

Part III: The Vendor Sponsored Project Review Process

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Determining if the Project is Vendor Sponsored Project or a Sponsored Project

Generally, a Sponsored Project is any program or project supported in full, or in part, by funding from outside sources or internal foundations that requires specific performance or specified commitment of effort by Allina or in any way obligates any Allina business unit to any type of performance or resource commitment. Examples include government grants and clinical trials sponsored by drug or device companies. There are two kinds of sponsored projects: 1) Vendor Sponsored Projects and 2) Sponsored Projects. (Refer to policies RES 301.00, “What is a Sponsored Project?” and RES 306.00, “Vendor Sponsored Projects Review Process” for additional information.)

The submission requirements for the SPRP differ depending on the type of sponsored project being reviewed. Therefore, the research site must identify the type of sponsored project being reviewed before proceeding. If the project meets the criteria for a Vendor Sponsored Project as described below, continue with this part of the Guide. If the project fails to meet any one of the criteria, proceed to the SPRP described in Part IV or Part V of this Guide.

Determining if the project meets the Vendor Sponsored Project Criteria

A Vendor Sponsored Project is a project where Allina provides a service that it performs in the normal course of business, where the service is ancillary to the operation of the project, and where little risk is associated with the service. A Vendor Sponsored Project must meet **all** of the criteria listed below:

- Allina provides the items or services which are only ancillary to the operation of the project.
- The project will not require third party payer billing by Allina.
- The researcher has documentation of approval of the project by an IRB.
- The project has a limited compliance accountability that flows back to Allina.
- No Allina employee is involved in collecting the information about research subjects except as part of his or her normal duties.
- It is not an inpatient study.
- The 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 (e.g., chest X-ray)
 - ~ tests appropriate for normal populations (e.g., a CT Scan)

Did the project meet *all* of the criteria for a Vendor Sponsored Project?

YES. Proceed with the instructions listed in this section, “The Vendor Sponsored Projects Review Process.”

NO. Proceed to the instructions listed in Part IV, “The Sponsored Projects Review Process,” or Part V, “Sponsored Projects Review Process for Medical Devices.”

Vendor Sponsored Project Review Process Purpose/General Statement

This section provides information for completing the “Vendor Sponsored Project Setup Worksheets,” submitting the worksheets to Allina, and the review process. Completing the Vendor Project Setup Worksheets is the first step of the process. A research site is subject to the Allina Vendor Sponsored Project Review Process if it meets the criteria found within the Research Compliance Policy RES 306.00 (Part I).

The Vendor Sponsored Projects Process is an abbreviated version of the SPRP. In order to qualify for Vendor Sponsored Project Review, the project must meet the Vendor Project Review Criteria identified in the previous section, “Determining if the Project is a Vendor Sponsored Project or a Sponsored Project.” (The Vendor Sponsored Project Review Criteria is also listed in policy RES 306.00, “Vendor Sponsored Projects Review Process.”)

Overview

- The research site must complete all applicable information in the Allina “Vendor Sponsored Project Setup Worksheets” as described in this section.
- The research site must complete the Vendor Sponsored Project Setup Worksheets for each new or different project.

Steps in the Vendor Sponsored Projects Review Process

Note: A Vendor Project Review Process Checklist appears in Part XI of this Guide.

The research site:

- Completes the Vendor Sponsored Project Worksheets
 - Vendor Project/Research Vendor Information Worksheet
 - Vendor Department Service Information Sheet (DSIS)
- Completes the Vendor Sponsored Project Certification Form (signature required)
- Completes the Vendor Written Agreement (signature required)
- Provides a copy of the IRB approval or exemption letter
- Provides a copy of the research informed consent
- Provides a copy of the same project abstract as the one submitted to the IRB
- Submits the documents listed above in the order specified in this Guide

How to Complete the Vendor Sponsored Projects Worksheets

This section outlines step-by-step instructions for completing the Setup Worksheets and submitting the project to the Sponsored Projects Administration (SPA).

