

Part IV: Sponsored Projects Review Process

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

A sponsored project is defined as any program or project supported by funding from an outside source that requires specific performance by Allina. Examples include government grants and clinical trials sponsored by drug and device companies. There are two kinds of sponsored projects: Vendor Sponsored Projects and Sponsored Projects. (Refer to policies RES 301.00 “What is a Sponsored Project?” and RES 306.00 “Vendor Sponsored Projects Review Process;” see Part I of this Guide 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, proceed to Part III of this Guide. If the project fails to meet any one of the criteria, continue with the process described in this section.

Determining if the Project meets the Vendor Sponsored Projects Criteria

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

- Allina provides items or services that are ancillary to the operation of the project.
- The project will not require third party billing by Allina.
- The researcher has documentation of approval of the project by an Allina or other IRB.
- The project has a limited compliance accountability that flows back to Allina.
- No Allina employee is involved in collecting information about research subjects except as part of his or her normal duties.
- It is 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 risk rates 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 Part III, “The Vendor Sponsored Projects Review Process.”

NO. Does the project involve the use of a medical device?

NO. Continue in Part IV.

YES. Proceed to the instructions listed in Part V.

Sponsored Projects Review Process

Purpose/General Statement

This section provides the information on completing the Sponsored Projects Setup Worksheets, submitting the worksheets to Allina, and the overall review process. Completing the Project Setup Worksheets is the first step of the SPRP. A research site is subject to the Allina SPRP if it meets the criteria found within Research Compliance Policy RES 305.00 (Part I).

Allina designed the SPRP to review sponsored projects that may be conducted within Allina facilities. As part of Allina's overall compliance program, it became necessary to evaluate and review projects that are conducted within Allina facilities for financial feasibility and billing compliance before final approval. It will be necessary for the research site to identify—in advance—how particular items and services within the project will be billed to a third party payer or paid for by the project's sponsor.

Note: The Sponsored Projects Review Process is separate from the Institutional Review Board (IRB) process.

Overview

- The research site must complete all applicable information on the Allina Sponsored Project Setup Worksheets as described within this section.
- The research site must complete these Sponsored Project Setup Worksheets for each new or different project.
- There are two types of sponsored projects: 1) medical device projects, and 2) all other types of sponsored projects. If the research site is conducting a medical device trial, go to Part V, "Sponsored Projects Review Process for Medical Devices." For all other types of sponsored projects, continue in this part and complete the worksheets in the Excel file entitled "*project04.xls*."

Steps in the Sponsored Projects Review Process

Note: A SPRP checklist appears in Part XI of this Guide.

The research site should submit the following:

- Completes the following Sponsored Projects Worksheets:
 - Sponsored Project/Research Information Worksheet
 - Schedule of Events (SOE) Worksheet
 - Protocol-Induced Cost (PIC) Worksheet
 - Department Service Information Sheets (DSIS)
- Completes the Sponsored Project Certification Form
- Completes a Purchase Service Agreement
- Provides a copy of the IRB Approval Letter
- Provides an abstract of the project (a copy of the one submitted to the IRB)
- Provides a copy of the entire Protocol
- Provides a copy of the Informed Consent, as submitted to the IRB or the version approved by the IRB
- Completes a Case for Support
- Submits the documents listed above in the order specified in this Guide.

How to Complete the Sponsored Projects Worksheets

This section outlines step-by-step instructions for completing the Setup Worksheets and submitting the project to SPA.

Note: Samples of the Sponsored Projects Worksheets are provided in Part XI of the Guide.

1. Open and Save the File

- To begin the Setup Worksheets, open the Excel file entitled “*project04.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 Sponsored Project/Research Setup Worksheets.” Buttons on this page will help the user navigate throughout the workbook.
- Start a new file by saving the “*project04.xls*” file under another file name.
- Click the file pull-down menu at the top left corner.
- Choose **Save As**.
- Choose a file name that is something other than “*project04.xls*.” SPA suggests a name that will be easy for you 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:
 - Information Form
 - Schedule of Events Worksheet or Schedule of Events in the Protocol
 - Protocol-Induced Cost Worksheet
 - Department Service Information Sheet
- To begin, click on the **Info_WS** button.
- After 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 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 Section, “Printing the Setup Worksheets.”
- Submit the project to SPA. See sections, “Submit Electronic Copy of the Excel File” and “Submission Requirements for SPA Review.”

These instructions apply to the Information Worksheet in *“project04.xls.”* The file is located in the c:\data\allina04 folder on your computer. Each field on this form with an asterisk (*) is a required field. If a required field does not apply, please indicate with “NA.” 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.

Sponsored Projects Research Information Worksheet

The Sponsored Project/Research Information Worksheet and submission requirements are necessary for any sponsored project, whether research or non-research related (programmatic), conducted by Allina employees or departments. The data must be submitted electronically. Please see Part IX, “Process for Allina Employees,” of this Guide for more information.

Note: The term “drug” is used throughout this section for simplification purposes. But it is meant to represent the purpose of the project.

1. General Information

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 a 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.

Number of Arms – Indicate the number of different methods (arms) being evaluated for this project. For example, a project with a control group and a treatment group would have two arms.

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

Pass-Through Entity – If you receive funds directly from an entity other than the original sponsor, list that entity here. Under federal law and Allina Medicare and Medicaid Policy 412-01.13, we have a duty to ensure that we do not have any relationships with persons or entities excluded from federal health care programs. If the project does not have a pass-through entity, enter “NA.”

Will any part of this project be paid for with governmental sponsored project funds, either directly or by pass-through, to your site? – If the project is funded by a governmental entity, please check “yes.” If the project is for an Allina employed activity, contact SPA to discuss the project. Please see Research Compliance Policy RES 300.00, “Federal and State Sponsored Projects Awarded to Allina Hospitals & Clinics” (Part I). All research sites must complete this question regardless of affiliation.

