Allina Hospitals & Clinics

November 2009
## Table of Contents

GETTING STARTED IN EPROTOCOL 4

Personnel Information 8

Review Fees 11

Vulnerable Subject Checklist 12

Study Sites 13

General Checklist 14

Funding 15

Potential Conflict of Interest 20

Protocol Information 22

  Expedited Paragraphs 22
  Purpose, Background, Collaborative Research, Qualifications of Study Personnel 24
  Subject Population 27
  Study Procedures and Alternatives 31
  Benefits 35
  Tissue Banking 38
  Medical Equipment 40
  Drugs and Biological Products 43
  Radiation 49
  Informed Consent 51
  Attachments 59

Assurance 62

Check for Completeness 63

Submit Form 64

Print View 65

Event History 67

Return Notes 68
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB–BIOMEDICAL EXEMPT FORM</td>
<td>59</td>
</tr>
<tr>
<td>General Checklist</td>
<td>70</td>
</tr>
<tr>
<td>Protocol Information: Exempt Categories</td>
<td>71</td>
</tr>
<tr>
<td>TERMINOLOGY DIFFERENCES</td>
<td>79</td>
</tr>
</tbody>
</table>
Getting Started in eProtocol

Welcome to eProtocol, Allina’s Institutional Review Board (IRB) submission system! Follow the instructions below to get started in the system.

1. If you do not have a user ID and password, access the user agreement on Allina’s Research Administration site.

2. Read and sign the user agreement; then submit it to Allina’s Research Administration. Upon receipt of your signed user agreement, administrative staff will email your user ID and password to you.

3. Please note the following as you begin working in the system:

   - eProtocol tracks all the actions on a study and who performs them. Therefore, please do not share your user ID or password with anyone else or use another person’s ID and password to access the system.

   - The system times out and will require you to log in if your account has been idle for 45 minutes.

   - Avoid uploading any Protected Health Information (PHI) in the system; if a document contains a subject’s name, please obscure or remove it before uploading the document.

   - When scanning documents to upload, ensure that the document is complete before attaching it in eProtocol. The document must be “a faithful reproduction of the original.”

   - Use the spell check feature, and proofread your responses before submitting your forms. The spell check feature identifies misspelled words by underlining them with a dotted red line. Please correct misspelled words so that your submission is as accurate as possible.

4. Log into eProtocol.

   a. You will be required to change your password the first time you access the system.

   b. Your home page will then appear.
5. Follow the tips outlined below when using the system.

a. **Use a recommended browser.**
   If you are using Windows, eProtocol works best when using Internet Explorer. If you are using a Mac, eProtocol works best when using Safari.

b. **Allow pop-up windows.**
   Pop-up blocking software prevents the eProtocol application from opening certain windows. You'll need to make sure that your browser has all pop-up blocking software disabled while using eProtocol. (See the FAQs for instructions on removing pop-up blockers.)

c. **Avoid using your browser's BACK button.**
   Instead, use the menus and links within the application to navigate.

d. **SAVE frequently.**
   eProtocol will time out after 45 minutes of inactivity. Only actions that cause the page to refresh or reload (such as saving or navigating to a new section) are indications to the system that your session is active.

e. **Be patient.**
   Some processes can take a minute to run. Although data is loading, your browser may not indicate activity.

f. **Read the Instructions.**
   Many pages in the application offer instructions on the page to guide you and to answer
the most common questions. You can also check the FAQ page for answers to eProtocol questions.

g. **Sign out.**
To protect your private information, always log off and shut down your browser completely (close all browser windows) when you are finished using eProtocol.

6. Click the “Create Protocol” button.

7. Enter the title of your study. Please use standard title capitalization (i.e., capitalize the first letter of each word with the exception of articles [a, an, and the] and prepositions with fewer than five letters).

8. Select the check box next to **IRB.** (For SPA submissions, please consult the SPA Forms User Guide.) Two form options will appear: “Biomedical—Expedited/Full Board” and “Biomedical Exempt.”

9. Decide whether your project requires expedited/full board review or whether it may qualify for an exemption. This decision will determine which of the forms you complete.

   Note: Researchers may not make an independent determination of whether a research study is exempt. The authority to determine whether a study is exempt from review is vested solely with the IRB or its designee.

10. Follow the instructions below if you selected the “Biomedical—Expedited/Full Board” form; consult the “Biomedical Exempt” form instructions if you selected that option.
IRB Biomedical Expedited/Full Review Form

The IRB Biomedical Expedited/Full Review Form has the following sections to complete for IRB review.

- Personnel Information
- Review Fees
- Vulnerable Subject Checklist
- Study Sites
- General Checklist
- Funding
- Potential Conflict of Interest
- Protocol Information (22 sub-sections)
- Assurance

In addition, eProtocol has several features that assist the researcher in completing the submission and receiving approval for the study.

- Check for Completeness: Identifies the sections that must be completed before the protocol can be submitted.
- Submit Form: Electronically sends the protocol to the IRB for review.
- Print View: Enables the user to print a hard copy of the protocol.
- Event History: Lists the actions that have occurred since the protocol was created.
- Return Notes: Explains any actions users must take if their submissions are returned to them.

Note:

The system requires you to complete the Personnel Information through Potential Conflict of Interest sections (in order) before proceeding to the Protocol Information sections.

- Click Spell Check in the top menu to spell check the entries.
- Click the Navigation Links on the blue navigation bar at the left to proceed to the section you wish to complete.
- Click the previous or Next icon to go to the previous or next page.
- Click Close in the strip above to close the Protocol Application Form.
- Click Save in the strip above to save the Protocol Application Form.

Each section is explained in detail below.
The Personnel Information section is the first (default) section that displays when a new protocol is created or an existing protocol is opened. Enter information regarding the personnel who will be participating in the study. The principal investigator is mandatory; the co-investigator, study coordinator(s), academic advisor, SPA contact, and other personnel may be added if they apply to the study. (Note: Study team members listed under “Other Personnel” have only view/read access; they cannot edit or submit forms. They also do not receive email notifications from eProtocol when there are changes to the status of the study.)
Follow the steps given below to add users in the Personnel Information.

**Step 1**

The Principal Investigator (PI) field auto-populates with the name of the user who created the protocol. You can change the field by clicking the binocular icon beside the name field. The Find User pop-up will display. Search for, select and add the user who will serve as the principal investigator.

You may search by First Name, Last Name or User ID. When the list of users appears, select the radio button next to the name of the person you wish to add.

![Find User](image)

**Step 2**

Enter any demographic details that do not display.

**Step 3**

Select the study-related role or roles that the PI will perform.

**Step 4**

Verify the dates of completion for CITI or NIH training. In the case of other training, enter the title and date. Upload documentation of this training in the Attachments section.
Step 5

Follow the steps above for entering details for other users except **Study Coordinators** or **Other Personnel**. For Study Coordinators and Other Personnel, click **Add**.

The pop-up will appear.

**Study Coordinator(s)**

*Please click on Add to add Study Coordinator*

**Step 6**

Follow steps 1 to 5 to enter details for **Study Coordinators** or **Other Personnel**, and click **Save**.

**Step 7**

If you wish to add a person who is not an existing user, click “Click here to add other personnel” in the **Find User** pop-up.

Note:

- Access links, if any, to view the related information and guidelines.
- To clear the details of any user, click **Clear**.
• To delete a user listed as Other Personnel, select the record and click **Delete**.
• All users except those listed as Other Personnel may edit and submit the Protocol.

### Review Fees

Review Fees are charged for all proposed research applications submitted. The fee is used to defray costs associated with review and ongoing monitoring of the proposed research. Fees are assessed for all industry-sponsored and/or externally funded studies, including studies conducted by Allina departments/services when funded by a non-Allina source (e.g., industry, foundation, grant, etc.).

**IRB Application: $2,000**

- **Review Fee Submitted to the IRB**
  - Check Number
  - Date Submitted

- **Review Fee Transferred Internally**
  - Date Submitted
  - Upload Internal Transfer form in the Attachments section.

- **Request for Invoice**

- **Request to Waive Fee**
  - Please explain why you believe the IRB should waive the fees for this study.

Select the payment option that applies to your study. If you select **Request to Waive Fee**, please provide a detailed explanation to support your request.
In this section, select the check boxes for any vulnerable subject populations that are part of your research.