1. Open and Save the File

- To begin the Setup Worksheets, open the Excel file “*vendor04.xls*” that SPA has provided. Enable the macros by clicking the **Enable Macros** button.
- The first page that opens is the introduction page entitled “Welcome to the Allina Hospitals & Clinics Vendor Sponsored Project/Research Setup Worksheets.” The buttons on this page will help you navigate throughout the workbook.
- Start a new file by saving the “*vendor04.xls*” file under another file name.
- Click the file pull-down menu at the top left-hand corner.
- Choose **Save As**.
- Choose a file name that is something other than “*vendor04.xls*.” SPA suggests a name that will be easy to remember, such as the project short title, the protocol number or the principal investigator’s name.

2. Complete the Worksheets

Please complete these worksheets in the following order:

- Allina Hospitals & Clinics Sponsored Project/Research Vendor Information Worksheet
- Allina Hospitals & Clinics Vendor Department Service Information Sheet
- To begin, click on the **Info_WS** button.
- Upon completing each worksheet, click on the **Go to Intro_Sheet** button to return to the **Intro_Sheet**. Additional instructions appear in the appropriate sections in this part of the Guide.
- Complete all Setup Worksheets.

3. Submit the Worksheets

- Save the completed worksheets.
- Click the disk icon at the top left-hand corner; *or*
- Click the file pull-down menu and choose **Save**.
- A prompt may appear to replace the existing file. Click **Yes**.
- Print the worksheets. See the Section entitled “Printing the Setup Worksheets.”
- Submit the project to the SPA. See sections, “Submit Electronic Copy of the Excel File” and “Submission Requirements for SPA Review.”

Each field on this form with an asterisk (*) is a required field. If a required field does not apply, please indicate with a N/A. Incomplete worksheets may be returned to the project site for completion, thus causing delays.

Error messages – In Column L of the worksheet, the word “error” appears if a required field is left blank. This “error” will disappear as you enter data. Projects cannot be submitted electronically if “error” messages appear in Column L.

Vendor Project Information Worksheet

1. General Information

Note: A sample of the Research Vendor Information Worksheets is included in Part XI of this Guide.

Project Title – List the full title of the project as described in the protocol or other documentation from the project sponsor.

Project Short Title – List an abbreviated title if the project site wishes to use one. Any written communication with SPA should reference the full title or a protocol number so that the project is not mistaken for another.

Study Protocol # – List the number assigned to the protocol by the sponsor.

Allina IRB # – If known, list the unique number assigned by the United, Mercy, Unity, Phillips Eye Institute or Abbott Northwestern IRB.

Project Sponsor – List the originating sponsor of the project. For example, Company X is sponsoring a project to test a drug it has developed; therefore, Company X is the sponsor.

Pass-Through Entity – If funds are received directly from an entity other than the original sponsor, list that entity here. Under federal law and Allina’s Medicare and Medicaid Policy 412-01.13, Allina is required to ensure that it does not have any relationships with persons or entities excluded from federal health care programs. If this project does not have a pass-through entity, enter N/A.

Anticipated Project Start Date – Estimate the date you expect to either accrue the first participant, start the written agreement, or begin the project, whichever occurs first. This must be a date in mm/dd/yy format.

Anticipated Project End Date – Estimate the date you expect to complete the final participant protocol-related therapy using Allina facilities. For Allina business units, this could also include completing the project or the written agreement ends. This must be a date in mm/dd/yy format.

Allina Facility – From the drop down box, select the facility where the participant may have services done. For example, if the research participant has an MRI at Abbott Northwestern Hospital, the Allina facility is Abbott Northwestern Hospital. For projects that will be taking place at multiple Allina facilities, please list each facility. If you have questions, contact SPA.

Note: If the Allina facility providing the service is not listed in the drop down box, it can be added by doing the following steps:

1. Go to the **Intro_Sheet**
2. Select Tools from the top of the screen
3. Choose the word “Protection”
4. Then select “Unprotect”
5. Go to cell T28 and enter the name

It is not necessary to protect the worksheet after the steps above have been completed.

Is this information being submitted for a new or previously denied project?

- **New** – Check this box if you are submitting a new project at this Allina facility.
- **Previously Denied** – Check this box if you are resubmitting a project that was previously denied.