Anticipated Project Start Date – Estimate the date you expect to either enroll 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 date the written agreement ends. This must be a date in mm/dd/yy format.

Allina Facility – Choose the facility (from the drop-down box) 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 or, if you have questions, contact SPA.

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

- Go to the *Intro_Sheet*
- Select *Tools* from the top of the screen
- Select *Protection*
- Then select *Unprotect*
- 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 this is a new project at this Allina facility.
- **Previously Denied** – Check this box if this project is being resubmitted after being 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.

Does this project meet the qualifying criteria as outlined in the Medicare Coverage of Clinical Trials ~ National Coverage Decision (NCD) as published by CMS? – Check either “yes” or “no.” See Part II of this Guide for additional information.

If the project does not meet the NCD, please check the appropriate box – Check “Outpatient Self-Administered Drug,” “No Reimbursement Allowed” or “Other” to identify the category that best describes the project. Projects checked as “Other” may involve the use of approved drugs or screening trials. The categories previously listed match closely those found in Part II of the Guide. For further information, refer to Part II of this Guide.

Self-Certification – No trials are covered based on self-certification as this time.

2. Principal Investigator or Project Director Information

Name – List the person at the research site who is responsible for the project, typically this is a physician.

Allina Employed – Check “yes” if the Principal Investigator is employed by Allina or acting in the capacity as an Allina employee, such as a medical director.

Practice Group/Allina Facility/Department – List the practice group if the Principal Investigator is acting on behalf of his or her private practice. If the Principal Investigator is acting on behalf of Allina either as an employed physician or as a medical director, list the Allina facility and department where he or she works.

Joint CCOP and CGOP Submission – Check only if the project is a joint CCOP & CGOP submission.

3. Research Coordinator or Project Contact Information

The research site should designate one person to coordinate the projects being conducted at Allina. Should questions arise about a project, Allina SPA will contact that person.

Name – List the person that Allina employees may contact with questions about the project.

Allina Employed – Check “yes” if the Project Contact is an Allina employee, otherwise select “no.”

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. The default is the address of the Principal Investigator.

4. Participant Information *(You may skip this section if your project does not involve research.)*

Estimated number of participants (at local site) – List the estimate of the total number of research participants expected to be enrolled at the Allina facility. This should be the actual number expected to be enrolled within Allina facilities as opposed to the number submitted to the IRB. The number provided will be used for analysis purposes.

- **Inpatient & Estimate** – Check this box if the research participants are going to be seen as inpatients and estimate the number expected at this Allina facility.
- **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.

Do you expect this project to result in additional inpatient days or increase the time necessary to provide outpatient services? Check either “yes” or “no.” If you checked “yes,” comment about the expected additional days or services. For example, if an inpatient is expected to be in the hospital for three days but, because of the trial, it is necessary the participant stay an extra day for monitoring. The extra day will result in additional costs for the hospital, but may not result in additional revenue for the hospital due to payment methods from third party payers.

5. Payment and Billing Information (*You may skip everything in this section, except Research Plan Code, if your project does not involve research.*)

Research Plan Code – List your RPC. SPA uses the RPC to track all projects and it is required. If your department is part of Allina or does not have a RPC, and the project you are submitting is not related to research, type “NA” in the field. (To obtain an application for a RPC, call SPA at 612-262-4926 or 612-262-4927.) See Research Compliance Policy RES 305.00 (Part I) for more information.

IND Number – (Investigational New Drug) List the IND number.

Check the box that describes the Phase of the study – Check the appropriate box, Phase 1 through 4, which indicates the drugs status in the FDA review process.

If the clinical trial is IND or IND-exempt, has the sponsor communicated this number to CMS? – Check either “yes” or “no.”

Until the clinical trials registry is established, in order for an IND- or IND-exempt trial to be covered, the trial's sponsors must identify themselves by sending an e-mail to clinicaltrials@cms.gov. For additional information, refer to <http://www.cms.hhs.gov/coverage/8d.asp>.

All researchers conducting IND or IND-exempt trials that qualify under the NCD must check yes; otherwise the project could be denied. If the sponsor has not communicated with CMS, please explain why in the comments section. Allina will not participate in the project unless the sponsor has notified CMS. Allina recommends that researchers have written documentation such as a copy of the e-mail identification from the sponsor of the communication between the sponsor and CMS.

Please check all the boxes that apply.

Check the appropriate box below that describes the purpose of the study. Some of the items may be redundant, but they will assist us in determining the types of projects being done within Allina.

Approved – Check this box if the project is evaluating an approved drug or pharmaceutical.

Off-Label Use – Check this box if the project is collecting data on the off-label use of a drug.

Compassionate Use – (a.k.a. Single Use) Check this box if the project will be using a drug under Compassionate Use provisions of the FDA. Contact SPA if you may have a project involving compassionate use for further guidance.

Support New IND – Check this box if the project involves an approved drug, but where a new indication is being studied.

Post-Marketing Study – Check this box if the project is part of a Post-Marketing Study. Careful attention must be made to projects of this type because of the potential for abuses. Research sites need to ask themselves the following:

- What is the purpose of the study? To assist in marketing or to answer questions now that the drug is in wide circulation.
- Has the FDA asked for additional data? Did the FDA ask the sponsor to collect additional data because of adverse events?
- Does the money being paid meet fair market value guidelines?

Exempt – Check this box if the drug is exempt from FDA review.

Other – Check this box and provide a description of the type of project being submitted. This could include medical devices being used in conjunction with a IND study. You may need to complete the “*device04.xls*” Excel file instead if the device is not provided free from the sponsor.

