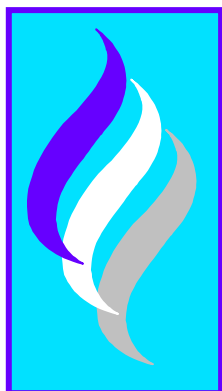


ALLINA RESEARCH ADMINISTRATION

RESEARCH COMPLIANCE PROGRAM



The Allina Hospitals & Clinics
Guide to Research Billing
and the
Sponsored Projects Review Process



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The Allina Hospitals & Clinics Guide to Research Billing and the Sponsored Projects Review Process

Foreword

At Allina Hospitals & Clinics, we conduct research on everything from implantable cardiac devices to bandages. The compliance issues surrounding research are complex and daunting: they include data and fiscal integrity, compliance with human subjects protection, conflicts of interest and billing compliance. The Allina Research Compliance Program is designed to identify and respond to these issues and to ensure we are “doing it right each and every time” when it comes to clinical research.

To help make it easier for you as the research investigator or coordinator, Allina has developed the *Allina Hospitals & Clinics Guide to Research Billing and the Sponsored Projects Review Process*. This guide is essentially a “how to” for research billing and research project approval. It is a tool to help you understand the guidelines, regulations and processes related to patient care billing during a research project, as well as the review of sponsored projects. The guide is available in hard copy from the Sponsored Projects Review Administration or online at http://www.allina.com/ahs/the_guide.pdf. Your feedback on the guide is welcome; call us at 612-262-4926 or e-mail us at spa@allina.com.

This guide was developed by the Allina Sponsored Projects Administration (SPA). Through the Sponsored Projects Review Process (SPRP), SPA has streamlined and formalized the processes related to billing for items and services provided during a research project. This focus on billing compliance is partially in response to the National Coverage Decision, which defines Medicare coverage of clinical trials. This process will allow Allina to more efficiently separate out research charges from charges for routine patient care.

Secondly, the purpose of the SPA is to formalize the approval process for sponsored projects. Researchers are asked to submit a uniform set of user-friendly forms. The information in the application will help us track research activity, provide a list of services required in the project, and define whether those services will be paid by a third-party payer or the research sponsor. Our staff will then conduct a high-level review and forward the proposal to the business unit, for the determination of whether the cost of the project supports the resources involved.

The goal of our research compliance program is to create an environment where research can be conducted in an ethical, legal and practical manner. Ultimately, it is our patients—as well as patients everywhere—who will benefit from the pioneering research that Allina supports.



Kurt Sargent
Manager, Sponsored Projects Administration



Kathryn May
Director, Research Administration

Introduction and Overview

The *Allina Hospitals & Clinics Guide to Research Billing and the Sponsored Projects Review Process* (Guide) provides principal investigators, project directors and research coordinators up-to-date guidance that will serve as the terms and conditions of conducting research within Allina Hospitals & Clinics (Allina). The Guide is available in electronic format from the Allina Sponsored Projects Administration, or on-line from the Allina Research Home Page at www.allina.com/ahs/research.nsf/page/spa/.

The Guide is divided into 11 sections and a preface. The following briefly describes the contents of each section:

Preface

Provides an introduction to the Sponsored Projects Review Process.

Part I – Policies and Procedures

Contains policies and procedures governing research compliance and sponsored projects. These policies and procedures provide researchers with guidance they must follow when conducting research at Allina. Types of policies and procedures include general research compliance, human subjects protection, research billing compliance and sponsored projects.

Part II – Billing Guidance

Provides copies of the National Coverage Decision (NCD) and Medicare Provider Bulletin, as well as various algorithms for Medicare Outpatient Self-Administered Drug Trials and clinical trials for which no reimbursement is allowed.

Part III – Vendor Sponsored Project Review Process

Provides a description of, and criteria for, a Vendor Project and gives instructions on how to complete the Vendor Project Setup Worksheets. Vendor projects are projects where Allina is acting as a vendor to the research site.

Part IV – Sponsored Project Review Process

Provides instruction for completing and submitting the Sponsored Projects Setup Worksheets for projects that are not vendor projects and do not involve the use of a medical device.

Part V – Sponsored Project Review Process for Medical Devices

Provides instructions for completing the Sponsored Projects Setup Worksheets for projects involving medical devices.

Part VI – Written Agreements

Contains information about written agreements. You can review the Written Agreement Policy RES 302.00 in Part I, Policies and Procedures.

Part VII – Plan Code and Other Billing Issues

Provides information about the use of the Research Plan Code.

Part VIII – Coding and Documentation

Contains information on coding and documenting research-related items and services.

Part IX – Process for Allina Employees

Outlines additional requirements for Allina Hospitals & Clinics employees. Includes information about fringe benefits, indirect rates, budgets and the Sponsored Projects Review Process for employees.

Part X – Contact Information

Provides contact names and phone numbers for people involved in the Sponsored Projects Review Process.

