

# Part X: Policies and Procedures

---

<b>Table of Contents</b>	<b>Page</b>
<i>General Research Compliance Policies</i>	
Research Compliance Program Policy RES 101.00	X-2
Research Billing Compliance Policy RES 102.00	X-6
<i>Sponsored Projects Policies and Procedures</i>	
Requirement for Complying with the SPRP Policy RES 300.00	X-8
Written Agreement Policy for Sponsored Projects RES 301.00	X-9
Investigation of Misconduct in Sponsored Projects Policy RES 302.00	X-11
Research Site Identified Protocol-Induced Costs Policy RES 303.00	X-12
Allina Research Pricing Policy	X-13
Exception to the Allina Research Pricing Procedure	X-15

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Research Compliance Program Policy</b>
<b>Page: 1 of 4</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 101.00</b>	<b>Revised:</b>

**Research Compliance Program Policy**

**Scope**

The Research Compliance Program (Program) covers all research conducted in Allina Health System through the Allina Health System Division and its wholly owned subsidiaries. This Program Statement is an overview of the responsibilities and obligations of all employees and researchers conducting research involving Allina patients or in Allina facilities.

**Purpose**

The goal of the Program is to establish and foster a culture that promotes prevention, detection and resolution of conduct that does not conform to the laws, regulations, and ethical guidelines pertaining to the conduct of research.

**Policy**

It is the policy of Allina Health System to comply fully and consistently with all laws, regulations and ethical guidelines pertaining to the conduct of research. Applicable regulations and guidelines include, but are not limited to, Medicare and Medicaid billing regulations, 45 C.F.R. 46 (Human Subjects Protection), *The Belmont Report*, the *Declaration of Helsinki*, and OMB Circulars A-110, A-122 and A-133.

The Program consists of seven key elements that facilitate prevention, early detection and remediation of violations of law. The Program also meets the criteria set out in the United States Sentencing Commissions Guidelines.<sup>1</sup>

**Oversight Responsibilities**

*Research Compliance Oversight Committee (RCOC):* The RCOC provides policy direction and oversight to the Program and advises the Research Compliance Program Director on matters arising from the implementation, operation and monitoring of the Program.

---

<sup>1</sup> A link to the Guidelines is in the reference section of this policy.

<b>Department: Research Administration</b>	<b>Policy Title: Research Compliance Program Policy</b>
<b>Page: 2 of 4</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 101.00</b>	<b>Revised:</b>

The RCOC is comprised of the Accountable Executives for Research Compliance at Abbott Northwestern, Unity, Mercy, and United hospitals, the Allina Corporate Compliance Officer, a member of the Allina Law Department, and the Research Compliance Program Director who chairs the RCOC.

The Committee’s responsibilities include: analyzing the current research regulatory environment; assessing existing Allina Health System research policies and procedures; recommending and monitoring the development of internal systems to ensure compliance with the Program; determining appropriate strategies to promote compliance with the Program and detect potential violations; monitoring internal and external audits and investigations for the purpose of identifying issues and deficiencies, and implementing corrective and preventive actions.

*Research Compliance Program Director:* The Research Compliance Program Director shall report on the status of the Program, as necessary, to the Accountable Executives for Research and, at a minimum, annually to the RCOC. These reports shall also include a summary of the results of compliance monitoring, billing reviews conducted by Audit Services, and any other relevant information requested by the RCOC.

*Accountable Executives for Research:* The Accountable Executives for Research Compliance have delegated the programmatic responsibilities for developing, implementing, and maintaining an effective compliance program to the Research Compliance Program Director. The Program Director shall provide regular reports on the status of compliance activities within the business units to the Accountable Executive for Research with a copy to the Corporate Compliance Officer.

## **Standards and Procedures**

The Program shall include: policies and procedures to ensure compliance, periodic training and education on compliance issues, the appropriate employee conduct to promote and protect the integrity of the organization, and ongoing monitoring to ensure that the standards of the Program are applied on a day-to-day basis. Education about these standards shall be provided to all employees.

The Corporate Research Compliance Policies are updated and maintained on the Allina.com website or on the Allina Knowledge Network by the Research Administration Department. The policies contain the written compliance policies for all business units and are kept current with changes in applicable laws and regulations. The Research Compliance Program Director is responsible for developing and implementing the necessary structures to ensure compliance with these policies.