Procedure to be Performed or Diagnosis – List the name of the procedure that will be done in the Allina facility or the reason the person may be in the facility. Use medical terminology or the common name for the procedure. If there is not a procedure, then list diagnosis or condition that brought the participant into the Allina facility.

Closest DRG, CPT, or ICD-9 – Indicate the nearest DRG, CPT or ICD-9 to the service described above. The sponsor should be able to provide this information. This number is used to analyze the project and any payment from a research site will be made using the average reimbursement for this DRG, CPT, ICD-9 or procedure. For example, if the research site (ultimately the sponsor) agrees to pay for a service because it was denied by a third party payer, it must pay at the rate listed on this worksheet or the actual DRG, whichever is higher.

Closest APC or CPT – Indicate the nearest APC or CPT to the service described above. The sponsor should be able to provide this information. This number is used to analyze the project and any payment from a research site will be made using the average reimbursement for this CPT, APC or procedure. For example, if the research site (ultimately the sponsor) agrees to pay for a service because it was denied by a third party payer, it must pay at the rate listed on this worksheet or the actual CPT and related codes, whichever is higher.

Enter the name of a comparable drug – List the name of a FDA *approved* drug that is the most like the investigational drug. If the project is collecting information about an approved drug, please list the alternative drug.

Check yes or no if the drug will be provided free of charge – Check either “yes” or “no” if the drug or other non-medical device item or service is being provided by the sponsor without cost to Allina.

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

6. Other Information

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

7. Allina Only

Sponsored Project Accounting Unit (Allina Only) – List the accounting unit where the expenses of this project are being recorded and to where the charges from the project may be transferred.

8. Full Time Equivalent (FTE) Information

Will new Allina FTEs be required for this project? – Check “yes” or “no” depending on whether hiring additional staff will be needed to meet the project objectives. For example, if an Allina department wishes to obtain a sponsored project to educate people about diabetes and needs to hire three new educators, the answer would be yes. If a department is using current staff, the answer would be no.

How many? – Indicate the number of FTEs needed to carry out the project. Using the example above, the number should be three, for the number of new FTEs.

Instructions for the Schedule of Events Worksheet

The purpose of the Schedule of Events Worksheet (SOE) is to identify items and services, which are considered, in good faith, to be either routine care or protocol-induced costs for the typical participant. For the purposes of these worksheets, “good faith” is defined as the absence of malice or any intention to deceive. The information on the SOE will provide documentation to support the billing of a third party payer by Allina, if applicable, and will also be used in the auditing and monitoring of the project.

Schedule of Events is a plan of care that the typical participant will receive during his or her participation in the research protocol. The plan may also be called a matrix, protocol table, schedule of study evaluation, study of activities, etc.

Note: There are three methods for completing the SOE requirement. Be sure to read the entire section before beginning. The file containing the Allina SOE is located in the “project04.xls” Excel file.

Routine Care is care that is medically reasonable, necessary, and ordinarily furnished (absent of any research programs) in the treatment of patients by providers under the supervision of physicians as indicated by the medical condition of the patients. By this definition, the appropriate level of care criteria must be met for the costs of this care to be reimbursable. Such care may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, skilled nursing and other related professional health services. Terms synonymous with routine care are usual patient care or standard care.

Protocol-Induced Costs are additional items or services that the typical participant will receive during his or her participation in a research protocol or study that are not routine care. Items or services that the participant would receive in the absence of a clinical trial are not considered protocol-induced costs, even if these items and services are also listed in the protocol. It is important for all parties involved with the project to be consistent in applying the criteria listed below for all projects. Protocol-induced costs include the following:

- Items or services provided solely to determine trial eligibility.
- Investigational item or service itself.
- Items or services required solely for data collection and analysis needs that are not used in the direct clinical management of the patient.
- Items customarily provided for free by the sponsor. *Note: This also means items and services that the sponsor covers wherever the study is being done, not just at the local research site.*
- Items or services which cannot be billed because of the lack of a specific charge; e.g., a phlebotomy for a sample that is to be sent to the sponsor or has no Medicare benefit category.
- Items or services which fall under a national non-coverage policy.
- Items or services which are statutorily excluded.

Note: Based on the criteria of the NCD, research-related items and services for certain types of trials are not covered by some third party payers. It is important to consider these criteria when identifying routine care and protocol-induced cost items and services. See Part II, “Billing Guidance” of this Guide for instructions and additional information. The Protocol-Induced Cost Worksheet Instructions in the next section also contain information about trial exclusions.

Routine Care versus Protocol-Induced Costs

When completing these worksheets, the Principal Investigator must ask, “Would I routinely order this item or service for a person with this condition if he or she were not participating in the protocol?” If the answer is yes, then the item or service is routine care. If the answer is no, the item or service is a protocol-induced cost.

Example: The participant's routine care plan calls for a chest X-ray every six months, for a total of two per year. The protocol schedule of events calls for a chest X-ray every two months, for a total of six per year. The X-rays received at six and 12 months are considered "routine care." In this case, the X-rays received at two, four, eight, and 10 months would be considered “protocol-induced costs.”

Using **one** of the following methods, you must identify the protocol-induced costs for your project:

A. The Schedule of Events included in the protocol

OR

B. The Allina Schedule of Events Form

OR

C. In some instances, it may be necessary to use both the Protocol Schedule of Events and the Allina Schedule of Events. Refer to section “C” for details.

1. Step One: Identify Protocol-Induced Costs (PIC)

A. Using the schedule of events included in the protocol to identify PIC:

You may use the SOE included in the sponsor protocol provided it is in table format and includes a study timeline. If the protocol includes a SOE for each study arm, you must identify the items and services as discussed below. However, if the protocol combines study arms and it is difficult to distinguish the different items and services, you may need to follow the instruction in Part C of the Schedule of Event Instructions.