- You must select at least one vulnerable subject population or the option that “No vulnerable populations will be included” in order to proceed to the next section.
- If you select Other, enter a description of the population in the text box below the item.
- Answer questions (b) and (c) if they apply to your study, or enter N/A if the questions do not apply.
Study Sites

Click the check box or boxes for the sites where you are planning to conduct your research.

- You must select at least one Study Site to proceed to the next section.
- If a text field appears beside your selection, enter the specific name of the clinic.
- For Other facilities, enter the name and address of the facility.

<table>
<thead>
<tr>
<th>Study Sites</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Select all that apply.</td>
<td></td>
</tr>
<tr>
<td>☐ Abbott Northwestern Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Allina Medical Clinic: Specify clinic name.</td>
<td></td>
</tr>
<tr>
<td>☐ Aspen Clinic: Specify clinic name.</td>
<td></td>
</tr>
<tr>
<td>☐ Buffalo Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Cambridge Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Mercy Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ New Ulm Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Owatonna Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Phillips Eye Institute</td>
<td></td>
</tr>
<tr>
<td>☐ Quello Clinic: Specify clinic name.</td>
<td></td>
</tr>
<tr>
<td>☐ River Falls Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ St. Francis Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ United Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Unity Hospital</td>
<td></td>
</tr>
<tr>
<td>☐ Other Allina-Owned Facility: Specify.</td>
<td></td>
</tr>
<tr>
<td>☐ Other Non-Allina Facility: Specify.</td>
<td></td>
</tr>
</tbody>
</table>
The purpose of the General Checklist is to determine whether the study involves any special situations that may require additional information. Please read through this section carefully, and select all that apply.

- Check the box by each statement that is true of your study.
- You must select at least one checklist option to proceed to the next section.

<table>
<thead>
<tr>
<th>General Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>The purpose of this section is to determine whether the study involves any special situations that may require additional information. Please read through this section carefully, and select all that apply.</td>
</tr>
<tr>
<td>This study will be submitted to Allina’s Sponsored Projects Administration.</td>
</tr>
<tr>
<td>This study involves services provided at an Allina facility.</td>
</tr>
<tr>
<td>This study will be funded through outside sources.</td>
</tr>
<tr>
<td>This study will receive federal funding (e.g., NIH, NSF, DOD, etc.).</td>
</tr>
<tr>
<td>This study may qualify for expedited review.</td>
</tr>
<tr>
<td>The principal investigator or other research personnel have a financial, personal, or professional conflict of interest related to the study as defined in Allina’s Conflict of Interest Policy.</td>
</tr>
<tr>
<td>Subjects will be paid for participation or reimbursed for expenses.</td>
</tr>
<tr>
<td>There is an Inter-institutional IRB Authorization Agreement to rely on Allina for IRB review.</td>
</tr>
<tr>
<td>This study will use human blood, body fluids, tissues, or cells (including cell lines) by drawing samples, accepting samples already drawn, receiving samples from any source, or in any other way.</td>
</tr>
<tr>
<td>If yes, provide the lab’s name.</td>
</tr>
<tr>
<td>Provide the lab’s location.</td>
</tr>
<tr>
<td>Biological specimens and/or data will be stored for future research projects.</td>
</tr>
<tr>
<td>The study involves the use of medical devices or equipment cleared/approved for marketing.</td>
</tr>
<tr>
<td>The study involves the use of experimental or investigational devices or equipment (i.e. not cleared/approved for marketing).</td>
</tr>
<tr>
<td>The study involves the use of commercially available drugs, reagents, or biological products administered to subjects (even if the drugs themselves are not being studied).</td>
</tr>
<tr>
<td>The study involves the use of investigational drugs, reagents, or biological products (i.e., not cleared/approved for marketing).</td>
</tr>
<tr>
<td>Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.</td>
</tr>
<tr>
<td>This study involves minors (i.e., children under the age of 18).</td>
</tr>
<tr>
<td>This study involves social, behavioral, or educational research.</td>
</tr>
</tbody>
</table>
ClinicalTrials.gov

<table>
<thead>
<tr>
<th>Is the study posted on <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a>?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes -- Specify number:</td>
</tr>
<tr>
<td>[ ] No -- Explain the reason below.</td>
</tr>
</tbody>
</table>

Enter the ClinicalTrials.gov number or the reason the study has not been posted.

Funding

Funding

Add external funding source(s) below: Sponsor, Federal, or Other. Select "None" above if there is no external funding for the study.

Sponsor(s)

Please click on Add to add Sponsor(s)

Federal Funding

Please click on Add to add Federal Funding

NOTE: Submit Allina’s Unaffiliated Investigator Agreement if the research study is federally funded (e.g., NIH, HIC, etc.) and the principal investigator is not affiliated with Allina Hospitals & Clinics.

Other Funding

Please click on Add to add Other Funding
No Funding

Select None at the top of the page if you are not receiving any funding to conduct the study. All Add buttons will disappear, and you will not be able to add other Funding options. (Uncheck the box to add funding.)

Funding Options

You can add information for funding received from various sources. Follow the steps given below to add different types of funding.

Sponsor(s)

Step 1

If you are receiving funding from a sponsor for the study, click the Add button on the Sponsor tab. The Add Funding pop-up will appear.
Step 2

Select the sponsor’s name from the drop-down menu. If the sponsor’s name does not appear, select Other, and enter the sponsor’s name in the text field under the drop-down menu.

Step 3

Enter the information about the sponsor and sponsor contact in the remaining fields.

Step 4

Click **Save**. The pop-up will close, and the record will be added to the **Funding Checklist** page.

*Federal Funding*

Step 1

If the study is federally funded, click the **Add** button on the Federal Funding tab. The **Add Funding** pop-up will display.

![Federal Funding Form](image)

Step 2

Select the “Type of Proposal” and the “Name of Funding Agency.”
Step 3

Enter the “Agency's Grant Name,” “Title of Grant Proposal,” “Name of Fellow,” and “Name of Awardee Institution.”

Step 4

Click Save. The pop-up will close, and the record will be added to the Funding Checklist page.

Other Funding

Step 1

Click the Add button on the Other Funding tab. The Add Funding pop-up appears.

Step 2

Enter the “Principal Investigator,” “Name of Donor,” and “Nature of the Donation.” All fields are mandatory.

Step 3

Click Save. The pop-up will close, and the record will be added to the Funding Checklist page.
Note:

- You can add multiple records for each funding option.
- Click the link of a Funding record to view or edit the record.
- Click Cancel in the pop-up to return to the Funding page without saving the entered details.
- To delete a Funding record, select the record by clicking the check box beside it, and click Delete.
Potential Conflict of Interest

The conflict of interest section begins with a brief policy statement and definitions of the key terms used in the questions that follow. Questions (a) through (h) apply to all research personnel on the study. The person completing the form must have knowledge of all potential conflicts of each member of the research team and their immediate families. (In these questions the word you refers to each person participating on the research study.)

Conflict of Interest: Please check Yes or No or N/A for each item below.

a) [ ] Yes [ ] No Does the research involve a drug, device, or biological invented by you, an immediate family member or other research personnel?

b) [ ] Yes [ ] No Is the research sponsored by an entity with which you, an immediate family member, or other research personnel have a paid consulting or advising relationship?

c) [ ] Yes [ ] No Will you, members of your immediate family, or other research personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) [ ] Yes [ ] No Will you, members of your immediate family, or other research personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) [ ] Yes [ ] No Do you, members of your immediate family or other research personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) [ ] Yes [ ] No Will payment you receive for services provided during the conduct of the research (e.g., investigator and research personnel time and tests) be consistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) [ ] Yes [ ] No Will you, your immediate family members or other research personnel receive salaries, royalties and other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $10,000 during the previous 12 months or are expected to exceed $10,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) [ ] Yes [ ] No Do you, your immediate family members, or other research personnel hold any ownership interests including stocks, bonds, or stock options that exceed $10,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.
Minimizing Risks and Disclosure to Subjects

i) ☐ Yes  ☐ No  Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?

If you checked Yes to any statement (a-h) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest. If there are more than two team members with potential conflicts of interest, please attach descriptions of the conflicts in the Attachments section.