Has, or will, this project be submitted to an Allina IRB for human subjects review? – Check either “yes” or “no” if your project has been, or will be, submitted for Human Subjects Review to either the United, Mercy, Unity, Phillips Eye Institute or Abbott Northwestern IRB. Check Community Cancer IRB if your project was submitted to the Community Cancer IRB.

Note: Only the IRB can determine if a project needs to be submitted for IRB review. Contact the Abbott Northwestern, Mercy, Unity, United or Phillips Eye Institute IRB at 612-262-4920.

2. Principal Investigator or Project Director Information

Name – List the person who is employed at the research site who is responsible for the activity of the project. No Allina employee can be a Principal Investigator or Project Director for a Vendor Project; they must follow the SPRP.

Practice Group – List the practice group if the Principal Investigator is acting on behalf of his or her private practice. **Projects done by an Allina employee or person acting in that capacity (e.g., medical director) are not eligible to submit a Vendor Project.**

3. Research Coordinator or Project Contact Information

Name – List the person whom Allina employees may contact with questions regarding the project.

Allina Employed – Check “yes” if the Project Contact is an Allina employee; otherwise check “no.” Generally, an employee of Allina participating in a project cannot qualify for a Vendor Project, unless a formal agreement exists between the non-Allina physician (group) and Allina. For example, if a physician group contracts with an Allina facility for staff time to help with research projects, there is a written agreement or contract for that work, and it is signed by a member of the business unit administration. Contact SPA at 612-262-4926 or 612-262-4927 if you have questions.

Practice Group/Allina Facility/Department – List the practice group if the Research Coordinator/Project Contact is supporting the activities of a Principal Investigator and his or her private practice. If the Research Coordinator/Project Contact is supporting the activities of a Principal Investigator who is acting on behalf of Allina (either as an employed physician or as a medical director), list the Allina facility and department.

4. Participant Information

Estimated number of participants (at the local site) – List the total estimated number of research participants expected to have services at the Allina facility.

- **Inpatient & Estimate** – No inpatient projects will be accepted as Vendor Projects.
- **Outpatient & Estimate** – Check this box if the research participants are going to be seen as outpatients and estimate the number expected at this Allina facility.
- **Other** – Check this box and explain what is expected of the Allina facility.

5. Payment and Billing Information

Research Site’s Plan Code – List your Research Plan Code. (To obtain an application for a plan code, call SPA at 612-262-4926 or 612-262-4927.)

6. Other Information

Do you foresee any services or items being conducted at an Allina Medical Clinic? – Check “yes” or “no.”

Comments – (optional) List any additional comments that may be pertinent to the project not covered in the form. Attach additional sheets if necessary.

Vendor Department Service Information Sheet (DSIS) Instructions

Purpose

The Department Service Information Sheet (DSIS) is used to obtain approval and an amount for the proposed fees for protocol-induced items and services. The DSIS should include all protocol-induced costs (PIC) listed on the Protocol-Induced Cost Worksheet. The DSIS must be signed by the Department Director and will serve as a proposal¹ between the research site and the Allina department. At some facilities, the vice president of the department may need to sign. The DSIS does not replace any written agreement executed and is subject to approval of the Accountable Executive of the Allina facility.

What to send to the department to get a price for a service – When requesting services from a department, you need to provide either the protocol or pertinent pages from the protocol to allow the department to adequately evaluate whether the service(s) can be done and to quote a price.

Note: Some of the information on the DSIS transfers automatically from other worksheets and does not need to be re-entered. These instructions are only for the items that did not transfer automatically and/or are not self-explanatory.

1. To be Completed by the Research Site:

Note: A sample Department Service Information Sheet is included in Part XI, the reference section of this Guide.

Service Department – List the department that will perform the service (e.g., radiology, lab, etc.). Complete a separate DSIS for each service department. For additional worksheets, click on the “Copy this sheet” button.

Note: Subsequent copies will be labeled DSIS (2), DSIS (3), etc. In order to access the copies, click on the tab at the bottom of the worksheet you wish to adjust.

Allina Facility – The Allina facility transfers automatically from the Information Worksheet.

