, and more.

Data Extraction

CRIA Analysts assist researchers with data extractions from the electronic medical record. Analysts review the protocol and IRB approval, determine of data sharing or data transfer contracts are needed, determine the variables needed for statistical and data analysis, and electronically extract data for studies.

Statistical Analysis and Consultations

If PIs do not have a statistician available for their study, a CRIA statistician can provide support. Before data collection, CRIA statisticians design the study's statistical analysis based on the study goals (e.g., decisions about data analysis, determining optimal sample size, conducting power analysis), discuss randomization schemes and create randomization schedules, and write the statistical analysis portion of protocols and grants.

Following data collection, CRIA statisticians can analyze data using descriptive statistics and tests of significance, evaluate the study's hypotheses using regression models, matching, or weighting techniques, or other appropriate methods, conduct supervised or unsupervised machine learning with predictive goals, and help interpret results and write methods and results sections of manuscripts.

Getting Started: Requesting CRIA Services

CRIA can receive requests for services in various ways. PIs can contact CRIA and describe their project, including any attachments such as the protocol, IRB approval, and data collection sheets.

There is also an online request form. The same request form can be found on the AKN by selecting Allina Health > Allina Health Research > Research Administration and selecting Allina Health REDCap. When filling the form, include all relevant documentation, if available.

Quick Tips

- When communicating with CRIA, be as specific as possible regarding data parameters and inclusion and exclusion criteria, study goals, and deadlines.
- Consider doing a prep to research request to find out how many patients would fit your inclusion and exclusion criteria. Is the research going to result in enough cases to be meaningful?
- Do you need funding for your research? CRIA can estimate the amount of effort their services will entail.
- Request a consult with a statistician to help write protocols and with data analysis.
- Most data extracts are delivered to the researcher in Excel format. Will that work for your analysis?

Research Grants and Finance

Essential Information

Contact: OfficeofSponsoredPrograms@allina.com

Allina Health's Research Grants & Finance (RG&F) office provides expert administrative support to all researchers, from pre-award through the award process on all grant mechanisms, including:

- Proposal Preparation
- Financial Analysis & Reporting
- Budget & Fiscal Management
- Administration of Funding

Research Grants

The Research Grants team collaborates with the Principal Investigator (PI), their department, and sponsors so that PIs may be successful in their research grants. Research Grants reviews and endorses project proposals, negotiates and accepts awards, and issues subawards on behalf of Allina Health. In addition, Research Grants establishes accounts in the financial system and fulfill sponsor's financial reporting requirements (see Research Finance).

Research Grants is responsible for the post award administration of research grants and awards. This includes reviewing proposals, setting up new awards, monitoring expenditures for compliance and funding, billing sponsors, preparing financial reports, and other post-award requests. The Research Grants team also assists PIs throughout the post award process. Research Grants supports Allina Research Teams by providing advice and assistance at all stages of grant-seeking and grant administration. The highest priorities are responding to staff working on grant proposals with impending deadlines and dealing with time-sensitive issues related to grant administration and academic program development. Research Grants also oversees institutional endorsement procedures and monitor compliance with federal requirements.

Research Finance

Research Finance provides financial management reporting and ad hoc reporting to Senior Research Management, Study PIs, and the Finance Department. On a regular basis, Research Finance provides oversight for award-related matters including indirect cost compliance, Research Cost Centers, and study/program income. Research Finance oversees the monthly and quarterly expenditure review and the federal effort certification process. Additional services include budget development, financial administration, and monitoring and reporting to Allina Health PIs seeking awards with federal, state, industry, and foundation organizations.

Research Finance is responsible for maintaining the financial integrity of all federal, state, industry, and foundation research grants and awards. Research Finance also develops research grant budgets and negotiates study budgets. Research Finance monitors all research related revenue and expenditures while ensuring that all budgets and financial activity is following appropriate regulations and guidelines. Lastly, the Research Finance team supports any required financial audits by sponsor(s).

Getting Started

Industry Awards for Research

If a PI is made aware of or interested in a particular study, they should contact their site director or manager. The site research staff will then work directly with the sponsor regarding feasibility, site qualification, start-up, etc. The PI cannot be involved in budget development or finance. This helps ensure that PI(s) do not prefer a particular study based solely on finances.