Complete the following steps:

Indicate the protocol-induced items or services by:

- placing a circle around those considered to be protocol-induced and to be performed in an Allina facility;
- placing a triangle around those considered to be Non-Allina Protocol-Induced Costs (NAP);
- writing “All services are routine care” on the top of the SOE if all items are routine care; and
- writing “All services are protocol-induced cost,” on the top of the SOE if all items are protocol-induced costs.

Note: Items that are not indicated are considered routine care and Allina may bill a third party payer according to the established guidelines set forth by Allina billing policies and procedures and the Medicare Coverage of Clinical Trial ~ National Coverage Decision.

If the protocol has a different SOE for each study arm, each arm should be marked according to the instructions. If the protocol does not include a SOE for each study arm, but uses a combined SOE, you do not need to complete Allina’s SOE provided that the items and services are easily distinguishable for the different arms.

Photocopy the (marked) schedule of events and send to SPA.

Note:

- *Items or services that have been combined into a single entry on the SOE worksheet must be listed as separate line items. (See Section C for additional information.)*
- *Any items or services that are not included in the Protocol Schedule of Events must be listed on the Allina SOE worksheet. (See Section C for additional information).*

SAMPLE of “Marked” Schedule of Events

The protocol-induced costs have been circled. The non-Allina protocol-induced costs have a triangle.

Protocol # 123456	Week 1	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12
Pregnancy Test	△ X △						△ X △
Hemaglobin Level	X			X			X
CT Scan	○ X ○		○ X ○				X
Physical Exam	X	○ X ○	X	○ X ○	X	○ X ○	X

Table SOE - 1

B. Using the Allina Schedule of Events (SOE) Worksheet to identify PIC

- Complete the SOE when the protocol does not include a schedule of events in table format or when the space for the protocol’s schedule of events does not allow for circles and triangles. Open the SOE Worksheet from the Sponsored Projects/Research Welcome Page (Excel sheet labeled **Intro_Sheet**) or by clicking the **SOE** tab located at the bottom of the worksheet.
- Identify the variations in each study arm using the following two methods:
 - Complete this form for each arm of the study
 - OR**
 - Complete one SOE and identify the changes between the various study arms, as shown in the following example.

Sample Allina Schedule of Events Worksheet

6	A	B	C	D	E	F	G	H	I	J	
6	Press the TAB key to move between fields										
7	<input type="button" value="Insert Column"/> <input type="button" value="Insert Row"/>	Study Arm	Study Timeline								
8			Day 1	Day 2	Day 3	Day 4	Week 4	Week 8	6 Months		
9	Service/Drug/Device/Equipment										
10	CLINICAL <input type="button" value="v"/>										
11	PHYSICAL EXAMINATION	All	RC	RC	RC	RC	RC	RC	RC		
12											
13	STANDARD TREATMENT <input type="button" value="v"/>										
14	Heparin	All	RC	RC	RC	RC					
15											
16	EXPERIMENTAL TREATMENT <input type="button" value="v"/>										
17	SuperThinner X	Treatment	PIC								
18	Placebo	Control	NAP								
19	LABORATORY <input type="button" value="v"/>										
20	DNA (NB PIC data collection only)	All	PIC			PIC			NAP		
21	Liver Blood (B PIC for complication)	All	PIC	PIC	PIC	PIC	PIC	PIC	NAP		
22	Enzyme Test (NB PIC)	All	PIC			PIC		PIC			
23	Standard Labs	All	RC	RC	RC	RC	RC	RC			
24											
25	OTHER <input type="button" value="v"/>										
26											
27	RADIOLOGY <input type="button" value="v"/>										
28	EKG	All	NAP			RC			RC		
29	CT Scan	All		PIC					RC		
30											

Table SOE-2

Complete the following sections:

- **Arm of Study** — Enter the arm of the study (e.g., Control Arm, Arm 1, etc.) or type “ALL” if you are completing only one SOE.
 - Note: Subsequent copies will be labeled SOE (2), SOE (3), etc. In order to access the copies, click on the tab at the bottom of the worksheet you wish to adjust.*
- **Study Arm** — If completing a combined SOE, where all study arms are on one SOE, identify the items or services that are different for the various study arms in this column. See Table SOE-2 for an example.
- **Identify the Study Timeline** — Use row eight of the worksheet to identify the study timeline (columns B and so on). Enter the time period when the participant will be receiving an item or service required by the protocol in the table. To add extra columns, click the “Insert Column” button. The column will always be inserted in Column L.
- **Identify the Service Categories and Procedures** — Column A identifies procedures and categories (clinical, lab, radiology, standard treatment, experimental treatment, and other services) in the protocol.
 - Click on the arrow to choose a category in which to separate the items or services.
 - Enter the item or service in the rows underneath the category title. Click on the cell below the category to add items or services.
 - To add more rows, click on a cell in the section where you want to add a new row. Click on the **Insert Row** button.
 - To delete a row, click on a cell in the row that you want to delete. Click the **Delete Active Row** button at the bottom of the worksheet.
 - **Classify the Item or Service** — Type “RC” in the table for each routine care item or service. Type “NAP” in the table for each protocol-induced item or service that will not be performed in an Allina facility. Type “PIC” in the table for each protocol-induced cost item or service that may be performed at an Allina facility.

C. Using the Allina SOE as a supplement to the schedule of events included in the protocol to identify PIC

There may be some cases in which you may need to use the protocol’s schedule of events and Allina’s SOE worksheet concurrently. The following scenarios describe when to use both types of schedule of events:

- **The schedule of events from the protocol does not include all protocol-induced costs.**

Instructions:

To report items or services which are *not included* on the schedule of events from the protocol, write “See attached” on the bottom of the SOE from the protocol, and list the item(s) on the Allina SOE.