<b>Department: Research Administration</b>	<b>Policy Title: Research Compliance Program Policy</b>
<b>Page: 3 of 4</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 102.00</b>	<b>Revised:</b>

Bills, claims and reports submitted to government payers must be consistent with published Medicare and Medicaid regulations and supporting materials. The protection of human subjects in research must be consistent with published regulations and ethical guidance. Research privacy in research must be consistent with the HIPAA Privacy Rule and MN Statute §144.335. In cases requiring interpretation of regulations or contradictory regulatory language, the Research Administration Department, in consultation with the Corporate Compliance Department and the Allina Law Department, will develop policies, procedures, and resolutions identifying the Allina Health System requirements and will assign accountability for implementation within the organization.

## **Training and Education**

Research compliance education and training will be provided to all employees and researchers so they can be knowledgeable regarding their role in the Program.

## **Monitoring and Auditing**

Regular compliance assessments will be conducted to evaluate the effectiveness of the Program and the underlying standards and procedures. Compliance assessments include, but are not limited to, ongoing monitoring and auditing activities.

Compliance monitoring consists of reviews conducted in the course of management activity at the operational level. The Research Compliance Program Director, with the RCOC, shall determine appropriate monitoring procedures.

Compliance auditing consists of independent reviews conducted by Allina Audit Services, typically after claims or data are submitted to government payers. Audit Services and the Corporate Compliance Officer, in consultation with the Research Program Director, determine the focus of billing reviews conducted by Audit Services.

The relevant senior operational managers, in consultation with the Research Compliance Program Director, are responsible for the development and implementation of corrective action plans as necessary to ensure compliance with the Program.

The Corporate Compliance Officer, General Counsel, Chief Financial Officer, or relevant Accountable Executives are empowered to stop billing in whole or in part when the results of compliance assessments indicate an unacceptable level of performance or when other compliance concerns arise.

<b>Department: Research Administration</b>	<b>Policy Title: Research Compliance Program Policy</b>
<b>Page: 4 of 4</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 102.00</b>	<b>Revised:</b>

## **Employee Reporting**

All employees are required to promptly report any good faith belief of non-compliance with the Program. Employees are strongly encouraged to resolve questions and concerns by first talking with their supervisor. Additional resources for employees are the Research Administration Director at 612.262.4921; Corporate Compliance Department at 612.262.4902; and the Integrity Line at 1.800.472.9301.

Reporting employees may request, and will receive, such anonymity as is possible consistent with the Program's responsibilities to investigate employee concerns and take necessary corrective action. There will be no retaliation in the terms and conditions of employment as a result of such reporting. Reports will be investigated pursuant to the Allina Health System Internal Investigation Policy 402-01.03.

## **Enforcement and Discipline**

The Program will be consistently enforced through appropriate sanctions and disciplinary measures when violations are identified and employee culpability is established. Employees will also be subject to discipline for failing to participate in research compliance efforts. Enforcement measures will be determined based on the severity and nature of the violation. Any employee who purposely makes a false accusation will be subject to appropriate discipline.

## **Response and Prevention**

Research Administration will follow the policy developed by Allina Corporate Compliance to address verified instances of non-compliance, to initiate necessary corrective action, and to prevent similar future offenses. Such response and prevention mechanisms will include the development of procedures and process improvements, additional employee training, self-reporting to appropriate governmental authorities, and repayment of any overpayments by government payers.

## **References:**

### Policy Cross Reference

None

### Regulatory Reference

<http://www.ussc.gov>

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Research Billing Compliance Policy</b>
<b>Page: 1 of 2</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number:</b>	<b>Revised:</b>

**Research Billing Compliance Policy**

**Policy**

It is the policy of Allina Health System (Allina) to consistently and fully comply with all laws and regulations pertaining to the billing of research-related charges for patients insured through Medicare, Medicaid and other third-party payers. Applicable laws and regulations include, but are not limited to, Medicare and Medicaid billing regulations and Allina contracts with third-party payers.

**Goal**

The goal of this policy is to ensure appropriate billing of research-related charges by all Allina business units.

**Scope**

This policy applies to all research-related charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within Allina.

