eProtocol 201:

A Guide for Users

Allina Hospitals & Clinics

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Introduction

This guide contains a collection of instructions and advice for performing various activities in eProtocol, Allina's online submission system. A few points to note . . .

- The topics selected for inclusion were based on the results of the Allina IRB Office's survey of eProtocol users, conducted in May 2010 (about six months after the implementation of the system in November 2009).

- You may notice that this guide includes very few screenshots. Including screenshots requires that guides such as this one be updated as often as the user interface changes, so we have purposely refrained from using them in the hope that this guide will have a longer "shelf life." In addition, screen shots increase the length dramatically, and we wanted to keep this guide as short as possible.

- Other eProtocol resources are available on the IRB/SPA Online Submission page of the Research Administration website. They include the following:

    - Frequently Asked Questions

    - eProtocol IRB Forms User Guide: New Protocol Forms

Accessing Approval Letters

New Studies, Amendments, and Continuing Reviews

- On your home page, click the Protocol ID link (under Active Protocols).
- Open the protocol form in View Mode.
- Click "Event History." (You may first need to click "Get Protocol"; then when the protocol loads, click "Event History.")
- Find the approval letter for the item you wish to access. (The approval letters appear in the last column.)
- Click the "Approval Letter" link to access the letter.
- Scroll to the bottom of the PDF to view the specific notes about your submission from the IRB.

Please note: The "customization" of the approval letters is a manual process, and each must be done individually after the board meetings. Therefore, please wait at least three business days after a meeting before contacting the IRB about the status of an approval letter for a new study, amendment, or continuing review.

Miscellaneous Forms, Protocol Deviations, and Report Forms (Local SAEs and Non-Local SAE Logs)

- Click the Protocol ID link (under Active Protocols).
- Open the protocol form in View Mode.
- Click "Event History" in the left navigation bar. (Depending on which form you are in, you may first need to click "Get Protocol." When the protocol loads, click "Event History.")
- Find the form you wish to access in the list of items.
- Click "View Attachments."
- Often, the approval letter attachment is labeled "IRB Acknowledgement Letter" and the date, or it is simply the IRB number for the study (e.g., 2315-1E).
- Click the link to the attachment to access the approval letter.

You may also open the form itself (e.g., a Miscellaneous Form).

- Open the form; then scroll to the Attachments section at the bottom of the page.
- Click the link to the attachment. Often, the attachment is labeled "IRB Acknowledgement Letter" and the date, or it is simply the IRB number for the study (e.g., 2315-1E).

Final Reports

- Click the Protocol ID link under Non-Active Protocols.
- Open the Final Report in View Mode.
- Scroll to the Attachments section at the bottom of the page.
- Click on the link "Study XXXX-X Closure."
- The closure letter will appear.

Occasionally, the closure letters are attached in the Attachment section of the Protocol Information. Follow these instructions:

- Open the Final Report.
- Click "Get Protocol."
- When the page opens, click the "22" icon at the top of the page.
- The letter may appear under the heading "IRB Office Document(s)."

Accessing Return Notes

The IRB uses Return Notes to request changes to submissions before they are placed on an agenda for review.

When you receive an email stating that a form has been returned to you, follow the steps below.
- Click the Protocol ID link under the appropriate heading—e.g., "Amendments."
- The "Return Notes" button is about two thirds of the way down the blue navigation bar on the left side of the screen.
- Click the Return Notes button and correct the items discussed in the notes. (Researchers cannot respond to Return Notes.)

Attaching Documents

Note: Never delete an attachment that has received IRB approval.

What Documents to Attach
Submit all documents that will be presented to subjects. These include . . .
- Consent forms
- Information booklets
- Questionnaires and surveys
- Recruitment materials (ads, brochures, posters, websites, etc.)
- Retention materials or incentives

In addition, you should submit any document that provides information about the study, including the following items:
- Case Report Forms
- Data Collection Instruments
- Explanatory diagrams
- FDA letters
- Grant information
- HIPAA Authorization Forms
- Instructions for Use
- Interview or focus group scripts
- Investigator's Brochures
- IRB approval letters from other institutions, if applicable

- PI Assurance
- Protocols

Where to Attach Documents

- Consent Forms: Attach clean and marked copies in Section 19.
- Assent Forms and Parental Permission Forms: Attach clean and marked copies in Section 20.
- Other Documents: Attach all other documents in Section 22.
- "IRB Office Document(s)": This heading is for IRB Office use only. You will find marked and approved copies of the consent form here as well as other documents on which the IRB has made comments.

How to Attach Documents

- Start in the appropriate section of the Protocol Information (e.g., Section 19, 20, or 22).
- For documents in Section 22 (the Attachments section), click the "Add" button.
- When the pop-up opens, select the best descriptor from the drop-down menu for the item you wish to attach. (Note: Do not select "IRB Office Document(s)" for anything you submit.)
- Click the "Choose File" button to browse for the document you wish to attach. A pop-up will appear, listing document files. By default the system accesses the last folder or location from which you uploaded a file, so you may need to change folders or locations to find the item you plan to attach.
- Select the name of the file to attach.
- By default the system uses the file name for the attachment name. But you can change the name, and you should do so if it contains non-standard abbreviations or names that those unfamiliar with the study would not recognize.
- Please **proofread** attachment names to ensure that there are no misspelled or errors in dates.