- **The schedule of events, from the protocol, combines protocol-induced cost and routine care into a single line item or category.**

Example: If the protocol schedule combines two or more drugs (one is the approved drug and one is the experimental drug) into one category called “Study Medications,” each drug must be listed separately on the Allina SOE.

Instructions:

Draw a line through the combined items or services listed on the SOE from the protocol. List the items or services as separate line items on the Allina SOE.

Sample of “Marked” Schedule of Events

Protocol # 98765	Week 1	Week 2	Week 3	Week 5	Week 7	Week 9	Week 10	Week 12
Lab	X		X		X			X
Global Assessment								
Study Medications	X		X		X			X

Sample of Allina Schedule of Events Form

Protocol # 98765	Week1	Week3	Week 7	Week 12
Clinical				
Study Drug A	RC	RC	RC	RC
Study Drug B	PIC	PIC	PIC	PIC

Separate the combined costs

2. Step Two: Transferring the Protocol-Induced Items and Services to the Protocol-Induced Cost (PIC) Worksheet

Upon completion of either the schedule of events from the protocol or the Allina SOE worksheet, transfer all protocol-induced items and services to be performed in an Allina facility to the PIC worksheet. Refer to the instructions for the PIC worksheet.

Instructions for the Protocol-Induced Cost Worksheet

1. Purpose

The Protocol-Induced Cost Worksheet (PIC) is used to summarize the PIC items and services and to identify how these items and services will be paid. The PIC and the SOE worksheets provide the documentation required to support the billing for the project by Allina and will be used as a monitoring and auditing tool by Allina. *Follow these instructions to complete the PIC worksheet in the “project04.xls” Excel file.*

Note: It is important that the PIC worksheet be updated when circumstances around the project change. As previously stated, this is the primary tool for monitoring and auditing.

Protocol-Induced Cost (PIC) refers to additional items or services that the typical participant will receive during his or her participation in a research protocol or study that are not routine care. Items or services that the participant would receive in the absence of a clinical trial are not considered protocol-induced costs, even if these items and services are also listed in the protocol.

2. How to Complete the PIC Worksheet

Complete columns A through F as indicated below.

Column A: List the Protocol-Induced Cost (PIC) indicated on the Schedule of Events (SOE)

Worksheet – List the protocol-induced items or services identified on the schedule of events that will be performed in an Allina facility (e.g., CT scans, hemoglobin tests, etc.). These are items and services for which Allina will bill the research site according to the Guide and Allina billing policies and procedures.

Column B: Identify Project Arm – Indicate the arm of the study to which the item or service applies (e.g., Control Arm, Arm 1, etc.). Group the items and services by arms of the study (i.e., all items and services for Arm 1 will be together and so on). It may be left blank if all arms are the same.

Column C: Facility’s Fee for This Service – Insert the amount the Allina facility is charging for the PIC item or service listed on the DSIS discussed in the next section.

Column D: Total # of PIC(s) from the Protocol/SOE – Using the Protocol or SOE, indicate the total number of PICs to be performed in an Allina facility for each item or service. For example, if the typical participant receives a total of six CT scans, two of which are routine care, and four of which are protocol-induced cost, the total number of PICs would be four. Do not include items or services indicated as NAP or with a triangle.

Protocol-Induced Cost – Protocol-Induced Costs are additional items or services that the typical participant will receive during his or her participation in a research protocol or study. Items or services that the participant would receive in the absence of a clinical trial are not considered protocol-induced costs, even if these items and services are also listed in the protocol. Protocol-induced costs include the following:

- Items or services provided solely to determine trial eligibility.
- Investigational item or service itself.
- Items or services required solely for data collection and analysis needs that are not used in the direct clinical management of the patient.
- Items customarily provided for free by the sponsor. *Note: This also means items and services that the sponsor covers wherever the study is being done, not just at the local research site.*
- Items or services which cannot be billed because of the lack of a specific charge; e.g., a phlebotomy for a sample that is to be sent to the sponsor or has no Medicare benefit category.
- Items or services which fall under a national non-coverage policy.
- Items or services which are statutorily excluded.

Column E: Enter “Yes” if the Sponsor is Paying Directly for the Service¹ – If the answer is yes, type “yes.” (Do not enter anything in this column if the answer is no.) This PIC may not be billed to a third party. The research site is responsible for payment to Allina upon receipt of a bill or an invoice. Allina will not bill a third party payer for items and services for which the researcher receives money directly from the sponsor. In other words, even if the services became billable because of medical necessity, it still could not be billed because the research site is receiving money for the service.

Column F: Total Dollar Amount of PIC to be Paid By the Research Site – The spreadsheet contains a formula that will calculate this number for you. (Column C times Column D.)

¹While this question addresses specifically being paid for an item or service, research sites need to be aware of the concept of fair market value and its relation to services that are billable protocol-induced cost or possibly even routine care. If the sponsor is paying a research site a sum that may be considered excessive for the amount of work performed by the researcher and research staff, then the research site needs to be able to justify the payment. In other words, the researcher is billing more to insurance so that he/she can keep the excess funds. For example, a Principal Investigator is doing a project and is receiving \$5,000 per patient and the only work he or she is doing is collecting a history and physical, but ordering a number of tests. Fair market value is a judgment call, but research sites should be sure to document and justify internally for what and how the funds are to be used.

Department Service Information Sheet

1. 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 listed on the PIC 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 over the department may need to sign the worksheet. The DSIS does not replace any written agreement executed and is subject to approval by 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, 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 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 do not transfer automatically and/or are not self-explanatory.

2. To be completed by the Research Site:

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. A sample DSIS is included in Part XI, “Reference” of this Guide.

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. This date should be in mm/dd/yy format.