Research Team Member(s) with Potential COI

Please click on Add to add Research Team Member(s) with Potential COI

By submitting this form, you are attesting that you have read the Allina Hospitals & Clinics Conflict of Interest Policy for Research Personnel and agree to abide by its terms, that you will update this disclosure form when new or changes in conflicts of interest arise, and that you will comply with any conflict management plan required by the Conflict of Interest Committee (COIC) and/or Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

If any of the research personnel or their immediate families have consulting arrangements, management responsibilities, equity holdings in the sponsoring company, or any financial relationship with the sponsoring company, select Yes in response to the appropriate questions. Then click Add and enter details concerning the conflict of interest.
Protocol Information

The Protocol Information section consists of several sub-sections where the investigator must provide information regarding the research study. Each section is explained in detail below, although many of the sections will not apply to every study.

Expeditied Paragraphs

<table>
<thead>
<tr>
<th>Biomedical Expedited Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>An expedited review procedure consists of a review of research involving human subjects by the IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committee.</td>
</tr>
<tr>
<td>In order to be eligible for expedited review, ALL aspects of the research must include activities that: (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed below and in the regulations at Federal Register Volume 63, No 216.</td>
</tr>
</tbody>
</table>

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) and (b) are met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research an marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which:
      i. an investigational device exemption application (21 CFR Part 812) is not required; or
      ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;
   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimen for research purposes by non-invasive means.
   Examples:
   a) hair and nail clippings in a non-disfiguring manner;
   b) dermalous teeth at time of exfoliation or routine patient care indicates a need for extraction;
   c) permanent teeth if routine patient care indicates a need for extraction;
   d) secretions and external secretions (including sweat);
   e) unannounced saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   f) placenta removed at delivery;
   g) induced fluid obtained at the time of rupture of the membrane prior to or during labor;
   h) intra- and sublingual dental plaque and calculus, provided the collection procedure not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures not involving general anesthesia or sedation routinely employed in clinical practice, excluding procedures involving x-rays or microscopes. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples:
   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) weighing or testing sensory acuity;
   c) magnetic resonance imaging;
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electrodensibility, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(6). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behaviours, including, but not limited to, race, sex, age, perception, cognition, motivation, identity, cultural, language, communication, cultural beliefs or practices, and social behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors, evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
The **Expedited Paragraphs** page is the first (default) section that displays when you click the Protocol Information link in the navigation menu at the left of the screen. Click Next to advance to Sections 1-4 if the study does not qualify for expedited review; if you believe the study may qualify for expedited review, follow the steps below.

**Step 1**

To enable the check boxes on this page, you must first select the item “This study may qualify for expedited review” on the General Checklist. If the items on the Expedited Paragraphs page are shaded (grayed out) and you wish to select one or more categories, return to the General Checklist, and select the statement regarding the expedited review. Then return to the Expedited Paragraphs page.

**Step 2**

Select one or more of the categories that apply to the study.

**Step 3**

Click Next to advance to Sections 1-4.

Note that you can navigate through the Protocol Information sections by clicking the section numbers at the top of the page. By hovering over the numbers, you can see the headings within that section.

Both the Protocol ID and the Study Title will be auto populated by the system; however, you can edit the title here if you wish. (The Protocol ID cannot be changed.)
You may edit the **Study Title** if you wish to do so. The **Short Title** is mandatory for studies that require submission to SPA.

Account for the time needed to receive IRB approval (and SPA approval, if applicable) when you enter the **Study Start Date**. Note: You must receive final approval from both the IRB and SPA (if applicable) before you may begin to recruit potential participants or perform other research-related activities.

Enter an estimated **Study End Date**. If you anticipate that the project could last indefinitely, select a date 10 years out, keeping in mind that this date can be extended later, if necessary.

---

**Purpose, Background, Collaborative Research, Qualifications of Study Personnel**

Complete each section. When a question is not applicable, enter N/A. Do not leave any sections blank.

1. **Purpose**

   Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

2. **Background**

   Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations if applicable. Attach references or a bibliography in the Attachments section.

Note the instructions at the top of the section. Each question requires a response. Enter N/A if a question does not apply to your study.

1. In the **Purpose** section, enter a brief summary of the purpose of the study and what you hope to learn from it.

2. Enter relevant **Background** information on the condition, procedure, product, etc. under investigation, including citations. Keep in mind that the IRB is most interested in assessing
the risks potential subjects will face; select information that will provide an objective picture of the product or procedure being studied.

3. Collaborative Research

If any non-Allina institutions or individuals are engaged in the research, explain here. NOTE: “In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research” (45 CFR 46.102[d],[f]).

If any non-Allina institutions or individuals are collaborating in the research, click Add below and complete the table. Attach any relevant IRB approvals in the Attachments section.

Non-Allina institutions

Please click on Add to add Non-Allina institutions

In the Collaborative Research section, provide an explanation for engaging any non-Allina institutions and individuals in the research. For example, if you are collaborating with a researcher from the University of Minnesota, enter information about the researcher; then click Add to provide details regarding IRB of the study at the other institution. The Non-Allina Institutions pop-up will appear.

Note: * denotes mandatory field.

<table>
<thead>
<tr>
<th>Non-Allina institutions</th>
<th>Save</th>
<th>Cancel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution Name: *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact or Affiliate of the Institution:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FWA Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local IRB Review: Yes or No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB Approval Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB Approval Expiration Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Enter the details regarding the other institution.

Contact or Affiliate of the Institution: The primary person involved in the research at the other institution
FWA Number: Federalwide Assurance Number—check the institution’s website or contact the other institution for this number.

Local IRB Review: Answer Yes if the other institution has also reviewed the study; No, if it has not.

IRB Approval Date: Enter the date the other institution provided final approval for the study.

IRB Approval Expiration Date: Enter the date before which the approval must be renewed at the other institution.

Then click Save. The pop-up will close, and the record of the non-Allina institution will be added to the Protocol Information page.

Note:

- To delete a non-Allina institution, select the record, and click Delete.
- Click the Institution Name to view or edit the record.

4. Qualifications of Study Personnel

a) Explain the study-specific expertise of the principal investigator, any co-investigators, or other key personnel listed in the application (e.g., sponsor certification in the use of the device).

b) Student Researcher Only: Describe the expertise you have, or have access to, that prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, or training).

In the Qualifications of Study Personnel section, describe the study-specific expertise of the key research personnel. Enter N/A if no special or additional training is required to conduct the study.
Subject Population

5. Subject Population

Describe the subject population:

Age Range:

Gender Breakdown:

Race/Ethnicity:
- American Indian or Alaskan Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or Pacific Islander
- White or Caucasian
- Racial/Ethnic Origins Not Recorded

Language/Literacy:

Select One

- English Speakers Only
- Non-English Speakers Included
- Not Applicable

Check all that apply.
- Control subjects
- Experimental Subjects
- Non-Patient Volunteers
- Placebo
- Randomization

a) How many subjects do you plan to enroll (i.e., your enrollment goal)? NOTE: You must receive IRB approval before increasing enrollment in the study.

b) How many people do you estimate you will take through the consent process (but not necessarily enroll) to get the number of subjects you need? Subjects who go through the consent process are counted toward the total number of subjects even if they have no further participation in the study (i.e. withdraw, screened out, etc.). Note that this is the number of subjects for which IRB approval will be granted.

c) If this is a multi-center study, what is the total number of subjects to be enrolled from all centers?

- In the respective textboxes, enter the Age Range and Gender Breakdown of the subject population. Specify N/A if appropriate.
- Then identify the Language/Literacy of the subject population. Note: If non-English speakers will be included, upload a translated consent form or short consent form(s) in the Attachments section. “Not Applicable” may be selected for chart reviews.
- Question (a) focuses on the number of subjects that you plan to enroll in the study; question (b) asks you to provide an estimate of the total number of subjects who will be
taken through the consent process. You must receive prior approval from the IRB before increasing the enrollment goal or the total number of subjects consented.

Note: These questions also apply to chart reviews; for such studies, the word subjects includes medical records.

Recruitment and Screening

6. Recruitment: Be as specific as possible in the details you include.

a) How will prospective subjects be identified and/or selected for study participation?

b) BY WHOM will prospective subjects be approached for study participation? If the researcher is the subjects instructor, physician, or job supervisor, explain what precautions will be taken to minimize potential coercion or undue influence to participate.

c) WHEN and WHERE will prospective subjects be approached for study participation?

d) List any recruitment materials (e.g., letters, flyers, advertisements [note the type of media and where it will be posted], scripts for verbal recruitment, etc.) to be used. Include a brief description of how each will be used. Attach these documents in the Attachments section.