Grants Funded by Government Agencies and the Allina Health Foundation

PIs and/or Project Directors should contact Research Grants and Finance as soon as possible upon learning of a potential grant or award opportunity. This ensures timely and accurate submissions. While some applications can require a substantial amount of work and detail, RG&F has several templates and documents that can be used for numerous types of submissions.

All Award Types

All potential research proposals that would involve funding should be routed through the RG&F team, regardless of sponsor. Additionally, non-research applications or grants receiving federal funding are managed by the RG&F team. In preparing for any budget submissions, helpful information may include:

- Staff (name and anticipated time on the award)
- Anticipated IRB determination (full, expedited, exempt)
- Pharmaceutical or medical procedures required
- Participant payment
- Supplies
- Equipment
- Travel
- Publication

RG&F provides most information via Microsoft products (Excel, Word, Outlook). Spending and revenue are tracked through Allina Health by the RG&F team. Expenses are updated and communicated monthly. Research teams should inform the RG&F team of any expenses, such as purchases, upon being made.

Quick Tips

- It is always better to ask; RG&F is happy to help!
- The sooner the better when it comes to getting started… budgets and applications can be time consuming, but RG&F is here to help.

Research Contracts

Essential Information

Contact: ResearchAgreements@allina.com

Research Contracts provides support in reviewing, editing, negotiating, and finalizing all research related contracts and agreements. These include but are not limited to agreements for a new study (e.g., clinical trial agreements, study work orders, awards and sub-awards), amendments, data use and data sharing agreements, and other miscellaneous research-related agreements (e.g., service or professional agreements, Core Lab agreements, independent contractor agreements, etc.). A list of the types of agreements is found in the Research Agreements and Contracts policy.

The Research Contracts team ensures agreement compliance with government regulations and Allina Health contracting guidance. They coordinate with investigators and research teams to draft and negotiate agreements that achieve business objectives while balancing Allina Health risk considerations and proactively communicate contract information with other impacted Allina Health business units and/or Research Administration personnel.

Getting Started

Awards Funded by Industry or Government Agencies

If a research study or project involves an industry or government sponsor, it must be submitted to Research Contracts for review. To submit to Research Contracts, complete the Research Agreement Submission Review Form available by contacting Research Contracts or on the AKN.

The OSP eProtocol User Guide explains how to use the eProtocol online submission system. To set up an account and request this User Guide or training, contact OSP Billing (OSPBilling@allina.com).

An Office of Sponsored Programs (OSP) eProtocol Form should be created “In Preparation” and the following documents should be attached in the Attachments page on eProtocol: the Research Agreement Submission Review Forms, the draft agreement, the draft budget, the draft informed consent, and the study protocol. Once the documents are attached, contact Research Contracts via e-mail with the eProtocol OSP ID and request that they review a new Clinical Trial Agreement (CTA).

Provider Arrangements

Per the Allina Health Provider Arrangements Policy 100.01, an agreement with a provider must be in writing in advance of any services and fair market value. If a research project involves a physician, physician group, or physician family member and is outside the scope of physician employment with Allina Health, the arrangement is subject to the Provider Arrangements Policy. If an investigator is unsure if the involvement of a physician, physician group, or family member is subject to this policy, contact Research Contracts.

Other Situations that Could Require Review by Research Contracts

If a research study or project requires disclosures of patient data, is paying or receiving compensation from a

party outside of Allina Health, or is otherwise partnering with an individual or entity that is not employed or not part of Allina Health, send an email to Research Contracts describing the study/project for a determination about whether an agreement is needed.

Amendments

If changes to agreements are necessary, send an email to Research Contracts describing the changes to the existing agreement with the sponsor's amendment document for review.

Quick Tips

- Any agreement related to a research study should be sent to Research Contracts for review.
- Contact Research Contracts as soon as possible to allow enough time for contract negotiations, if needed.

Research Integrity
(Human Research Protection Program, IRB, & Research Conflicts of Interest)

Essential Information

Contact: IRB@allina.com and ResearchCOI@allina.com

The mission of Allina Health's Human Research Protection Program (HRPP) and its Institutional Review Board (IRB) is to protect and respect the rights and welfare of subjects involved in human research overseen by this organization. This includes human subjects research involving Allina Health employees, facilities, patients, or data.