For multi-site projects: It is necessary to first copy the DSIS for the number of Allina facilities performing work for the project. Enter a facility name on each DSIS. These worksheets must be signed by the Department Director and, if applicable, the Vice President for that facility. The price may vary at each facility for a particular service.

Estimated Number of Participants Expected at this Department – This number transfers from the Information Worksheet. You may change this number to reflect the number of patients expected in the particular department.

Anticipated Start Date – List the date when services are expected to begin in this department. The default is the anticipated project start date listed on the Information Worksheet. Change this date if it is different from the default date.

Column A: Protocol-Induced Items and/or Services for Research Project – List the items and services to be performed in the Allina department.

¹ Since the DSIS may be filled out prior to the project being final, the information may change. The price is considered a proposal until approved by the Accountable Executive.

Column B: CPT Code – In order to provide the most accurate price possible, it is suggested that the CPT code be listed in this column.

Column C: Estimated Number of Services Expected – List the maximum number of expected items and services for each participant. For example, if “Arm 1” has two tests and “Arm 2” has three tests, then three should be listed on the form.

Column D: Facility’s Gross Charge – To be completed by the department. This is the charge that will appear on the bill from the CBO. If the Allina Lab is the only services done, the price may be the net amount owed. More information is listed below.

Columns E: Facility’s Fee – To be completed by the department. This is the amount that the research site will have to pay for the protocol-induced cost item or service.

*Note: Prices are subject to change by the business units depending on various factors and will be provided in writing to the research site, except in the case of the Reference Lab¹. The price changes can be for various factors, including inflation adjustment or that the actual service is more involved than originally thought or conveyed. The research sites are responsible for implementing the price change immediately after being informed. **Research sites could see a price increase for projects that last longer than two years.***

Column F: Percent Discount – Use the formula $1-(E/D)$ to calculate the discount if the department has not already done so.

¹ The Allina Reference Laboratory (Allina Lab) is the name used for services that take place only at the Allina Lab and not part of any other outpatient or inpatient service. Because the price often quoted for research is the same rate charged to other organizations that use the Allina Lab, the prices are usually adjusted for inflation or cost. The Allina Lab bills at the Reference Lab rate and not the gross charge. The Allina Lab does these changes once a year. You can differentiate the prices for the Reference Lab and normal patient care by identifying who sent the bill and the look of the bill. Items to look for include:

- The Reference Lab bills come from the Allina Lab and not the Allina CBO or Allina facility.
- The bills come on an Allina statement and not on either the patient statement or screen prints.
- Often the participant’s name or initials are listed, along with the date of service, and the test performed.

2. To be Completed by the Service Department Director

In evaluating items or services requested by a research site, the Department Director needs to be aware of the following when agreeing to participate in the project and generating the price.

The department should “cross out” and initial any items or services that will not be conducted by the department. For example, radiology receives a DSIS that contains a chest X-ray and a 2D-echocardiogram; radiology does not do a 2D-echocardiogram, therefore, radiology would draw a line through the service. For another example, the DSIS lists a blood draw that requires extensive DNA testing, and the lab does not have the staff to support the testing. However, if the lab is willing to draw the blood for shipping to another location, it should draw a line through the DNA procedure, but indicate the price for the blood draw and shipping charges, if applicable.

Facility’s Gross Charge – The gross charge is the price for an item or service before any discounts are applied. The Department Director will provide this information.

Facility’s Fee for This Service – Enter the amount the department will accept from the research site for the protocol-induced items and services for this project.

- The Department Director may need to divide the item or service requested by the research site into individual components because of the billing system (e.g., a full body CT may need to be billed as a head CT, chest CT, etc.). The department will need to clarify the items and services to be provided on the DSIS so the research site will be able to identify the items and services on the bill from the business office.
- The Department Director must evaluate the level of service that is required by the protocol/research site and include the extra costs on the DSIS. For example, the DSIS may say chest X-ray, which for this example means single view, but in actuality is a two-view. Those extra requirements and costs should be identified on the DSIS.
- The Department Director may increase the price originally quoted for the services by providing notice to the site in writing. This should be done with caution as the research sites have budgets that are difficult to change. However, there are instances where it is appropriate. Some examples are listed below:
 - ~ The item or service cost is greater than originally expected. This may be a result of the protocol or explanation from the research site was unclear when originally quoted and the service required more work. This is especially true when the service is outside the norm and it is solely associated with the study.
 - ~ A supply cost increased significantly, especially drug or device costs.
 - ~ Inflation. It may be appropriate to increase cost for inflation in the case of longer projects, especially those more than two years duration.