Information about the recruitment methods is a very important part of the IRB’s review of a study. Be specific in your explanation of the details of the recruitment criteria and precautions that will be
taken to minimize potential coercion or undue influence to participate in the study. If you identify an individual in question (b) who is not listed in the Study Personnel section, describe the person's relationship to the subjects and the appropriateness of the contact.

For item (d) list any recruitment materials to be used and specify the details of their use. For example, if you plan to use web banner ads to publicize the study, indicate the types of web sites on which they will appear.

7. Screening

a) Provide criteria for subject inclusion.

b) Provide criteria for subject exclusion.

c) If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain your rationale for the restrictions.

d) If prospective subjects will be screened via tests, interviews, etc. prior to entry into the "main" study, explain how, where, when, and by whom the screening will be done. Note: Consent must be obtained for screening procedures as well as the main study procedures. As appropriate, either (1) Create a separate "Screening Consent Form," or (2) Include screening information within the consent form for the main study.

In the Screening section, provide the criteria for subject inclusion and exclusion; then explain the rationale for any gender or race/ethnicity restrictions. Explain how, where, when, and by whom screening will be done in section (d). Specify N/A as applicable.
Compensation, Reimbursement, and Costs

8. Compensation, Reimbursement, and Costs to Subjects

a) Describe the plan for compensating or reimbursing subjects. If subjects will be compensated for their participation, explain in detail the amount and methods or terms of payment. (If no compensation or reimbursement will be provided, indicate N/A in the field below.)

Include any provisions for partial payment if a subject withdraws before the study is complete.

When subjects are required to provide their Social Security Numbers in order to be paid, this data must be collected separately from consent documentation. Describe security measures that will be used to protect subjects’ identities.

b) Discuss the rationale for the amount, method, and terms of compensation; include a description of the appropriateness of compensation for the study population and how you will avoid any undue influence it may have on the subjects’ decision to participate.

c) Costs to Subjects: If applicable, list and describe any costs or charges that subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, indicate N/A.)

Describe the plan for compensating or reimbursing subjects under (a). Be certain that you have responded to each of the three parts of this item. In item (b) discuss the reasoning for the amount, method, and terms of compensation identified in item (a). For instance, if subjects will receive $50 for each follow-up appointment, you might explain that the appointments may last an hour or that the amount is reimbursement for the subjects’ time and travel expenses.

Then describe any costs or charges subjects or their insurance carriers will be expected to pay under item (c). Indicate N/A as appropriate.
9. Study Procedures

a) Describe in chronological order how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures, etc.), including follow-up procedures.

b) Indicate the frequency and duration of visits/sessions as well as the total time commitment for the study.

c) Identify any procedures that are experimental/investigational, and explain how they differ from standard procedures (medical, psychological, educational).

d) If a placebo will be used, provide the rationale, and explain why active control is not appropriate.

e) Study Endpoint(s): What are the guidelines or end points by which you can evaluate the alternative treatments during the study?

f) When will the study end if no important differences are detected?
In the Study Procedures section, provide thorough answers to each of the questions. Note that item (b) requires an estimate of the time commitment required of subjects (e.g., 6 visits over a year’s time for a total of 18 hours).

If the study involves deception, clicking Yes in response to the question will enable the textbox so that you can enter the rationale for its use.

Describe any appropriate alternative resources, procedures, or courses of treatment that are available to prospective subjects. If the alternative is simply not to participate, state that in the textbox.
Risks and Discomforts

11. Risks and Discomforts

a) Indicate if any of the following risks are involved in this study.
   - Administration of physical stimuli (other than auditory or visual stimuli associated with normal classroom situations)
   - Deprivation of physiological requirements (e.g., nutrition, sleep)
   - Manipulation of psychological and/or social variables (e.g., sensory deprivation, social isolation, psychological stress)
   - Physical exertion beyond normal clinic procedures
   - Possible invasion of privacy of a subject or family, including the use of personal information or records
   - Presentation of offensive, threatening, or degrading material
   - Probing for information that an individual might consider to be personal or sensitive
   - Other risks to which subjects may be exposed - Please identify below.

b) Of the risks and discomforts identified above, note the likelihood (probability) and degree (magnitude) of potential harm.


c) Discuss measures that will be taken to minimize risks or discomforts to subjects.
Two of the seven criteria (as mandated by the Office of Human Research Protections [OHRP]), that the IRB must consider when evaluating research relate to the risks involved in the proposed study: “(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.” And “(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result” (§45 CFR 46.111).

It is essential to provide sufficient details in this section so that IRB members can make appropriate determinations about the study. Focus not only on accurately listing the risks involved but also on describing how you and your study team will minimize those risks (item [c]).

Note that item (d) requires you to explain how adverse events will be managed. For example, what steps will research team members take if a participant experiences an adverse event during a research-related activity? Question (e) pertains to the process of reporting such events and others to the IRB. You may wish to distinguish between serious and non-serious events in your response. Non-serious events may be reported to the IRB at the time of continuing review if you detect any trends in them.
Benefits

12. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or society. If subjects will not benefit directly from study procedures, state this.

Note: Do not include compensation/payment of subjects in this section since remuneration is not considered a "benefit" of participation in research.

In the textbox under the Benefits heading, list and describe any potential benefits to individual subjects, group of subjects, and/or society. Directly state if it is unlikely that subjects will benefit from the study intervention,

Data Collection, Protection, and Monitoring

13. Data Collection, Protection, and Monitoring

a) Indicate which of the following will be used for data collection. Select all that apply.
   - Case Report Forms (CRFs) - Attach copies in the Attachments section.
   - Data banks, archives, medical records
   - Existing registry
   - Filming, video, or voice recording of subjects
   - Other: Please identify.  

b) How will study records be stored? Select all that apply.
   - Locked storage file cabinet
   - Password-protected electronic database
   - Secure Internet site
   - Other: Please identify.  

c) Explain how subject privacy will be protected and how confidentiality of subject information will be maintained.
d) Who will have access to study records or specimens?


e) Does your study require data to be electronically transmitted? If Yes, describe how data will be securely transmitted.


f) Does your study require special handling of digital radiologic images?
   □ No, it does not.
   □ Yes, it does. Please identify the security measures below.
     □ De-identification for secure transmission
     □ Storage in a study-specific folder
     □ Other. Please identify.


g) Will there be an independent Data Safety Monitoring Board for this study?
   □ Yes--In the space below, describe the Data Safety Monitoring Plan (DSMP). Note: NIH may require a DSMP for some projects.


   □ No--In the space below, explain how safety monitoring will be conducted.
The **Data Collection, Protection, and Monitoring** section of the application addresses issues related to the confidentiality and privacy of the data that will be collected. Answer each of the questions (a-h) as they apply to your study.

Note: Many of the textboxes are shaded; clicking the check box above the respective boxes will enable or “un-gray” the box so that you can provide details regarding your **Yes** or **No** response.
Tissue Banking

14. Tissue Banking Form

Intent to Bank Tissue
a) Does the consent form include the information that sample(s) will be used for tissue banking? □ Yes □ No □ N/A
b) Can subjects continue to participate in the main study if they decline participation in the tissue banking portion of the study? □ Yes □ No □ N/A

Use of Samples
c) How will tissue bank sample(s) be used?

Identification of Samples
e) Will the sample(s) have identifiers or a link to identifiers? □ Yes □ No □ N/A

Disclosure of Results to Subjects
f) Will research findings be given to the subject’s physician? □ Yes □ No □ N/A
g) Will research findings be given to the subject? □ Yes □ No □ N/A

If Yes, answer questions 1) through 5) below.
1) Will subjects be given the option of being informed of the results of their testing?

2) How will research findings be disclosed?

3) At what point in the research, will the findings be disclosed to subject?

4) What information will subjects receive?
The **Tissue Banking** section of the application requires completion only if you will be collecting and storing samples for additional research. Note that the check boxes and textboxes will be disabled (“grayed out”) unless you have checked the item in the **General Checklist** that relates to tissue banking: “Biological specimens and/or data will be stored for future research projects.”

Answer each of the questions regarding the proposed tissue banking. Also, keep in mind that the information provided in this section should concur with the information presented to prospective subjects in the consent form.
Medical Equipment

15. Medical Equipment

If the research involves use of medical equipment, explain whether the equipment is approved for marketing and routinely employed in clinical practice.

In the Medical Equipment section, indicate whether the medical equipment, if any, is routinely employed in clinical practice. Specify N/A as appropriate.