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

Column B: CPT Code – In order to facilitate the department providing as accurate a price as possible, it is suggested that the CPT code be listed in this column.

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 C: Estimated Number of Services Expected per Participant – 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 Allina. If the Allina Lab provided the only service done, the price may be the net amount owed. More information is listed below.

Column 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.

3. To be completed by the Service Department Director

In evaluating items or services requested by a research site, the Service 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 2D-echocardiogram thus, radiology would draw a line through the service. Another example: the DSIS lists a blood draw that requires extensive DNA testing, and the lab does not have the personnel 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 Service Department Director will provide this information.

¹ The Allina Reference 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 Allina Lab, the prices are usually adjusted for inflation or cost. The Allina Lab bills the Reference Lab rate and not at the gross charge. The Allina Lab makes 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 format. Items to look for include: 1) the Reference Lab bills come from the Allina Lab and not the Allina CBO or Allina facility, 2) the bills come on an Allina Statement and not on either the patient statement or screen prints, or 3) often the participant’s name or initials are listed, along with the date of service, and test performed.

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 result if the protocol or the 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 just because of 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 over two years.

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.

Phone – Enter the contact person's area code and phone number.

Fax – Enter the contact person's area code and fax number.

Internal Zip – Enter the contact person's internal zip.

Service Department Director Signature – Signature of the director of the department who reports to a vice president of the business unit.

Date – 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 over the particular department. (Abbott is the only hospital that currently requires this.)

Date – Enter the date the DSIS was reviewed and approved by the vice president.

The Principal Investigator must certify each project submitted to Allina for which he or she is solely responsible. Any project submitted without a signed Certification will be returned. A project cannot be conducted within Allina until SPA receives a signed Certification. *These instructions and information are applicable to the Principal Investigator Certification in the “project04.xls” Excel files.*

Principal Investigator Certification

Why do the Setup Worksheets need to be certified?

The Sponsored Projects Review Process designed by Allina relies on trust. When billing for services, Allina will rely on the information submitted by the Principal Investigator to be 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 the identified items and services are either routine or protocol-induced and if these items and services can be billed to a third party payer. He or she is also stating the sponsor’s provision for payment.

How to complete the Certification Form

- 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.

Sponsored Project Certification Principal Investigator Certification for Sponsored 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:

- All of the information I have submitted to Allina as part of this proposed project, including but not limited to, the "Schedule of Events" and "Protocol-Induced Care Worksheet," is accurate in all material respects.
- I have accurately identified health care services that are routine care for the study population and do not constitute (a) investigational drugs, medical devices or procedures, or (b) non-billable protocol-induced costs. At Allina's request, I will provide information which supports my conclusions regarding services identified as routine care on the "Schedule of Events" and "Protocol Induced Care Worksheet."
- I will abide by Allina policies and procedures, 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 & Clinics Guide to Research Billing and the Sponsored Projects Review Process* (Guide) for the completion of the "Project Setup Worksheets" or "Vendor Project Setup Worksheets" and the project being submitted is in accordance with those instructions.
- I understand that I am responsible for the conduct of this project in Allina facilities.
- I agree to update the information I have provided to Allina as part of this proposed project if changes occur or errors are discovered.
- 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.

Project Title: _____

Study Protocol # (as assigned by sponsor): _____

Principal Investigator/Project Director Signature

Date

Principal Investigator/Project Director Name Printed

Department Director Signature (Allina Department Projects Only)

Date

Allina Administrative Approval

The signature below is for those Research Sites operating as a business unit of Allina that require approval by the vice president responsible for the department prior to submission to Allina SPA. Contact SPA at 612-262-4926 if you have questions.

Vice President Signature* (if required) (Allina Department Projects Only)

Date

Instruction for Completing a Case for Support

At Allina, research plays an important role in continually improving the care our patients receive. However, because of the many challenges currently facing health care, we must carefully prioritize the types of research in which we participate and support. For this reason, the research site must now submit, as part of the SPRP, a statement about the potential impact this project will have on Allina facilities and the patients they serve. Projects submitted without a Case for Support will be delayed or returned until the document is received.

All project submissions must include a letter or other documentation (not pages from the protocol) answering the following questions (please try to use layman's terms, when practical). Not every question needs to be answered, but please try to be as complete as possible. This information will be used to evaluate the project, and lack of critical information could result in a project being denied.

Key areas and questions to address:

- A brief overview of the project.
- What are the proposed benefits to patients?
- What would be gained by doing the research?
- What is the standard treatment option?
- What are the advantages and disadvantages for the Allina facility if participating in the project?
- If the project involves an approved device, why is the study being done?
- Additional considerations. This is the opportunity for the Principal Investigator to address issues that aren't identified elsewhere within the SPRP or re-emphasize a particular issue. For example, the patient may be in the facility longer, but the treatment drugs are provided free. In cases like the example on the following page, it may be necessary to provide some numbers about the financial impact.

An example appears on the following page.

Example: Case for Support Device XYZ

Overview

Device XYZ is a drug-eluting stent from D Corporation. Device XYZ is used to treat patients with cardiac stenosis and is expected to prevent restenosis or relogging of the artery. Using stents, either drug-eluting or bare metal, prevents the need for cardiac surgery.

Benefit to Patients

- Should the XYZ stent work as described in the protocol, it should prevent the need for further catheterization of the artery.
- Does not require open heart surgery
- Faster healing time
- Shorter stay in the facility

Gain by Doing the Research

If the device works as expected, it should prevent patients from needing to be re-admitted for additional procedures. It is also expected that this type of stent will replace bare metal stents.

Standard Treatment

Standard treatment for a person with arterial stenosis is either angioplasty or angioplasty with the insertion of a stent.

The Advantages and Disadvantages

Advantages

- Patients would prefer not to be re-admitted for a procedure in the future
- No surgery
- Shorter stay for the patient
- The care is relatively the same as not receiving the drug-eluting stent.