Part XI – Reference Materials

Provides reference materials such as a glossary of terms, a list of abbreviations and a sample of completed Setup Worksheets.

Preface

Why do we need a Sponsored Projects Review Process (SPRP)?

Research plays a vital role at Allina, which is to expand our understanding of clinical medicine, thereby improving the care provided to our patients, as well as patients everywhere. To promote the continued viability of research at Allina, we have a responsibility to make informed decisions about the sponsored project activity occurring at our facilities. In addition, the SPRP represents Allina's response to the numerous legal and regulatory challenges currently facing clinical research. The SPRP helps to ensure that the research conducted at Allina will be legal, ethical and financially sound. If we meet these goals, our research will provide maximum benefit to our patients.

What is the Sponsored Projects Review Process?

The SPRP is a program that supports Allina's compliance with the laws, regulations, and its own policies pertaining to the financial and business aspects of conducting research. The SPRP is divided into two areas: 1) sponsored projects review and 2) billing compliance.

1) The Sponsored Projects Review component of the SPRP promotes compliance with the financial and regulatory requirements for government and non-government funded projects and ensures that sponsored project activity is systematically reviewed and approved by Allina management before it is initiated.

2) The Billing Compliance component of the SPRP ensures that research-related expenses are billed legally, appropriately, and in accordance with the Medicare National Coverage Decision for Clinical Trials Decision (NCD), issued on September 19, 2000 and other guidelines by governmental and non-governmental payers. This part of the program includes initial support for the claims Allina submits for research-related services.

The SPRP consists of a series of worksheets (Project Setup Worksheets) that provide Allina with a summary of the billing and cost factors associated with a project. In addition, a written agreement must be executed between the research site and Allina that documents the rights and responsibilities of both parties with respect to the project. Finally, the research site is required to use a special insurance code (Research Plan Code) when scheduling research-related services, which may not be billed to a third party payer for study participants in order to prevent claims from being sent to that payer.

What are the roles in the Sponsored Projects Review Process?

An overview of the steps in the SPRP and the party responsible for their completion is listed as follows:

Investigator/Research Site/Project Director

- Applies for and uses the Research Plan Code
- Completes the Project Setup Worksheets and Certification
- Completes the Written Agreement
- Reviews bills for non-billable research-related charges
- Notifies SPA about changes to approved projects

Sponsored Projects Administration (SPA)

- Reviews project for completeness and compliance requirements
- Submits the project to the Accountable Executive at Allina
- Provides notice of approval or non-approval by the accountable executive

Accountable Executive (AE)

- Reviews project
- Approves or denies project

In accordance with Allina Hospitals & Clinics policy, any clinical research investigator, whether internal or external to Allina, must comply with the Sponsored Projects Review Process (SPRP) if he or she intends to engage in sponsored projects at an Allina facility. *The Allina Hospitals & Clinics Guide to Research Billing and the Sponsored Projects Review Process (Guide)* identifies the requirements of the SPRP and provides instructions to assist investigators and their staff in meeting these requirements.

Disclaimer

The Guide was developed, and is maintained and distributed by the Allina Research Administration (RA). This document provides guidance for those who are engaged in the conduct of clinical research. However, the Guide is not intended to constitute legal advice in the conduct of clinical research to anyone other than those who are employed by Allina. Physicians who are on the medical staff of an Allina facility, but who are not employed by Allina, may wish to consult with their own attorneys regarding their own professional and legal responsibilities in connection with these research projects.

Changes to the Guide

Rules, regulations and government-issued guidance governing the conduct of clinical research and reimbursement for medical services provided to research subjects are constantly changing. To reflect these changes, Allina periodically updates the Guide and its policies. We will make every attempt to make those updates on a timely basis. However, we cannot guarantee that every Allina policy is immediately updated as the rules change, or that everyone involved in research at Allina has been provided access to the updated Guide. If you have any doubts whether you are working with the most recent version of the Guide, please contact SPA. *Please note that the most recent version of the Guide will be published on the Allina website.*

The Guide is intended to provide general guidelines for research billing, and any specific questions for a particular project should be directed to SPA. Furthermore, while the content of the Guide provides general information pertaining to billing for research items and services, it is the research site's responsibility to follow standard billing practices for the items and services surrounding that patient/participant's care (e.g., pre-authorization, etc.).

Electronic Transmission

In order to complete and send the Guide worksheets to SPA, investigators are required to provide significant and potentially confidential data regarding their studies. This data will be kept confidential and will be used only by those parties who need to know, such as SPA staff. Those submitting materials electronically to SPA should use reasonable safeguards to maintain the security of the transmission, but must be aware that no electronic submission is completely secure or confidential. Furthermore, anyone submitting materials to Allina in connection with the policies and worksheets contained in the Guide is encouraged to retain an electronic and hard copy of the submitted materials.

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Pricing

The instructions and examples contained in the Guide are for clarification purposes and are not intended to provide guidance on specific billing issues. Each Allina facility is independent and decisions surrounding a project at one facility will not carry over to another. Prices are subject to change from project to project.