Service Department Contact Person – List the person in the service department who should be contacted for scheduling a service, answering questions about a service, or for any other issue related to the department.

Service Department Director Signature – Signature of the director of the department who reports to a vice president of the business unit. Enter the date the DSIS was reviewed and approved by the Service Department Director.

Vice President’s Signature (if required by facility) – Abbott Northwestern Hospital requires that all DSIS forms are signed by the vice president accountable for that particular department. (Abbott is the only hospital that requires this.) Enter the date the DSIS was reviewed and approved by the vice president.

Vendor Sponsored Project Certification Instructions

The Principal Investigator must certify each project submitted to Allina for which he or she is solely responsible for the conduct of that project. Any project submitted without a signed Certification will be returned. A project cannot be reviewed within Allina until SPA receives a signed Certification. It is acceptable to submit a fax copy.

Why do the Setup Worksheets need to be Certified?

The Vendor Sponsored Projects Review Process is based on the principle of trust. When billing for services, Allina will assume that the information submitted by the Principal Investigator is accurate. It is expected that he or she has completed the worksheets in good faith and in accordance with all applicable laws, regulations and the Allina policies and procedures contained within this Guide.

What Does it Mean to Certify?

When a Principal Investigator certifies the Setup Worksheets, he or she is stating that he or she agrees to abide by applicable laws and regulations and Allina policies.

How to Complete the Certification

- View and print the Certification Form.
- Go to the “Intro_Sheet” and click the ***Go to Certification*** button.
- Click the ***Print Certification*** button.
- The Certification will also print when you click the ***Print Entire Workbook*** button.
- Read the Certification Form.
- Consult with your own legal counsel if you have questions regarding any of the items in the Certification.
- Sign the Certification Form.
- Place the signed document on top of the required items for SPA review.

The Certification shown here is for reference only. The copy included within the Project Setup Worksheets is the version that will be updated as necessary.

Principal Investigator Certification for Sponsored Vendor Projects Form

Introduction

Allina recognizes the value sponsored projects and research bring to the patients we serve and is committed to pioneering the latest treatments for our patients. These Certifications are needed to facilitate Allina's decision-making and to ensure sponsored projects and research are conducted in a manner compliant with all applicable law and payer policies.

Certification

As the Principal Investigator/Project Director of this project, I certify the following:

- I will abide by Allina policies and procedures and those of the IRB of record, including, but not limited to all policies, conditions and requirements of the IRB, applicable laws and regulations, and will comply with sponsor's protocol and policies to the extent consistent with Allina's policies and applicable laws.
- I have read and understood the *Allina Hospitals and Clinics Guide to Research Billing and the Sponsored Projects Review Process* ("Guide") for the completion of the "Project Setup Forms" or "Vendor Project Setup Forms" and the project being submitted is in accordance with those instructions.
- I understand that I am responsible for the conduct of this project in the Allina facilities.
- I agree that I or my staff will cooperate, in good faith, with Allina to assist in conducting any review or investigation should that be required for billing or compliance purposes.
- I understand that Allina may suspend its participation in this project for any reason upon providing written notice.
- I agree to update the information I have provided to Allina as part of this proposed project if changes occur or errors are discovered.

Project Title*:

Study Protocol # (as assigned by sponsor)*: _____

Principal Investigator/Project Director Signature

Date

Principal Investigator/Project Director Name Printed

Do not adjust any of the print areas or clear any print areas on any sheet in the workbook. Adjusting the print areas will cause the setup worksheets to print incorrectly.

Printing the Excel Vendor Sponsored Project Setup Worksheets

1. What to Print

The research site should print the following:

- Vendor Project Information Worksheet
- Department Service Information Sheet for each department
- Principal Investigator Certification (can be accessed from *Intro_Sheet*)

2. How to Print

Choose any method below to print the completed worksheets.