Disadvantages

- The drug-eluting stent is more expensive than a bare metal stent. This could be increased if multiple stents are used.
- The stent is not provided free by the sponsor since it can be billed to third party payers.
- Procedure may need to be redone should the drug used with the stent not prevent restenosis.

Summary

Drug-eluting stents, should they work as claimed, will be a major improvement in the quality of care of patients with blocked arteries. While the cost for these stents is significantly more than for bare metal stents, it is important to be at the forefront and to gain experience in using the stents before they are approved and adequately reimbursed by third party payers.

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 Sponsored Project Setup Worksheets

1. What to Print

The research site needs to print the following:

- Sponsored Project Information Worksheet
- Schedule of Events Worksheet (if applicable)
- Protocol-Induced Cost 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)

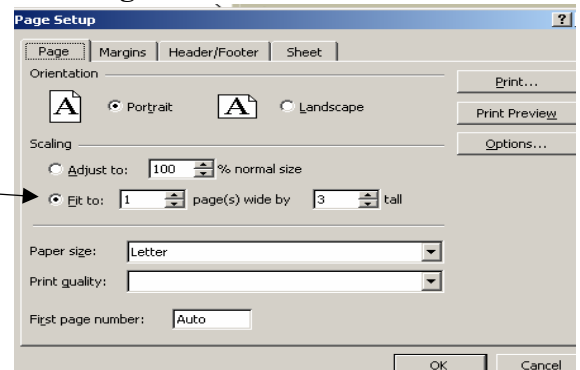
- Select the sheet that you want to print. (The sheet tab should be white instead of gray.)
- While holding down the **Shift** key, click on the sheets or over the range you wish to print. The sheets that will print will all turn from gray to white.
- Choose **File** and **Print** or click the **printer 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 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 the *Info_WS* prints on more than three pages, please 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 3 tall



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

Each research site must submit an electronic version of the Sponsored Project/Research Information Worksheet (**Info_WS**). Allina SPA requires this information to track projects being conducted within Allina facilities. *Follow the instructions below for electronically submitting the “project04.xls” Excel file.*

Submitting an Electronic Copy of the Excel File

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-hand 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” file, pastes the data from the Information Form 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 is ready to be sent 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 Requirements for Sponsored Projects Review

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

1. What to Submit (in the following order):

- A signed Principal Investigator Certification
- Abstract – Include the abstract that was submitted with the IRB application. *We do not need the entire IRB application.*
- Sponsored Project/Research Information Worksheet
- Copy of the Protocol Schedule of Events (SOE) and/or the Allina Schedule of Events Worksheet with identified PIC(s). (The SOE from the protocol should also be in its original location within the protocol.)
- Protocol-Induced Cost (PIC) Worksheet
- A Case for Support
- Copies of all the signed Department Service Information Sheets
- Two signed original copies of the Purchase Services Agreement (see Part VI)
 - Research Sites internal to Allina must include budget information
- A copy of the entire Protocol (**single-sided**)
- A copy of the IRB Approval or Exemption letter.
 - If IRB approval is pending for the project, submit all other materials for SPA review while awaiting final IRB approval. Send the letter to SPA upon receipt. SPA and the Accountable Executive will not approve the project without notification of IRB approval.
- Research Informed Consent Form, as submitted or approved to the Allina IRB.

Allina employees must also submit the following:

- Budget
- Budget narrative – explanation of the budget items included in the budget

Send the 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.

2. Confirmation

- An e-mail will be sent to confirm that SPA received all required project materials.
- You will be contacted if any questions arise during the review, either by the Accountable Executive or SPA.

The Sponsored Project Review Process

Upon receipt of a complete proposal,

Allina SPA will:

- review the Project Setup Worksheets and all submissions;
- review any Written Agreements;
- review budgets for Allina personnel; Allina departments and employees, please see Part VIII of this Guide;
- make recommendations to the Accountable Executive; and
- submit the project to the Accountable Executive.

The Accountable Executive will:

- review the project for appropriateness within the Allina facility;
- review the project and Project Setup Worksheets to ensure Allina is adequately reimbursed;
- either approve or deny the project (see the following section for more information);
- sign any written agreements; and
- return the information to SPA.

SPA will inform the research site of the outcome of the Accountable Executive's review.

Approval or Denial of a Project

After review of the project by the Accountable Executive (AE), he or she will decide, based on the interest of the Allina facility, if it should participate in the project. The AE has the authority to deny any project proposed for his or her facility.

Project Approval or Approval with Conditions

To approve a project, the AE will do the following:

- Check the Approval or Approved with Conditions box on the AE Approval/Denial Form.
 - If the project is approved with conditions, list the conditions in the box below.
 - Sign the AE Approval/Denial Form.
 - Sign each of the two Written Agreement copies.
 - Return the project to SPA.
-
- SPA will notify the research site in writing of the AE's decision.
 - If the AE places conditions on the project, the research site must agree to these conditions before the approval letter is sent.
 - If the research site does not agree with the conditions in the approval, then the research site should follow the steps in the project denial section below.
 - After the research site receives the letter from SPA, the project may begin within the Allina facility that approved the project. Any changes after that time will need to follow the "Changes in an Approved Project Policy" (Research Compliance Policy RES 304.00, Part I of this Guide) and the "Changes in an Approved Project Procedure" (Research Compliance Procedure RES 304.01, Part I of this Guide).

Note: Even though your project may be approved by the AE, it may not begin until the IRB has reviewed it and given written approval.

