

Part VI: Written Agreements

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Introduction

The purpose of written agreements 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.

An appropriate written agreement must be executed between individuals or entities and Allina for services Allina provides as part of a sponsored project/research. For more information, you may refer to Research Compliance Policy RES 302.00 “Written Agreement Policy for Sponsored Projects” (Part I of this Guide).

Descriptions of the types of written agreements are described below. Allina has developed written agreement templates and are available by contacting SPA.

Other items relating to written agreements

Allina facilities have the right to suspend a project should the costs be higher than originally projected, payment is denied by third party payers and it is believed this will continue, or any reason the facility deems appropriate.

Allina does not sign agreements with external research sites and sponsors that relate to the entire study. Allina will sign agreements with sponsors relating to limited requirements of Allina’s participation in the study (e.g., such as, confidentiality and study materials). Check with SPA if you have any questions.

In cases where an entire visit is denied by a third party payer, the research site will be responsible for the entire visit. Payment will be based on the DRG or CPT assigned at the outset of the project or the actual DRG or CPT, including additional costs for additional items or services, such as medical devices.

Types of Written 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.
- Provisions of the agreement will include, but are not limited to:
 - Scope of service
 - Payment terms
 - Reporting obligations
 - Compliance obligations
 - Indemnification, publication and intellectual property rights

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

- This type of agreement will be used when Allina is not a party to the contract with the sponsor, but is providing services to such a party.
- Provisions of the agreement will include, but are not limited to:
 - Scope of service
 - Payment terms
 - Billing compliance
 - Confirmation of Allina IRB approval

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).
- **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)

Instructions for Completing Written Agreements

Introduction

Allina has created templates for two types of written agreements that should be used for conducting research in Allina facilities. The information provided below is provided to instruct the research site on how to complete the written agreement templates.

Process for Research Site

1) Determine the type of written agreement before completing

- The information provided in the previous section ([Types of Written Agreements](#)) will help you determine which type of agreement to use.

2) Open the appropriate written agreement

- Vendor Services Agreement → *vsa04.doc*
- Purchased Services Agreement → *psa04.doc*

3) Save the document as a different file

- Choose **File>Save As**
- Name the document and click **Save**.

4) Enter data in each field

- The document opens in the first data entry field (Expected Day Agreement Begins).
- Tab to subsequent fields and enter appropriate information.
- Refer to the written agreement sample in Part XI for any questions about the data fields or call Allina SPA at 612-262-4926 or 612-262-4927.

Note: If you wish to propose any changes to the written agreement, see the next section ([Proposing Changes to a Written Agreement](#)) prior to completing the next steps.

5) Re-save the written agreement.

6) Print two copies of the appropriate written agreement

- Click the **printer icon** three times
- **Or**
- Choose **File>Print** and enter **2** for the number of copies to print

7) Sign the two written agreements

- Written agreements must be signed by an authorized person who can enter into legal binding agreements on behalf of the entity (e.g., president).

8) Submit the written agreement to Allina SPA

- Submit two signed, original copies, along with the one of the Project Setup Worksheets and one copy of each of the other documents required for the SPRP, as discussed in Parts III, IV or V of this Guide. (One original will be returned to the research site if the project is approved.)

Send to:
Sponsored Projects Administration
Internal Mail 10105
Allina Health System
PO Box 43
Minneapolis, MN 55440-0043

Deliver to:
Allina Commons at Midtown Exchange
Sponsored Projects Administration
Mail Route 10105
2925 Chicago Ave South
Minneapolis, MN 55407-1321

Proposing Changes to a Written Agreement

A research site may suggest changes to the written agreement templates. These instructions will allow the research site to make changes to the written agreement template. Any changes to the written agreement may require legal review, which may delay the review process time for several weeks.

- 1) Follow steps 1-4 as described on previous page
- 2) Save the file before proceeding
- 3) Making changes to the text of the written agreement
 - Unprotect the document
 - Choose *Tools>Unprotect document* (Any change to the body of the document must be tracked)
 - Choose *Tools>Track Changes>Highlight Changes*
 - Check the box “*Track Changes While Editing*”
 - Make the necessary changes to the text
 - Re-save the document
 - Print one copy of the proposed written agreement with the “tracked changes.”
- 4) E-mail the proposed written agreement electronically to Sponsored Projects Administration at spa@allina.com
 - Sponsored Projects Administration may request additional information about the project.
 - Sponsored Projects Administration and the Allina Legal Department will review proposed changes and work with the research site on any proposed changes.
- 5) It is recommended that you send the proposed agreement as soon as possible. After reviewing the agreement, Sponsored Projects Administration will return it to the research site.
- 6) Upon receipt of the approved changes, the research site needs to accept or reject the changes in the Word document.
 - Accepting or rejecting changes
 - Choose *Tools>Track Changes>Accept or Reject Changes*
 - Click either the *Accept* or *Reject* button for each proposed change.
- 7) Save the written agreement.
- 8) Print two (2) copies.
- 9) Sign the two (2) written agreements. The agreements must be signed by authorized person. This is a person that can enter into legal binding agreements on behalf of the entity (e.g., president). Agreements must be signed prior to submission to Allina.
- 10) Submit the written agreements to Allina Sponsored Projects Administration.
 - Submit two signed, original copies, along with the Project Setup Worksheets and other documents required for the Sponsored Project Review Process, as discussed in Parts III, IV and V of this Guide. (One original will be returned to the research site if the project is approved.)

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