To print each completed sheet

- Click the **Print this Sheet** button located at the top of each worksheet to print the active sheet.

To print the entire workbook

- Click the **Print the Entire Workbook** button located on the *Intro_Sheet*.

To print multiple sheets at the same time:

Contiguous Sheets (next to each other)

- Select the sheet that you want to print. (The sheet tab should be white instead of gray.)
- While holding down the **Shift** key, click on the sheets or over the range you wish to print. The sheets that will print will all turn from gray to white.
- Choose **File** and **Print** or click the **printer icon** on the toolbar.
- To remove the selection, hold down the **Shift** key. Click on the sheet that starts the selection (its name is in bold).

Noncontiguous Sheets (not next to each other)

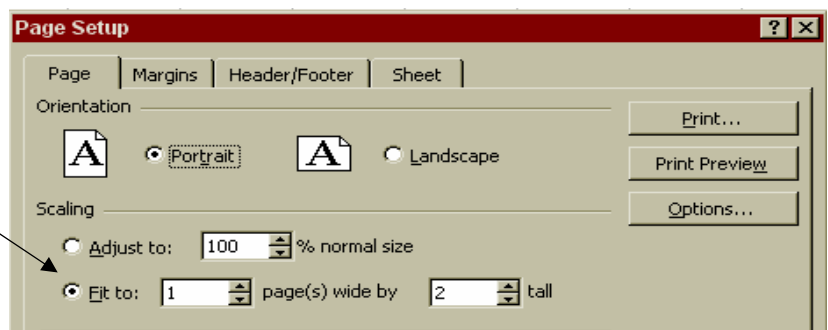
- Select the sheet that you want to print. (The sheet tab should be white instead of gray.)
- While holding down the **Ctrl** key, click on the sheets you wish to print. The tabs of the sheets selected to print will turn from gray to white.
- Choose **File** and **Print** or click the **printer icon** on the toolbar.
- To remove a sheet from the selection, hold down the **Ctrl** key. Click on the sheet you do not want to print.

If it prints on more than two pages, do the following:

- Click the **Print Preview** button
(piece of paper with magnifying glass)

Or

- Choose **File, Page Setup**
- Select **Fit to:**, 1 page wide by 2 tall



If you encounter any problems with printing, contact SPA at 612-262-4926 or 612-262-4927.

Submitting an Electronic Copy of Excel File

Each research site must submit an electronic version of the Vendor Project/Research Information Worksheet (**Info_WS**). Allina SPA requires this information to track projects being conducted within Allina facilities. The process is fairly straightforward and is described below.

Notes about the electronic data file

- The electronic file may be submitted at anytime provided the research site will be conducting the project within an Allina facility and the information on the worksheet is unlikely to change.
- The electronic file collects only data on the **Info_WS**.
- The electronic file is SPA's method of tracking projects and your project will not be reviewed until the electronic file is received.
- Contact SPA if you have any questions about the process for electronic submissions.

1. Save the File

- Complete all required worksheets in the project file.
- Make sure the **Info_WS** is free of errors, except for those marked as not applicable or NA.
- Save the file.
- Click on the file pull-down menu in the top left corner.
- Choose **Save**.
- A prompt to replace the existing file will appear. Click **Yes**.

OR

- Click the **Save** icon on the tool bar (usually the third icon from the left).
- Close any other Excel worksheets, except this file.
- Go to the **Intro_Sheet**. Click on the button titled **Make File for Allina SPA**.

Note: Clicking the button opens the "allina04.xls" Excel file, pastes the data from the Information Worksheet within the file and resaves it. The file does require confirmation that it is okay to paste over the data currently located in the "allina04.xls" file. Click the "yes" box with the mouse. The file should close and it is ready to send to SPA.

2. Send the File to Sponsored Projects Administration

- Open your e-mail application.
- Address the e-mail to spa@allina.com
- Select **Attach File**. Follow the e-mail application's instructions for attaching a file.
- Choose the "c:\data\allinasprp" folder. Select the "**allina04.xls**" file. It may appear as Allina with the **Excel** icon right before the name.
- Click the **Open** or **Attach** button. The "**allina04.xls**" file may appear in the body of the e-mail.
- Send the e-mail to spa@allina.com

3. Confirmation

Allina SPA will send an e-mail confirming that the data has been received and successfully entered into the system.