**Overview**

Accountability for compliance with laws and regulations pertaining to the billing of research-related charges is primarily vested with the investigator conducting the research activity and with each Allina business unit where the research will be conducted. Allina shall ensure that services it provides are billed in compliance with applicable laws, regulations, and Allina policies. Appropriate billing of professional fees remains the responsibility of the investigator.

Individuals assigned primary accountability for billing compliance at each Allina business unit will necessarily obtain and rely upon the cooperation of investigators conducting research studies within Allina. Investigators are responsible for identifying all research-related charges to be generated by a given project and for communicating this information to Allina.

Local research billing compliance management appointed for Allina and, with the support of Allina Research Administration, will be responsible for the establishment of Research Billing Compliance Procedures.

**Management**

This policy will be managed centrally by Allina Research Administration and implemented within the business units by local compliance management.

Local compliance management shall be accountable for ensuring its business unit's compliance with Allina Research Billing Compliance Policies and Procedures.

<b>Department: Research Administration</b>	<b>Policy Title: Research Billing Compliance Policy</b>
<b>Page: 2 of 2</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number:</b>	<b>Revised:</b>

## **Documentation**

In all cases, published Medicare and Medicaid regulations and contract language with third-party payers will serve as Allina documentation of billing and other claim submission expectations as they apply to research-related charges.

In cases of multiple interpretations, vague expectations or contradictory regulatory language, Allina will supplement published regulations with Allina Research Billing Compliance Policies and Procedures that clearly set forth Allina's expectations.

## **Education**

Research Billing Compliance Policy and Procedure information and education will be provided to both Allina employees and other individuals involved in the conduct of research within Allina. The education will be appropriate to each individual's role in the process of identifying and billing research-related charges. The focus of such education will be to inform those individuals of their accountability and the expectations for their performance.

## **Monitoring and Auditing**

Allina will conduct ongoing local monitoring and periodic corporate audits to evaluate compliance with this policy and related procedures. Follow-up audits will be conducted as necessary to measure the success of any remedial actions implemented following monitoring activities or previous audits.

## **Employee Reporting**

All Allina employees are required to report any good faith belief of any violation of law or regulations, or any non-adherence to third-party payer contracts, related to the billing of research-related charges by Allina business units. Subject to the obligation of Allina to investigate, such reporting shall be confidential. In any event, employees are assured that they shall not be subject to any form of retaliation in the terms and conditions of their employment based on such reporting.

Employees shall make required reports to their supervisors, unless for some reason the employee is uncomfortable making a report to his/her supervisor or has concerns that the supervisor will not take appropriate action in response to a report. In such situations, the employee should contact Research Administration Director at 612.262.4921, Corporate Compliance Officer at 612.262.4901, or the Integrity Line at 1.800.472.9301. Supervisors who receive such reports shall contact one of these individuals in the event they need assistance in investigating the report or implementing any remedial actions necessary, and in the event the report identifies a matter that exposes Allina to significant risk.

## **Enforcement**

This policy and related procedures will be consistently enforced through appropriate sanctions and disciplinary measures when violations are identified. Enforcement measures will be determined based on the severity and nature of the violation. Any discipline of employees who are union members shall be conducted pursuant to the disciplinary process outlined in the applicable union contract.

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Requirement for Complying with the SPRP Policy</b>
<b>Page: 1 of 1</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 300.00</b>	<b>Revised:</b>

**Requirement for Complying with the Sponsored Project Review Process**

**Policy**

It is the policy of Allina that any person, internal or external, who wishes to engage in research or other sponsored project activities, as described below, within an Allina facility follow the Sponsored Projects Review Process.

**Projects with one or more of the characteristics set forth below may require that the research site follow the SPRP and submit the project to Allina Sponsored Projects Administration (SPA):**

- The use of an investigational drug or research medical device within an Allina facility;
- The project requires the approval of an IRB;
- A research project comparing approved medical devices, when it is not standard within Allina or data is specifically collected to determine how the devices compare to each other.
- An Allina hospital or clinic provides items or services related to a project that may or may not be billed to a third party payer;
- May or may not be sponsored, but the items or services being provided could be considered outside the scope of routine care;
- The use of a humanitarian use device; or
- Allina Sponsored Projects Administration (SPA) determines the project must be submitted to SPA.