Investigational Devices

16. Investigational Devices

Complete the items below for each Investigational Device to be used on subjects.

Investigational Devices

Please click on Add to add Investigational Devices

Attach the manufacturer’s device specifications (including model numbers and sizes) to the SPA submission for all devices.

In the Investigational Devices section, add details for each investigational device that will be used on subjects. Note that the Add button is enabled only if you select the check box for the investigational devices in the General Checklist.

Follow the steps given below to add each investigational device to be used in the study. List only one device on each pop-up form.

Step 1

Click Add. The Add Investigational Device pop-up will appear.
Step 2

Enter the Device Name and Manufacturer; then explain how dispensing of the investigational device will be controlled.

Regulatory Status: The FDA is responsible for defining the development, testing, approval, and marketing of each medical device. Except for certain low-risk devices, each new medical device must be submitted to the FDA for review and assignment of its regulatory status. For more information, see FDA Information Sheet, titled "Medical Devices."

Select a device category that best describes the study device's regulatory status and enter the details below.

- **a) FDA Approved Device:** A device approved by the FDA for distribution, marketing, sale to, and use by the public for the study's indication.
  - Is the device lawfully marketed in the U.S.? [ ] Yes [ ] No
  - Is the device being used for its FDA-approved indication? [ ] Yes [ ] No

- **b) Investigational Device Exemption (IDE)**
  
  Please select ONE option that describes the use of the device in the study.
  
  - New Indication--FDA Approved Device: A device NOT approved by the FDA for distribution, marketing, sale to, and use by the public for the indication used in the study.
  - Investigational: An FDA designation that permits a manufacturer to lawfully ship an unapproved device for use in a research study.

  IDE #: 

  Please select the FDA-assigned device category.

  - Category A
  - Category B
Step 3

As the form indicates, there are five FDA regulatory statuses of medical devices. Select the radio button of the status that best describes the study device. Note that only one radio button may be selected for each device.

- **c) Humanitarian Use Device (HUD):** An FDA designation for a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. For more information about Humanitarian Use Devices, see FDA's "Humanitarian Device Exemption: Final Guidance."

  Humanitarian Use Device (HUD) Number

- **d) 510(k) Status:** A device determined by the FDA to be "substantially equivalent" to an existing device that is legally marketed in the U.S. Until a 510(k) device is approved, it is still considered investigational. For more information, see FDA information Sheet, titled "Premarket Notification [510(k)]."

  510(k) Number:

  Provide the name of an equivalent device, and attach sufficient documentation to justify 510(k) status.

- **e) Nonsignificant/Significant Study:** A study in which the IRB is asked to make a risk determination about a device and its use when it has not been assigned an IDE from the FDA.

  1) Are you requesting that the IRB determine the risk level of this study?  
     - Yes  
     - No  
     - N/A

     If Yes, complete items (2) and (3) below. The IRB's risk determination of a medical device (and the study in which the device is used) is based on the proposed use of a device in an investigation and not on the device alone. The IRB will consider the nature of harm that may result from use of the device. The IRB risk determination will be made by the IRB at a convened meeting. This determination does not qualify for expedited review. For more information and a list of devices with their risk designation, see the FDA Information Sheet titled "Significant Risk and Nonsignificant Risk Medical Device Studies."

  2) Please select the risk status for your study device.

     - Nonsignificant Risk Device: The study device does not meet the definition of a significant risk device. Nonsignificant risk devices should not be confused with the concept of "minimal risk," a term used in the IRB regulations to identify certain studies that may be approved by an expedited review. Attach sufficient information to justify the non-significant risk determination.

     - Significant Risk Device: A study device that presents a potential for serious risk to the health, safety or welfare of a subject and (1) is an implant or (2) is used to support or sustain human life or (3) is of substantial importance to diagnose, cure, mitigate or treat disease or otherwise prevent impairment of human health or (4) otherwise presents a potential for serious risk to the health, safety or welfare of a subject. Significant risk device studies must be conducted in accordance with full Investigational Device Exemption requirements. For information on how to obtain an IDE, visit the FDA Web site.

  3) Has another IRB determined whether the device is significant or non-significant risk?  
     - Yes  
     - No  
     - N/A

     If Yes, attach documentation in Attachments section.
Step 4

Enter any required information (e.g., IDE number, Category A or B, etc.) for the selected FDA status.

Step 5

Respond to the SPA items at the bottom of the page.

Step 6

Scroll to the top of the screen and click Save.

The pop-up will close, and the record will be added to the Protocol Information page.

Note:

- To delete an Investigational Device record, select the record and click Delete.
- Click the Device Name link to view or edit the record.

Drugs and Biological Products

If you will administer any investigational or commercial drugs or biological products to subjects during the study, enter details concerning them in this section.

a. Begin by identifying whether the study involves the use of a combination drug/biological product and device.
b. Indicate whether the drug will be dispensed by a hospital pharmacy.
c. From the drop-down menu, select the phase of the drug study, if applicable.
17. Drugs and Biological Products

a) Does your study involve the use of a combination drug/biological product and device? If yes, you must complete and submit the Medical Device Form.

b) If the drug/biological product is being used in a hospital, will it be dispensed by the hospital pharmacy?

Provide the following information about the study drug or biological product. ALL fields are required for each drug entered. You may provide the location (title and page number) where the information can be found in the protocol, investigator’s brochure, package insert, or other reference. These materials must be attached in the Attachments section.

- Phase:

Note that there are three section tabs on the Drugs and Biological Products page:

- Investigational Drugs or Biological Products
- New Indication for Approved Drugs or Biological Products
- Drugs Being Used for Their Approved Indications

Add all INVESTIGATIONAL drugs, reagents, or chemicals to be administered to subjects during this study.

Investigational Drugs or Biological Products

Please click on Add to add Investigational Drugs or Biological Products

Add all commercial drugs, reagents, or chemicals to be administered to subjects for a NEW INDICATION.

New Indication for Approved Drug or Biological Product

Please click on Add to add New Indication for Approved Drug or Biological Product

Add all commercial drugs, reagents, or chemicals to be administered to subjects for their approved indication.

Drugs Being Used for Their Approved Indications

Please click on Add to add Drugs Being Used for Their Approved Indications
You may see only one or two tabs, depending upon the selections you made in the General Checklist. If you do not see the appropriate section or sections, return to the General Checklist and revise your selections. Please avoid entering a drug under the wrong heading.

Adding “Investigational Drugs or Biological Products” or “New Indications for Approved Drug or Biological Product”

Follow the steps below to add “Investigational Drugs or Biological Products.” The same steps apply to “New Indication for Approved Drug or Biological Product.”

**Step 1**

Click the **Add** button to enter information about the drug or biological product. The pop-up will display.

**Step 2**

Enter the “Trade Name or Biological Product” and other required details, including the Investigational New Drug (IND) number.

- Select **Yes**, **No** or **N/A** for the questions concerning whether the study has been submitted to the Institutional Biosafety Committee and whether the drug is provided free to your site or Allina.
- Then provide the sponsor’s cost of the investigational drug.

**Step 3**

Enter the required information about the drug or biological product. You may refer to pages within the protocol or investigator’s brochure in response to the items below.
### eProtocol IRB Forms User Guide

**Manufacturer:**

<table>
<thead>
<tr>
<th>Chemical Structure:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Pharmacology:**

<table>
<thead>
<tr>
<th>Form of Administration:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Maximum Tolerated Dose in Humans:**

<table>
<thead>
<tr>
<th>Toxicity Observed:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Pharmacokinetics Data:**

<table>
<thead>
<tr>
<th>Procedure for Minimizing Adverse Events:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

---

**Step 4**

Then answer **Yes**, **No** or **N/A** to the questions about the holder of the IND.

<table>
<thead>
<tr>
<th>Is IND held by the sponsor? If Yes, provide a copy of the investigator's brochure and the sponsor's protocol in Attachments Section #22. *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(circle one)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is IND held by the Investigator(s)? If Yes, provide a copy of the IND application letter submitted to the FDA in Attachments Section #22. *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(circle one)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
Step 5

Click Save at the top of the form. The pop-up will close, and the record will be added to the Protocol Information page.

Note:

- To delete an entry, select the record by checking the box beside the drug name; then click Delete.
- Click the trade name link to view/edit the record.

Adding “Drugs Being Used for Their Approved Indications”

Follow the steps below to add all the commercial drugs that will be administered to subjects as part of the study.