Project Denial

To deny a project, the AE will do the following:

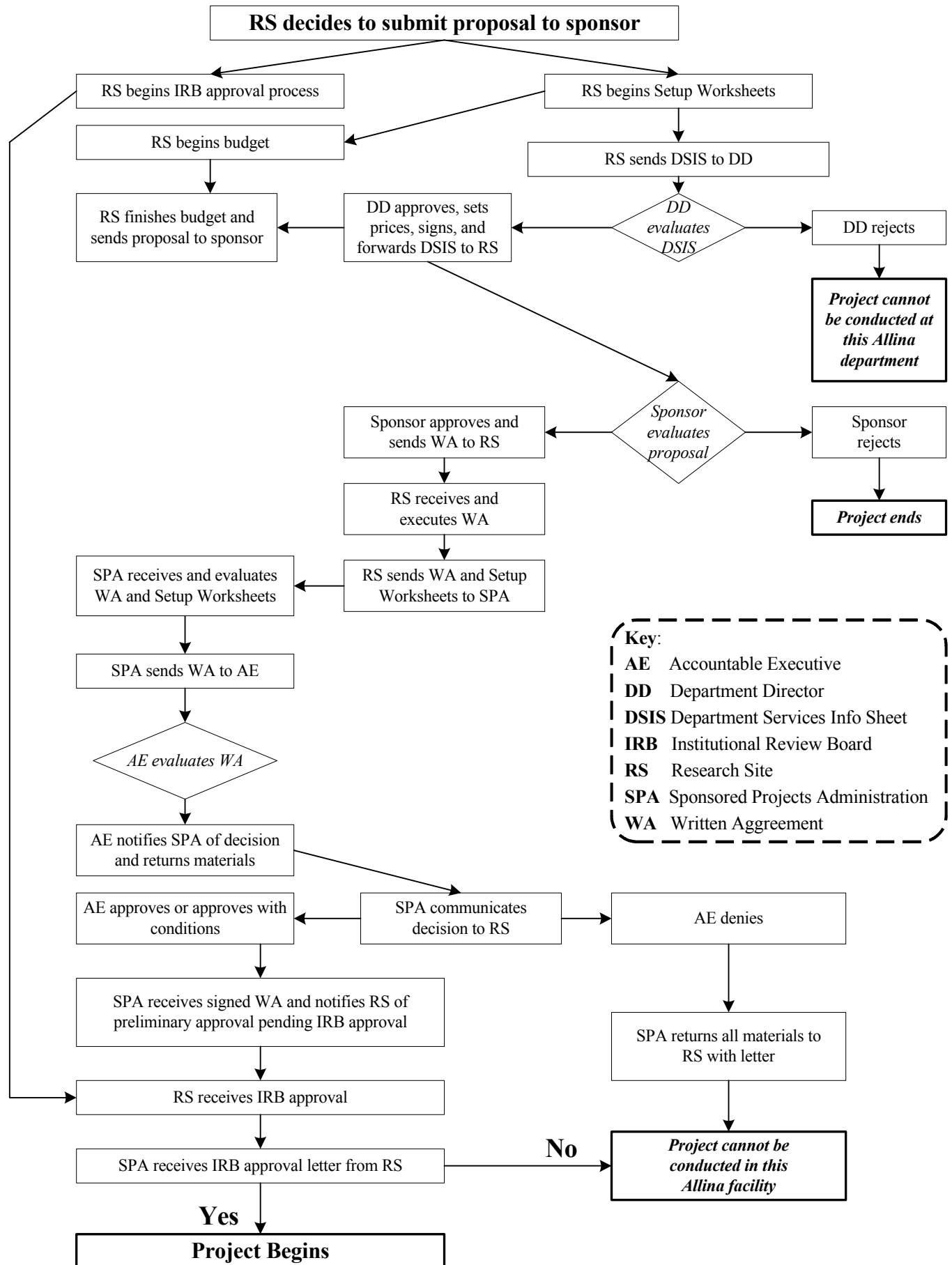
- Check the "Denial" box on the AE Approval/Denial Form.
- State the reasons why the project is being denied.
- Sign the AE Approval/Denial Form.
- Return the project to SPA.

SPA will then inform the research site in writing of the decision.

Upon receipt of the denial, the research site may choose to do the following:

- Resubmit after making the required changes outlined in the denial letter. For example, Allina was providing supplies free for the project, but the research site decides to pay. The project must be resubmitted following the submission guidelines and the "Previously Denied" box on the Sponsored Project/Research Information Form must be checked.
- Not conduct the project in an Allina facility.
- If the research site is not able to make any changes to the project, a meeting may be scheduled between the Principal Investigator and the Accountable Executive to negotiate a solution. Please contact SPA for assistance.

Sponsored Projects Review Process for Research Sites External to Allina



Completing the Project Change Form

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, “Policies and Procedures” located in Part I of this Guide.

There are three types of project changes:

1. Qualifying Status Change

A qualifying status change is a change in whether a project meets the definition of “Clinical Trial Services that Qualify for Coverage” as described in the Medicare National Coverage Decision. The research site will notify Allina SPA **immediately** when there is a change in qualifying status of a project as described in the Medicare National Coverage Decision.

2. Major Change

A major change is a material change that may impact Allina’s participation in the project. Major changes must be submitted within five business days of the proposed change.

Major changes include:

- changes to executed Written Agreements;
- changes to the Schedule of Events, Protocol-Inducted Cost Worksheets, or Department Service Information Sheets;
- a change in the Principal Investigator or project sponsor;
- a change in the number of participants by at least 10%;
- a change in IDE or IND status;
- a change in address of the Principal Investigator or research site;
- a change in the project site or the addition of new Allina sites; and
- the project ends for any reason.

3. Minor Change

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

How to Complete the Project Change Form

- Open Word
- Click the ***Open Folder*** icon or choose ***File/Open***
- Look in ***C: drive***
- Double click ***Allinasrpr 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.

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 when 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]