**Characteristics of projects that generally don't meet the SPRP:**

Registry study and no items or services are ordered specifically for the study

A Medical record or chart review study

The research site is just using the Allina IRB and all personnel and services are done in an external clinic

Please contact SPA if you have questions.

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Written Agreement Policy for Sponsored Projects</b>
<b>Page: 1 of 2</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 301.00</b>	<b>Revised:</b>

**Written Agreement Policy for Sponsored Projects**

**Purpose**

The purpose of this policy is to ensure that Allina appropriately documents its rights and responsibilities relative to its participation in sponsored projects and all research. This includes, but is not limited to, documentation of the services Allina will provide and the reimbursement, if any, it will receive for those services.

**Policy**

An appropriate written agreement must be executed between individuals or entities and Allina for services Allina provides as part of a sponsored project/research. The requirements for a written agreement will vary depending on the nature of Allina’s role in the project and the complexity of the services to be provided. The types of agreements to be used are described below:

**Types of Agreements**

**Project Agreement** - This is an agreement in place between Allina and the project sponsor.

- This type of agreement will be used when the individual conducting the project is an Allina employee or Allina has some direct connection to the project, other than the location of the project.
- The sponsor typically provides the agreement.
- Allina typically will not be a party to an agreement with a research site, unless approved in advance by SPA.
- Allina may enter into a special project agreement with a sponsor for medical device trials in order to properly document Allina’s and the sponsor’s obligations surrounding the project.

**Purchased Service Agreement** This is an agreement between Allina and the individual or party under contract with the sponsor.

**Humanitarian Use Device (HUD) Agreement** – This agreement between Allina and the Research Site is limited to projects using a humanitarian use device at an Allina facility.

**Vendor Agreement** –This is an agreement between Allina and the individual or party under contract with the sponsor. In general, this agreement will be used when Allina is not party to the contract with a project sponsor, is providing services to such a party in a vendor capacity only, and is not billing any third party payers for services rendered. To use the Vendor Agreement, all the following criteria must be met:

- **Allina provides the items or services that are only ancillary to the operation of the project.** For example, Allina is performing a service and has no other responsibility than to perform that service (e.g., performing a chest x-ray).

<b>Department: Research Administration</b>	<b>Policy Title: Written Agreement Policy for Sponsored Projects</b>
<b>Page: 2 of 2</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 301.00</b>	<b>Revised:</b>

- **The project will not require third party billing by Allina.** For example, when a participant enters an Allina facility for a chest x-ray only (or other work as described above), the Principal Investigator will be billed directly. No insurer will be billed for the items and services provided by Allina.
- **The researcher has documentation of approval of the project by an IRB (Allina or other).** Projects that meet the Vendor Project criteria must submit a copy of the IRB's final approval or exemption letter with the Vendor Project Worksheets. You should contact one of the Allina IRBs if you have questions; the number appears in Part IX of this Guide.
- **The project has a diminished compliance accountability that flows back to Allina.** Allina does not assume any compliance obligation such as federal billing regulations, grants management, etc.
- **No Allina employee is involved in collecting the information about research subjects except as part of his or her normal duties.** For example, lab personnel drawing a standard lab for a project would be considered a normal duty. However, an Allina employee that is collecting survey data for a research site is in a direct relationship with the research site and is required to follow the SPRP.
- **Not an inpatient study**
- **Service cannot involve the use of:**
  - investigational drug(s)
  - investigational device(s)
  - invasive procedures
  - tests, *excluding*:
    - ~ standard venipuncture and normal lab testing
    - ~ tests with low rates (risk) of complications (i.e., chest X-ray)
    - ~ tests appropriate for normal populations (i.e., a CT scan)

## Procedure

SPA will make available on its website all versions of Allina

Written agreement templates and instructions for completing and suggesting changes can be found at <http://www.allina.com/ahs/research.nsf/page/spaforms>

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Investigations of Misconduct in Sponsored Projects Policy</b>
<b>Page: 1 of 1</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 302.00</b>	<b>Revised:</b>

**Investigations of Misconduct in Sponsored Projects Policy**

Sponsored Projects Administration will follow Allina's Research Misconduct Policy for any suspected misconduct in the Sponsored Project Review Process (SPRP), Federal award or other sponsored project activity.