Step 1

Click the Add button. The pop-up will appear.

Step 2

Enter the drug name and other required details. As with the information entered for investigational drugs, you may refer to pages within the protocol or investigator’s brochure in response to the required items.
Step 3

Click **Save**. The pop-up will close, and the record will be added to the Protocol Information page.
Note:

- To delete an entry, select the record by checking the box beside the drug name; then click **Delete**.
- Click the trade name link to view/edit the record.

**Radiation**

18. Radiation

a) Will radiation be used as part of this study (including as part of routine care)?

If Yes, check all that apply, and describe their use.

- Radiation used for routine care

- Radiation used in addition to routine care
Select Yes, No, or N/A for questions (a) and (b). If the answer is Yes, describe each type, including radiation used for standard care. Note that if you have submitted the study to the Radiation Safety Committee, you must upload (attach) a copy of the approval letter in the Attachments section (22).
Informed Consent

19. Informed Consent

Add the Consent Forms, Altered Consent Forms, and/or Waiver or Alteration of Consent needed for this research. You will be asked to provide relevant background information for each consent document or waiver. (Note: Do not include child/minor assent forms and assent waivers or parental permissions forms here since these are addressed in the next section. Also, attach translated/foreign language versions of any consent materials in the Attachments section.)

Allina defines “consent” as an agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the capacity to understand the information transmitted and its implications, after having been informed of the physical, psychological and personal risks and potential benefits inherent in a research study. Consent is usually demonstrated by signing a consent form (45 CFR 46.116).

The consent form can also be presented as a “short form” document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a “summary” of the information that is presented to the participant must also be provided for IRB approval, and there must be an impartial witness to the oral presentation. The witness and the participant must sign the short form. The “short form” method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Researchers may request a waiver or alteration of consent to waive the requirement for the research consent process or alter some or all of the elements of the research consent process if the research meets the criteria for a waiver or alteration.

Note: If you are attaching multiple consent forms and the consent process has already been described for another consent form, simply refer to the other form (e.g., "consent process is the same as the process for Group A").

<table>
<thead>
<tr>
<th>Informed Consent</th>
<th>Add</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please click on Add to add Informed Consent</td>
<td></td>
</tr>
</tbody>
</table>

In this section, you will upload the consent documents and respond to questions concerning the consent process. Follow the steps below to add the consent documents.

Step 1

Click Add. The Informed Consent pop-up will appear.

Step 2

Enter a descriptor for the consent form in the Title field—for example, “Main Study Consent Form” or “Screening Consent.”
Note: * denotes mandatory field.

**Informed Consent**

- **Consent Form Descriptor (e.g., Main Study Consent):**
- **Consent Information Type:**
  - Consent Form Sample
  - Alteration of Consent Regulations
  - Waiver of Consent Regulations

Note:

- The “Consent Form Sample” link will connect you to the sample consent form on Allina’s IRB Forms page.
- The “Alteration” and “Waiver” links will connect you to the federal regulations concerning those consent options.

**Step 3**

Select the form type from the **Consent Information** drop-down menu.

Note: * denotes mandatory field.

**Informed Consent**

- **Consent Form Descriptor (e.g., Main Study Consent):**
- **Consent Information Type:**
  - Consent Form Sample
  - Alteration of Consent Regulations
  - Waiver of Consent Regulations
  - Consent Form

Different fields will appear, depending upon the “Consent Information Type” you select from the drop-down menu. These fields will enable you to add information about the consent process and attach required documents.
Consent Forms

a. Click the check box by “Attachment” to attach the consent form; doing so will enable the “Browse” option.

b. Click **Browse**, and select the consent document you wish to upload.

c. Then respond to each question about the consent process.

d. Repeat the process for each consent form you will use in the study. Note that you may refer to previously entered information if the consent process is the same for an additional form.
Request for Waiver or Alteration of Consent

Consent Form Descriptor (e.g., Main Study Consent):*
Main Study

Consent Information Type*
Request for Waiver or Alteration of Consent

a. Select the “Request for Waiver or Alteration” item from the drop-down menu.
b. Respond to the question if you are requesting an alteration.
c. Then select Option A or B, depending upon the nature of your research.

Waiver or Alteration of Consent: To qualify for a waiver or alteration of one or more elements of informed consent, EITHER criterion A or B must be met. Select the applicable criterion, and provide your justification in the fields below.

A. (1) The research involves no more than minimal risk of harm to the subjects.
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
(3) The research could not practicably be carried out without the waiver or alteration. and
(4) Whenever appropriate, the subjects will be provided with pertinent information after participation.

Note:

Although there is only one textbox, please ensure that you explain how the research you plan to conduct meets each of the four criteria.
B. (1) The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or service; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs, and
(2) The research could not practicably be carried out without the waiver or alteration.

Note:
If you select Option B, please ensure that you explain how the research you plan to conduct meets both of the criteria.

Child Assent and Parent/Guardian Permission

20. Child Assent, Parental Permission
Add the Assent Document(s) and Parent/Guardian Permission Form(s) needed for this research. You will be asked to provide relevant background information for each assent document.

An "assent document" is a form or script of the information that will be conveyed to the child about the study. In general, researchers must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 15-year-old is not usually suitable for a 7-year-old child).

A Parent/Guardian Permission Form is a document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child’s participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

In this section, you may add assent forms and parental permission forms if they apply to your study.

Follow the steps below to add these documents. You may add as many documents as your study requires.
Step 1

Click **Add**. The **Add Documents** pop-up will appear.

Step 2

Follow these steps to complete the items on the pop-up form:

- a. Enter the name of the assent form or parental permission form in the **Title** field.
- b. Select the form type from the drop-down menu.
- c. Click the check box by **Attachment** to attach the document and enable the **Browse** option.
- d. Click **Browse**, and select the document to attach.
- e. Then respond to the questions about the consent process.

Step 3

Click **Save**. The pop-up will close, and the record will be added to the Child Assent/Parental Permission page.

Note:

- On the “Child Assent, Parental Permission” page, click the **Title** to view/edit the record.
- Click the **Attachment** link to open or save the attachment.
- To delete a record, select the record and click **Delete**.

**Health Insurance Portability Accountability Act (HIPAA)**

This section addresses the use of Protected Health Information (PHI). Begin by responding to questions (a), (b), and (c). Selecting **Yes** in response to question (b) will enable the textbox; in it enter the details of your plan to comply with HIPAA requirements. Specify **N/A** as appropriate.

**21. Health Insurance Portability and Accountability Act (HIPAA)**

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual’s PHI to be disclosed or used in research without the person’s authorization (i.e., IRB Waiver of HIPAA Requirement Authorization). For more information, consult [HIPAA Research Guidance](#).

If **Yes** (and a limited data set will not be used), EITHER provide a HIPAA Authorization Form in the Attachments section OR request/add a Waiver/Alteration of HIPAA Authorization below.
Follow the steps below to add the HIPAA Waiver/Alteration information.

**Step 1**

Click **Add**. The Add HIPAA Waiver/Alteration pop-up will appear.
HIPAA Information Waiver Type*

SelectOne

- Waiver of Authorization
- Alteration of Authorization

a) Provide a brief description of the Protected Health Information (PHI) that is to be excluded from the informed consent if a waiver or alteration is requested.

b) Explain how the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.

c) Explain why the research could not be practicably carried out without the waiver/alteration of HIPAA Authorization.

d) Explain why the research could not be practicably carried out without access to and use of PHI.

e) How will you protect the health information from improper use and disclosure?
f) Describe your plan for destroying identifiers at the earliest opportunity consistent with the conduct of the research, or provide a justification for retaining them.

Step 2

Select either the **Waiver** or **Alteration of Authorization**.

Step 3

Respond to each criterion, explaining why your study qualifies for the waiver or alteration. Do not enter N/A for any of the items.

Step 4

Click **Save**. The pop-up will close, and the record will be added to the **HIPAA** section.

Note:

- Click the link to the record under **HIPAA Waiver/Alteration** to view or edit the record.
- To delete a HIPAA record, select the check box next to the record, and click the **Delete** button.

**Attachments**

In this section, you will attach documents related to the study. Follow the steps below to attach documents.

**Step 1**

Click **Add**. The **Add Attachment** pop-up will display.
Step 2

Select the Document Type.

Step 4

Browse for and attach the document. The name of the document will automatically be updated in the Attachment Name field.