Human Research Protection Program (HRPP)

The Allina Health Human Research Protection Program (HRPP), in partnership with its research community and IRB, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices. We strive to safeguard and promote the health and well-being of human research subjects by ensuring that their rights and safety are protected. All actions of Allina Health Research, including conduct and review, are guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

The HRPP provides reoccurring and on-demand trainings for the research community and conducts routine and for-cause reviews, including pre- and post-launch visits of new research studies. The HRPP provides guidance and consultation regarding quality improvement in the conduct of ongoing or new research. The Human Research Protection Program promotes and maintains ethical research that is compliant with institutional policies, state and federal regulations, and best practices for protecting human subjects.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) is an ethical oversight committee that has the authority to review, approve, modify, or disapprove research protocols submitted by researchers appropriate and student investigators. Allina Health has one internal IRB and uses the services of external IRBs for the review of studies under the auspices of the Allina HRPP. All studies, regardless of whether the internal or external IRB will be the reviewing IRB, must be submitted first to the IRB Office's electronic submission, IRBNet. The Allina IRB Office also accepts submissions for engagement and human subjects research determinations, clinical use of humanitarian use devices (HUDs), and expanded access uses of a test article.

Research Conflicts of Interest

Allina Health is committed to evaluating, identifying, and managing individual Conflicts of Interest (COI) and Institutional Conflicts of Interest (ICOI) to protect patients who participate in research at Allina Health and to safeguard the integrity of the research conducted at Allina Health.

Allina Health has a Research Conflicts of Interest Committee (RCOIC) and designees that evaluate and address the interests of personnel involved in federal projects or funded/sponsored research as well as institutional interests to help ensure that the work is free from potential or actual bias, pursuant to the Outside Interests and Conflicts Management (OICM) Policy. Researchers may have financial or non-financial COI related to their research projects. ICOI may arise from the financial interests of Allina Health as an organization, or by personally held interests of Allina Health's key officials for research due to their leadership and supervisory responsibilities.

All researchers, unless otherwise specified by the IRB or OICM offices, listed on an application for sponsored or funded research to the Allina Health IRB Office must complete the COI Smart disclosure form requested through ResearchCOI@allina.com. The disclosures must include all financial and non-financial interests held personally, or by their spouse or dependent children. This disclosure must be made at the following times:

- Prior to the submission of a proposal for federal funding
- Prior to the approval of a funded/sponsored research protocol by the IRB
- Annually, after IRB approval of the research or federally funded project
- Within 30 days of knowledge of new interests or changes to current disclosures. ***It is especially important that researchers update their COI Smart disclosure form throughout the year, within 30 days of a new or updated disclosure, to ensure that potential COI is up to date and remains appropriately managed.***
- As otherwise requested by Research Integrity and/or the office of OICM

If the RCOIC or designee determines that a researcher or the Institution has a financial or non-financial COI, a conflict management plan (CMP) will be issued to the researcher or Institution and will apply to the federally funded project or funded/sponsored research for the duration of the project or research. The CMP must be submitted by the researcher or the researcher's team to the IRB of record if the researcher is noted to have a COI with the entity that is sponsoring/funding the research or federally funded project. If an Informed Consent exists for a research or federally funded project, COI language may be required to be incorporated into the informed consent. If there is an Institutional COI, the OICM office will work with the researcher or research team to notify the IRB of record as well as incorporate appropriate Institutional COI language to the informed consent.

Researchers must also complete conflict of interest training by completing the CITI COI training module prior to engaging in funded/sponsored projects and must renew this training every 4 years or as required by the Allina Health IRB or OICM office.

Getting Started

IRBNet and the Forms & Templates Library

Researchers who will serve as Principal Investigators or who will make submissions to the IRB as part of their role should have an account on IRBNet, selecting Allina Health as the Research Institution.

Once the account is active, the Forms & Templates Library provides resources about using IRBNet, application documents, checklists, guidance documents, templates for consent forms, and more.

Prior to Submitting to the IRB

Prior to submission to the Allina Health IRB Office, new researchers will want to ensure their study has completed the requisite scientific review completed by the appropriate Allina Health Research Council as listed in this document and required training as described below.

To initiate the conflicts of interest review process when required, new researchers may contact Research COI (ResearchCOI@allina.com) to complete an annual disclosure or this process can be initiated by the IRB Office at the time of initial submission.