Findings related to any investigations conducted by SPA will be brought to the Research Compliance Oversight Committee for further action and any disciplinary action, which may include referral to sponsors or the government.

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Research Administration</b>	<b>Policy Title: Research Site Identified Protocol-Induced Costs Policy</b>
<b>Page: 1 of 1</b>	<b>Effective Date: August 2008-August 2011</b>
<b>Approved by: Research Compliance Oversight Committee</b>	<b>Review Date: August 2011</b>
<b>Reference Number: RES 303.00</b>	<b>Revised:</b>

**Research Site Identified Protocol-Induced Costs Policy**

**Purpose**

The purpose of this policy is to state that items and services credited off of a research participant's account by the research site staff are considered protocol-induced costs as defined in the Guide.

**Background**

As part of the SPRP, research sites must submit worksheets to identify which items and services associated with the research project are routine care and which services are for research only (protocol-induced costs). The Principle Investigator must certify the analysis is accurate and in accordance with billing regulations. Once services have been provided to a research participant, the bill is sent to the research site for review. It is the responsibility of the research site staff to identify all protocol-induced charges for the business office to remove prior to a claim being sent to a third party payer.

In the course of conducting internal audits, it has been found that research sites are identifying charges for removal that appear to be routine care rather than protocol-induced costs as indicated on the Setup Worksheets submitted at the beginning of the project. It is essential that the documentation and billing be clear and consistent with the protocols. The SPRP is designed to place the responsibility on the research site of identifying those services that should be removed, as they have the knowledge and expertise to make that determination.

**Policy**

It is the policy of the Allina that any charge identified for removal from the patient's account, by the research site, will be considered a protocol-induced cost. Therefore, that charge may not be billed to a third party payer and will not be refunded to the research site.

**ALLINA HEALTH SYSTEM**  
**System-wide Policy**

<b>Department: Finance</b>	<b>Policy Title: Allina Research Pricing Policy</b>
<b>Page: 1 of 2</b>	<b>Effective Date: February 2008-February 2011</b>
<b>Approved by: Finance Council</b>	<b>Review Date: February 2011</b>
<b>Reference Number: 101-27</b>	<b>Revised:</b>

**Allina Research Pricing Policy**

**Scope**

This policy applies to all Allina Hospitals & Clinics (Allina) business units and all researchers purchasing research items and services from Allina.

**Purpose:**

Allina recognizes the value of research to its patients, physicians, market differentiation for centers of excellence, and philanthropic support. This value must be balanced by a collaborative, streamlined process that proactively incorporates strategy, budget planning, and corporate compliance requirements. This policy provides a framework for establishing a uniform pricing structure for research-related services provided by Allina.

**Policy**

It is the policy of Allina to have one uniform pricing structure for researchers purchasing research items or services from Allina business units. Research rates will be set annually by the Allina Finance Council and will be applied to all research-related services provided the research project has been submitted through the Allina Sponsored Projects Review Process. Projects that fail to follow the Allina Sponsored Projects Review Process will not be eligible for discounted research rates.

**Exceptions**

The Allina Research Compliance Oversight Committee (RCOC) will review and approve or deny exceptions to the research pricing policy. A vote of the majority of RCOC will determine if the exception is approved or denied. Voting may be done in a manner that is convenient to members of the RCOC.

**Procedure**

**Allina Finance Council will:**

Evaluate the economic impact of supporting clinical research on Allina's financial performance against the benefits to Allina's mission and business strategy on an annual basis, in accordance with the Allina planning and budgeting cycle.

<b>Department: Finance</b>	<b>Policy Title: Allina Research Pricing Policy</b>
<b>Page: 2 of 2</b>	<b>Effective Date: February 2008-February 2011</b>
<b>Approved by: Finance Council</b>	<b>Review Date: February 2011</b>
<b>Reference Number: 101-27</b>	<b>Revised:</b>

**The Research Compliance Oversight Committee (RCOC) will:**

1. Establish the criteria for when a research project will require RCOC financial review before being approved.
2. Develop the process for reviewing requests for exceptions to the Research Pricing Policy.
3. Review projects that may have a significant financial impact or other risk to an individual business unit or Allina as a whole.
4. Propose, on an annual basis, a research rate(s) to the Allina Finance Council.
5. Assure transparency of information regarding clinical research support in order to achieve applicable legal and regulatory compliance and accurate financial reporting and disclosure.
6. Assure, on an annual basis, that the net benefits to Allina of supporting clinical research are positive.
7. Review exceptions to the research rate granted during the previous year to determine if the exception criteria are appropriate or in need of modification.
8. Work with Sponsored Projects Administration to ensure that all exceptions to the Research Pricing Policy are documented for compliance purposes.