Step 5

Click Save. The pop-up will close, and a link to the attachment will appear on the Attachments page as shown below.
22. Attachments

Add appropriate attachments (e.g., federal grant/sub-contract, questionnaires, surveys, advertisements, reference list, investigator’s or sponsor’s protocol, investigator’s brochure, etc.) in this section.

<table>
<thead>
<tr>
<th>Protocol Type</th>
<th>Attached Date</th>
<th>Submitted Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Protocol 423190</td>
<td>11/08/2009</td>
<td></td>
</tr>
</tbody>
</table>

Note:

- Click the link under Document Type to view the attachment.
- To delete an attachment, select the check box by the record, and click Delete.
Assurance

The Assurance section lists various obligations of the Principal Investigator.

Assurance

The Principal Investigator of this study provides the following assurances:

The eProtocol application submitted for this study is complete and accurate.

The PI acknowledges responsibility for the conduct of this project as described in the IRB application.

The PI has evaluated the protocol and determined that s/he has sufficient resources to conduct the study as submitted and necessary to protect subjects who enroll in the study.

All co- or sub-investigators, study coordinators, and other research personnel to whom the principal investigator delegates study-related responsibilities will receive thorough training in human subjects protections as well as in the specific details of study procedures.

The principal investigator will not begin the study until s/he has received notification of final IRB approval. If SPA approval is required, s/he will not begin the study until s/he have received notification of final SPA approval.

The principal investigator acknowledges his/her responsibility for the accuracy of all documents research personnel submit to the IRB on his/her behalf.

The principal investigator will comply with all IRB requests to report on the status of the study.

The principal investigator will seek and obtain prior approval from the IRB for modifications in the study, including changes in procedures, consent forms, etc.

The principal investigator will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.

The principal investigator will notify the IRB when his/her research has been completed or terminated.

Note: If applicable, attach the Federal Grant Application (including competing renewals), investigator’s brochure, and protocol for all industry-sponsored clinical trials. You will be prompted for these in the Attachments section.

The Principal Investigator has read and agrees to abide by the above obligations.

Step 1

Read the items carefully.

Step 2

Check the box by “The Principal Investigator has read and agrees to abide by the above obligations.”

Note:

You must agree to the obligations to complete the protocol submission process.
Check for Completeness

Before you submit the protocol, click the Check for Completeness link in the left navigation panel.

A pop-up will display a list of the sections that are incomplete.

<table>
<thead>
<tr>
<th>Protocol ID: 2009-01</th>
<th>Principal Investigator: Aherton, Michael</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical</td>
<td></td>
</tr>
<tr>
<td>S.No.</td>
<td>Resolution</td>
</tr>
<tr>
<td>1</td>
<td><strong>Purpose</strong> - Complete Section 1</td>
</tr>
<tr>
<td>2</td>
<td><strong>Background</strong> - Complete Section 2, Specify N/A as appropriate</td>
</tr>
<tr>
<td>3</td>
<td><strong>Collaborative Research</strong> - Complete Section 3(a), Specify N/A as appropriate</td>
</tr>
<tr>
<td>4</td>
<td><strong>Qualifications of Study Personnel</strong> - Complete Section 4(a) and 4(b), Specify N/A as appropriate</td>
</tr>
<tr>
<td>5</td>
<td><strong>Subject Population</strong> - Complete Section 6(a) and 6(b), Specify N/A as appropriate</td>
</tr>
</tbody>
</table>

Each of the incomplete items listed is a link to the various sections of the Application Form. Click each link, and add the required information.

Note:

To return to the list, click the Check for Completeness link in the left navigation panel. The system will check the protocol and refresh the list of incomplete sections.
Submit Form

To submit the form to IRB Committee for review, click **Submit Form** in the left navigation panel.

The confirmation pop-up will display.

Do you want to submit the IRB Protocol 2009-01-002(Atherton)?

[Yes] [No]

In the pop-up, click **Yes** to submit the form. If there are any missing details, the Check for Completeness pop-up will display again.
Print View

To print the Protocol Application Form, click the **Print View** in the left navigation panel.

The Print View Decision pop-up will appear.

**Step 1**

Select the option—Protocol Only, Protocol with Comments, or Comments only—for the item(s) you wish to print. (The term “Comments” refers to the IRB’s comments about your study. There will be no Comments if the protocol has not yet been submitted to the IRB.)
Step 2

By default, all sections are selected. Un-select the options for the sections you do not wish to print by checking the appropriate check boxes.

Also by default, the page orientation is set to “Portrait.” You may select “Landscape” if you wish to change the page orientation.

Step 3

Click **OK** at the bottom of the window. An Adobe.PDF file will be created and opened. You may save it to your computer by clicking **File**, then **Save As** in the upper left-hand corner of the window.

Note:

After the protocol is reviewed and commented on by the IRB, the other two options—Protocol with Comments and Comments only—will be enabled.
Event History

To view the history of the protocol, click **Event History** in the left navigation panel.

The Event History section will display.

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>View Attachments</th>
<th>Consent Forms</th>
<th>Letters</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/30/2009</td>
<td>PROTOCOL CREATED</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This section provides a summary of the major events over the study’s history: Date, Status (including creation and submission), View Attachments, Consent Forms, and Letters from the IRB. Key emails from the IRB will also appear in the **Email History** section.

You may access **Attachments** that have been attached to the protocol by clicking the document link in the **View Attachments** column. To view **Letters** generated for the protocol, click the link to the letter in the **Letter** column to view the approval letter.

Note:

Approval letters are available after the IRB has approved the protocol.
Return Notes

After your protocol has been submitted, the IRB Administrative Office will conduct an initial check before assigning it to an IRB for review. In its pre-review, office staff will check to ensure that . . .

- The correct application form was used.
- The application is complete.
- It includes all of the necessary attachments, etc.

If the submission is incomplete, the staff will return the protocol to you. This action releases the protocol to you with full EDIT capability so that you can make any necessary adjustments. If a protocol is returned, you will receive an email notification, alerting you to the return.

The Protocol Status that displays on your home page will note that the submission has been returned. Open the protocol by clicking on the Protocol ID link, and click the button in the left-hand menu labeled Return Notes as shown below.

![Return Notes Menu](image)

Clicking Return Notes will open a small window with information about the reason for the protocol return and instructions about how to proceed. When you are ready to resubmit the protocol, simply click the SUBMIT PROTOCOL button just as you did for the initial submission.
IRB Biomedical Exempt Form

Before beginning an Exempt Application, ensure that your proposed study fits at least one of the categories for exempt research. If you are not certain that the study qualifies, contact the IRB Administrative Office to discuss the project. You will be required to complete and submit the Expedited/Full Board Application if the study is not exempt.

The following sections are identical to those in the Expedited/Full Board Application: Personnel Information, Study Sites, Funding, and Potential Conflict of Interest. Only the sections that differ from the Expedited/Full Board Application are described below.

Review Fees

An administration review fee is charged for all proposed research applications submitted. The fee is used to defray costs associated with review and ongoing monitoring of the proposed research. Fees are assessed for all industry-sponsored and/or externally funded studies, including studies conducted by Allina departments/services when funded by a non-Allina source (e.g., industry, foundation, grant, etc.).

A fee of $300 is charged to review an IRB Exemption Application.

- **Review Fee Submitted to the IRB**
  
  Check Number
  Date Submitted

- **Review Fee Transferred Internally**
  
  Date Submitted

  Upload Internal Transfer form in the Attachments section.

- **Request for Invoice**

- **Request to Waive Fee**

  Please explain why you believe the IRB should waive the fees for this study.
Select the payment option that applies to your study. (Note that the review fee for an exempt study is $300.) If you select **Request to Waive Fee**, please provide a detailed explanation to support your request.