Training Requirements

Principal Investigators who are new to research or new to Allina Health Research are required to complete Principal Investigator training. This training is complementary to other training requirements and tailored to the type of research (e.g., clinical trials or chart reviews) and research responsibilities of the investigator. Prior to submitting to the Allina Health IRB Office for the first time, contact the IRB Office to discuss this training.

Researchers involved in human subjects research are also required to complete CITI training. CITI COI training is required for funded/sponsored projects or research.

Following the required training and access to IRBNet, researchers will be prepared to submit projects on IRBNet for IRB determinations and review.

Quick Tips

- Complete the COI Smart Annual Disclosure by contacting Research COI (ResearchCOI@allina.com) and remember to update this disclosure within 30 days of a new or updated disclosure.
- If you have questions about IRB requirements or need a consult to determine your submission type or whether the internal or an external IRB should review your study, contact the IRB Office.
- The IRBNet Forms & Templates page contains checklists of all required documents needed for specific types of submissions.

Office of Sponsored Programs & Research Billing

Essential Information

Contact: OSPBilling@allina.com

The Office of Sponsored Programs (OSP) and Research Billing team manages the billing compliance and research pricing review process for clinical services associated with research studies. Ensuring billing compliance has important legal and regulatory implications and ensures Allina Health research patients do not receive inaccurate billing.

OSP functions also include:

- providing research fee schedules and pricing information for any clinical services not billable to research participants as standard of care,
- liaising with Allina Health Lab and Pharmacy to ensure accurate pricing for their services,
- reviewing investigational devices (IDEs) and setting up devices or novel procedures in Excellian,
- answering research billing and coding questions,
- creating research study ("RSH") records in Excellian,
- validating contract and billing documentation is complete and stored in the central database, eProtocol,
- issuing final Research Administration approval for studies requiring OSP review,
- quality checks of research site billing reviews for all research participant visits,
- ensuring accurate invoicing for clinical, billable services to research sites,
- assisting in accounts receivable activities (payment) for clinical services related to research studies.

Getting Started

For All New Research Studies/Projects

1. Review OSP Review Criteria to see if the study or project must be submitted for billing compliance, research pricing, or investigational product use review.

2. If yes to the above and new to OSP-Research Billing and eProtocol, email OSPBilling@allina.com for access to the eProtocol online submission system and to obtain the required eProtocol User Agreement.

3. The research site or PI must submit the study through the **eProtocol online submission system** according to the **OSP eProtocol User Guide** and **Minimum Requirements for eProtocol Submission**.

4. If study is interventional, a comprehensive Medicare Coverage Analysis ("MCA") is required to be completed by external vendor, WCG. Cost of the MCA is billed to research site (sponsors are familiar with this cost and requirement).

New Researchers involved in Studies with Billable Services

Visit: OSP Webpage: Office of Sponsored Programs and Research Finance

Read: Allina Health Research OSP-Research Billing Policies:

001: Use of Excellian (Epic) Research Functionality
200: Research Billing Compliance
201: Requirement for Complying with the Research Operations Review Process
203: Research Site Responsibility for Identification of Non-Billable Items and Services

New Researchers involved in using Excellian Research Functionality

Researchers who will be associating and/or linking research patients to research studies or research bill reviews, must complete Excellian Research Functionality Training
ALEXRCT1132 - Excellian Functionality for Research Studies – Search Keyword: Research

Definitions

Interventional study (clinical trial) – 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 Glossary Terms | ClinicalTrials.gov).

Clinical, billable services – any services billed through Excellian (Epic) hospital, clinic, or specialty billing. Includes lab services (draws, processing, etc.) and/or pharmacy preparation and dispense services.

Coverage Analysis ("CA") (aka, Medicare Coverage Analysis) (MCA) - Allina Health ("AH") documentation of billing or non-billing (not allowable) determination for clinical research services performed per research protocol(s) at AH facilities. Includes a detailed review of all research study protocol events where all billable items and/or services that occur within the study protocol are either billable or non-billable using Medicare qualifying clinical trial criteria (CMS NCD 310.1), other, applicable CMS NCDs or LCDs, or standard clinical practice support. All protocol directed services identified in documentation as one of: standard of care ("S"), research ("R") or otherwise non-billable ("NB").

Quick Tips

- For questions about the eProtocol submission or requirements or needing assistance, contact OSPBilling@allina.com.