**Allina Research Administration will:**

1. Work with the business units to implement research pricing.
2. Track exceptions to the policy for reporting to the Allina Finance Council at least annually or as requested.

**Allina Business Units will:**

1. Assign a business analyst to work with Sponsored Projects Administration and research sites in pricing research items and services.
2. Forward all requests for exceptions to Allina's Research Pricing Policy to Sponsored Projects Administration for review by the RCOC.

**Definitions**

**Research Rate** — the discounted amount Allina will accept as payment for research-related items and services. Researchers must comply with the Allina Sponsored Projects Review Process in order to qualify for the research rate.

**Exception** — a price granted to a research site by the RCOC for research-related items and services that is below the standard research rates set by the Allina Finance Council.

# ALLINA HEALTH SYSTEM

## System-wide Procedure

<b>Department: Finance</b>	<b>Policy Title: Exception to Allina Research Pricing Procedure</b>
<b>Page: 1 of 2</b>	<b>Effective Date: February 2008 – February 2011</b>
<b>Approved by: Finance Council</b>	<b>Review Date: February 2011</b>
<b>Reference Number: 101-27a</b>	<b>Revised:</b>

### Scope

This procedure applies to all Allina business units and all researchers requesting an exception to Allina Research Pricing Policy #101-27.

### Purpose

The purpose of this procedure is to establish a process for granting exceptions to the Allina Hospitals & Clinics (Allina) Research Pricing Policy #101-27.

**Definition** - An exception is defined, for the purpose of the policy, as a research price that is lower than the standard research discount approved by the Allina Finance Council.

**Criteria** - The following criteria will be used by the RCOC in evaluating whether to grant an exception to the Allina Research Pricing Policy:

- Financial feasibility – the financial impact on Allina business unit(s)
- Alignment with Allina or business unit strategy
- Other criteria, such as, public recognition, academic benefit, or physician recruitment

### Procedure

**Below is the process for obtaining an exception to the Allina Research Pricing Policy:**

- Research site will contact the SPA Manager to discuss the need for the exception and to discuss the process that needs to be followed.
- The SPA Manager will provide a document titled “Pricing Exception SBAR” (SBAR) for the research site.
- The Research Site will complete the Situation and Background Section of the SBAR, along with the other materials listed below and forward electronically to the SPA Manager.
- SPA will conduct an analysis of the SBAR and consult with the Research site as necessary to complete the SBAR.
- SPA Manager will work with the business unit’s research accountable executive and provide additional support.
- The business unit’s research accountable executive will determine next steps, such as, consulting with the Research Site, obtaining additional information or department.
- If the research accountable executive does not support the exception, no exception will be granted.
- If the research accountable executive agrees to support the exception, he/she will notify SPA who will begin the process of scheduling the RCOC to obtain approval according to Allina Policy 101-27.

<b>Department: Finance</b>	<b>Policy Title: Exception to Allina Research Pricing Procedure</b>
<b>Page: 1 of 2</b>	<b>Effective Date: February 2008 – February 2011</b>
<b>Approved by: Finance Council</b>	<b>Review Date: February 2011</b>
<b>Reference Number: 101-27a</b>	<b>Revised:</b>

### **Research Site**

The researcher must provide the RCOC with the following information:

- Complete the Pricing Exception SBAR
- Validation of all financial assumptions (e.g., public recognition, academic benefit, etc.)
- Detailed financial analysis of the project and proposed sponsor agreement including budget

### **RCOC**

The RCOC will:

- Review all submission materials
- May invite the researcher to attend a RCOC meeting to discuss the request
- Render a decision in a timely manner
- Document reasons for its decisions
- Catalog its decisions

### **Research Administration**

Allina Research Administration staff will:

- Provide administrative support to the RCOC
- Maintain minutes of RCOC meetings
- Maintain a database of RCOC decisions
- Provide reports to the RCOC as requested