Submission Guidelines for Vendor Sponsored Projects

Upon completion of the Setup Worksheets and their electronic submission, submit a hard copy of the following information to SPA.

What to Submit (in the following order):

- A signed Vendor Sponsored Projects Certification Form
- The Vendor Information Worksheet
- The Vendor Department Service Information Sheets signed by the Allina department director(s)
- Two signed copies of the Vendor Services Written Agreement (“*vsa.doc*”) (see Part VII of this Guide)
- A copy of the final IRB approval or exemption letter
- A copy of the Research Informed Consent
- An abstract (a copy of the one submitted to the IRB) of the project or summary of the protocol

Send Materials to:

Sponsored Projects Administration
Internal Zip 10105
Allina Health System
PO Box 43
Minneapolis, MN 55440-0043

Note: The research site should maintain a complete copy of the proposal.

Upon receipt of the project, Allina SPA will send an e-mail to confirm that SPA received all required project materials. You may be contacted to provide additional information.

Vendor Sponsored Project Review Process

Upon receipt of a completed proposal, Allina SPA will:

- Review the Vendor Project Information Worksheet and DSIS
- Review the Written Agreements
- Consult with the Accountable Executive who will either approve or deny the project
- Send an approval or denial letter after the project review is complete (if your project was denied, you will also receive further instructions and the reason for the denial)
- Notify the research site of the project approval status

Completing the Project Change Form for a Vendor Project

The purpose of this form is to notify and seek approval from Allina for changes to an approved project. The form needs to be completed for all types of changes to a project. For more information, refer to Policy RES 304.00 and Procedure RES 304.01 located in Part I, “Policies and Procedures,” of this Guide.

1. There are two types of project changes for Vendor Sponsored Projects

A. Major Change – a material change that may impact Allina’s participation in the project. Major changes must be submitted within five business days of the change. Major changes include:

- changes to executed written agreements;
- changes to Department Service Information Sheets;
- a change in the Principal Investigator or project sponsor;
- a change in the number of participants of at least 10%;
- a change in address of the Principal Investigator or research site;
- a change in the project site or the addition of new Allina sites; or
- the project ends for any reason.

B. Minor Change – any change that is administrative in nature and does not directly affect the scope of the project, such as an e-mail address.

2. How to Complete the Project Change Form

- Open Word
- Click the *Open Folder* icon or choose *File/Open*
- Look in **C: drive**
- Double click *Data\Allinasprp Folder*
- Double Click *Project Change Form*
- In the document:
 - insert the Principal Investigator’s name and address,
 - insert the complete protocol title and number, and
 - insert the items to be changed, the previously reported information, and the new information and the reason.

The Principal Investigator must sign and date the Project Change Form in order for SPA to acknowledge the changes.

3. Additional Information about the Form

- You may add more rows if necessary by clicking the *Table* pull-down menu and choosing *Insert Row*.
- The data inserted into the table is to provide guidance on how to fill out the form. You may delete this information after completing the change form for your project.

Fax or mail the completed Project Change Form to:

Sponsored Projects Administration
Internal Zip 10105
Allina Health System
PO Box 43
Minneapolis, MN 55440-0043
Fax: 612-262-4953

Project Change Form

[Date]

[Add PI address info below]

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

RE: [Insert Full Protocol Title and Number]

I request that Sponsored Projects Administration record the following changes to the project.

This project no longer meets the qualifying status in the NCD.
Fax immediately to 612-262-4953.

Item to be Changed	Previously Reported Information	New Information	Reason for Change
<i>Example:</i> Project Sponsor	<i>Example:</i> Minnesota Department of Health	<i>Example:</i> MN Dept of Human Services	<i>Example:</i> Change in Sponsor

I hereby certify that the information previously attested to in the Principal Investigator Certification remains accurate with the changes listed above.

 Signature of Principal Investigator

 Date

 [Type in, or print, Principal Investigator's Name]