**General Checklist**

<table>
<thead>
<tr>
<th>General Checklist</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The PI of this study is a student or completing the study to meet degree requirements.</td>
<td></td>
</tr>
<tr>
<td>This study will employ questionnaires or surveys. Attach a copy of each instrument in the attachments section.</td>
<td></td>
</tr>
<tr>
<td>The PI and/or study personnel already have permissible access to the records or specimens (through a job or internship).</td>
<td></td>
</tr>
<tr>
<td>This study will be funded through outside sources.</td>
<td></td>
</tr>
<tr>
<td>This study will receive federal funding (e.g., NIH, NSF, DOD, etc.).</td>
<td></td>
</tr>
<tr>
<td>The principal investigator or other research personnel have a financial, personal, or professional conflict of interest related to the study as defined in Allina’s Conflict of Interest Policy.</td>
<td></td>
</tr>
<tr>
<td>Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.</td>
<td></td>
</tr>
<tr>
<td>The study involves the use of human blood, body fluids, tissues, or cells (including cell lines) already drawn or banked (stored).</td>
<td></td>
</tr>
<tr>
<td>If you checked the statement above, identify the lab's location:</td>
<td></td>
</tr>
<tr>
<td>Is the study posted on <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a>?</td>
<td></td>
</tr>
<tr>
<td>Yes – Specify number:</td>
<td></td>
</tr>
<tr>
<td>No – Explain the reason below.</td>
<td></td>
</tr>
</tbody>
</table>

The purpose of the General Checklist is to determine whether the proposed study involves any special situations that may require additional information. Checking certain boxes also enables future pages.

- Check the box by each statement that is true of your study.
- You must select at least one checklist option to proceed to the next section.
Protocol Information: Exempt Categories

To qualify for exemption, the study must fit one or more exempt categories. Select one or more of the paragraphs the Protocol is related to. You must select at least one Exempt Paragraph to proceed to the next section and complete the Protocol Application Form. When you select a paragraph, you need to select one or more related check boxes.

Research activities that involve one or more of the categories listed in this section may be exempt from the full requirements of IRB review. HOWEVER, investigators are NOT authorized to make this determination. Allina IRB staff must make the determination of exemption based on regulatory and institutional criteria. All procedures in a protocol must meet exemption criteria for the study to be deemed exempt.

NOTE: The exemption categories below do not apply to research involving prisoners, subjects vulnerable to coercion, persons considered to be legally incompetent, and certain types of research with children as noted below. Additionally, categories 1 thru 5 do not apply to research regulated by the Food and Drug Administration (FDA).

Select one or more of the following paragraphs from 45 CFR 46.101(b).

- (1) EDUCATIONAL PRACTICES: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- (2) EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained in recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing employability, or reputation.

  Surveys on sensitive or personal topics that may cause stress to study participants are not exempt from IRB review. This exemption also does not apply to children unless the research involves observation of public behavior in which the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior."

- (3) EDUCATIONAL TESTS, SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR (Research NOT exempt under Category 2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2), if: (i) the human subjects are elected or appointed public officials or candidates for public office, or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
If you select Category 4, you must also select one of two options under it. Note that if you select the first option—“The PI and/or study personnel will have access to or create a link that would make it possible to identify subjects”—the study does not qualify for exemption. You should close the application and, instead, create a protocol, using the Expedited/Full Board Application.
Protocol Information

Read each item carefully, and respond to each in as much detail as possible; if an item does not apply to your study, enter N/A. Take note of the items that require supporting documentation to upload in the Attachments section.

The system has a built-in spell feature that will identify common words that are misspelled by underlining them with a dotted red line. Please note and correct misspelled words so that your submission is as accurate as possible.

Title
Exempt Study

You may edit your title here if you wish to do so.

Proposed Start Date: [ ] Proposed End Date: [ ]

Complete the items below. Specify N/A as appropriate. Do not leave any sections blank.

1. Purpose of the Study

In non-technical language, briefly describe the research question(s) and/or hypotheses. Attach the protocol or research plan.

When entering the start date for your study, please allow time for IRB approval of your exemption.
2. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., interventions/interactions with subjects, data collection, photographing, audio- and/or videotaping), including follow-up procedures.

b) Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

c) Will audio or video taping occur? Describe what will become of the tapes after use (e.g., shown at scientific meetings, erased, etc.). Describe the final disposition of the tapes.

d) If the proposed research involves the use of existing data/specimens, check all that apply.
   
   □ i) The research involves data from publicly available sources.
   □ ii) The data will be recorded by the investigator in such a manner that subjects cannot be identified.
   □ iii) Any link to identifying information has been destroyed.

   e) Will surveys, questionnaires or other materials be used to collect data?
   □ Yes: Attach copies of all data collection materials.
   □ NO
3. Subject Population

a) Describe criteria for inclusion and exclusion of subjects or the charts to be reviewed in this research study. (Note: If this study includes a vulnerable population, it does not qualify for exemption.)

Note that questions (a) and (b) apply to chart reviews as well as other types of exempt research. Please do not enter N/A for these items.

b) How many participants/records do you plan to recruit/access?

4. Risks/Discomforts

To qualify for an exemption, the study must not pose any risks to subjects. Describe all known risks and discomforts associated with the study, noting the likelihood (probability) and degree (magnitude) of potential harm. For chart reviews, consider the risk of a breach of confidentiality.

This question is one of the most important on the application. Carefully assess the risks posed to subjects, including the possibility of a breach of confidentiality.

5. Confidentiality

a) Explain how you will protect subjects’ privacy. Note: According to the IRB Guidebook, published by the Office of Human Research Protections, privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Please keep this definition in mind as you respond to this item.

b) Describe how you will maintain the confidentiality of subjects’ information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.
5. Confidentiality

a) Explain how you will protect subjects’ privacy. Note: According to the IRB Guidebook, published by the Office of Human Research Protections, privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Please keep this definition in mind as you respond to this item.

b) Describe how you will maintain the confidentiality of subjects’ information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.

c) Who will have access to study records or specimens? (Please identify specific team members by name.)

d) How will the records be secured? Please describe specific measures you will take.

e) Will data be collected anonymously (i.e., NO identifying information from subjects will be collected, recorded, or linked to the study data)? If not, please explain. NOTE: If you are seeking an exemption under Category 4, you must collect your data anonymously. If you are collecting any identifiers, the study does not qualify as exempt, and you will need to complete the Expedited/Full IRB Application. (Data are not anonymous if there is a code linking them to personally identifiable information.)
f) Indicate whether the data/specimens will be destroyed at the end of the study. If data will not be destroyed, explain why, where, in what format, how long the data will be retained, and who will have access to them.

g) If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them? NOTE: “Existing” means data or specimens collected (i.e., on the shelf) prior to the proposed research. It includes data or specimens collected for research and non-research activities.

6. Informed Consent

Add the Consent Forms, Altered Consent Forms, and/or Waiver or Alteration of Consent needed for this research. You will be asked to provide relevant background information for each consent document or waiver. (Note: Do not include child/minor assent forms and assent waivers or parental permissions forms here since these are addressed in the next section. Also, attach translated/foreign language versions of any consent materials in the Attachments section.)

Allina defines “Consent” as an agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the capacity to understand the information transmitted and its implications, after having been informed of the physical, psychological and personal risks and potential benefits inherent in a research study. Consent is usually demonstrated by signing a consent form (45 CFR § 46.116).

The consent form can also be presented as a “short form” document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a “summary” of the information that is presented to the participant must also be provided for IRB approval, and there must be an impartial witness to the oral presentation. The witness and the participant must sign the short form. The “short form” method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Researchers may request a waiver or alteration of consent to waive the requirement for the research consent process or alter some or all of the elements of the research consent process if the research meets the criteria for a waiver or alteration.

Note: If you are attaching multiple consent forms and the consent process has already been described for another consent form, simply refer to the other form (e.g., “consent process is the same as the process for Group A”).

Consult the Informed Consent instructions presented above for the steps required to address consent.
7. Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement/Authorization). For more information, consult HIPAA Research Guidance.

Consult the HIPAA instructions presented above for the steps necessary to address HIPAA requirements.

8. Attachments

Add appropriate attachments (e.g., federal grant/sub-contract, questionnaires, surveys, advertisements, protocol, etc.) in this section.

Consult the instructions above for attaching documents to your study and for completing the Assurance section.

Before you submit the protocol, click the Check for Completeness link in the left navigation panel, following the instructions provided above. Enter any missing information or attachments; then submit the protocol according to the instructions for submitting studies to the IRB.
Terminology Differences

Some of the terms used in eProtocol differ from those of Allina’s IRBs and research community. Here are some of the words to note:

- **Protocol**
  In eProtocol, the word *protocol* has two meanings; in its general sense, it refers to the entire study, but it is also used in a specific sense to refer to the document that describes the study.

- **Designated Reviewer**
  The *designated* reviewer is eProtocol’s term for *expedited* reviewer.

- **Panel Manager**
  At Allina the *panel manager* refers to IRB administrative staff.

- **Panel**
  eProtocol uses the word *panel* to refer to the IRB committee.