Deleting Unneeded Forms

If you have created a form that you do not need, you can delete it by following these steps. (Reminder: eProtocol refers to all forms as "Protocols.")

- Click the "Delete Protocol" button on your home page. Note: The system will not allow you to delete approved studies or items that have been submitted to the IRB.
- When the page opens, select the checkbox next to the item you wish to delete.
- A pop-up will appear, asking "Do you want to delete the selected Protocol(s)?"
- Click "Yes."
- A message will appear at the top of the screen: "Protocol(s) XXXX-X have been deleted."
- Return to your Home Page by clicking the "Home Page" link.

Determining Which Form to Use

The most common error users make is submitting a revised document or study revision on a Miscellaneous Form. The IRB Office will return such submissions for two reasons:

- Revised documents need to be part of the study protocol. Attachments to Miscellaneous Forms do not appear in Section 22 of the Protocol Information.
- Revisions to the study require IRB approval before they can be implemented. The IRBs vote on Amendments; they do not vote on FYI items submitted for IRB acknowledgement. (Amendments and Miscellaneous Forms appear in separate places on IRB agendas.)

After a protocol has been approved, only two forms allow you to change information in the original application: the Amendment Form and the Continuing Review Form. Thus, only one of these forms may be active at any given time. If you are submitting an Amendment that alters information in the original application, you should also make the changes in the Protocol Information itself rather than just describing the change on the Amendment Form.

Because an Amendment and Continuing Review Form cannot be submitted concurrently, it is always very important to note the date your study expires. If the expiration date of your protocol is near, you should start a Continuing Review Form instead of an Amendment. You can include protocol amendments on a Continuing Review Form by describing the proposed change in response to the study's progress.

Use the table below to determine which form to use for common situations that arise during a study. If a situation arises that does not appear below, please feel free to consult the IRB Administrative Office for assistance. (For more information about eProtocol forms, see the forms tips.)

Event or Item	Form
Adverse Event To be a reportable adverse event, an incident must meet the three criteria described below. If one or more of these criteria do NOT apply, this event does not need to be reported to the IRB. For more information, consult the FDA's "Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs Improving Human Subject Protection." • *Unexpected:* The event is not mentioned in the consent form, investigator brochure, protocol, package insert, or label. OR it is unexpected in its frequency, severity, or specificity. • *Related:* The event was associated with, caused by, or probably caused by a study activity, agent (e.g., device or drug), or procedure. • *Serious:* The event caused harm to participants or others or placed them at increased risk of harm (including physical,	Report Form

Event or Item	Form
psychological, economic, or social harm). However, if your sponsor requires you to submit a report to the IRB, please do so even though it may not meet all three criteria. If this is the case, please state in your description of the event that you are submitting it at the sponsor's request.	
Changes to the Study • Additions to or removal of study personnel (The IRB does not charge a fee for amendments that are solely personnel changes.) • Alterations to or introduction of *information booklets* • Changes in the study population • Consent or assent form changes • HIPAA Authorization revisions • Increases in *enrollment goals* • Investigator Brochure revisions • New or revised *recruiting materials of any sort* (ads, posters, websites, etc.) • Procedural changes • Protocol amendments • Updates to other documents such as Instructions for Use, package inserts, etc.	Amendment Form
Closing or Terminating a Study Note that once you open a Final Report Form, you will not be able to create any other forms for a study.	Final Report Form
Continuing Approval for the Study	Continuing Review Form
Deviations or Violations of the Protocol Significant protocol deviations or violations must be reported to the IRB within 10 working days of the occurrence. Significant deviations or violations are those that (1) affect the rights, safety, or welfare of study subjects; (2) change the risk/benefit ratio; (3) affect the scientific design of the study; or (4) violate an ethical principle. Non-significant deviations or violations may be reported to the IRB at the time of continuing review. For more information, consult the "Study Deviations, Violations and Exceptions" section of Allina's Institutional Review Boards (IRB) Policies and Procedures Manual. Note that investigator-initiated studies also must comply with the protocol deviation reporting policy.	Deviation Form
Requests for Compassionate Use	Miscellaneous Form

Event or Item	Form
Sponsor Communications • Annual Progress Reports • DSMB Reports • Sponsor communications such as emails or letters regarding enrollment holds	Miscellaneous Form
Unanticipated Problems	Report Form

Emails

eProtocol automatically generates emails to alert users to changes in the status of a study. These emails are **not** considered the official notifications of IRB approvals; they simply notify users that they should log into the system to access information regarding the study.

FAQs Regarding System Emails

Who receives emails?
Anyone named in the Personnel Information section will receive study emails with the exception of those listed under "Other Personnel." If someone is receiving system emails and does not need to, you may move that person to "Other Personnel" (with the exception of the PI).

I'm not receiving emails for a study, but I think I should be. What's wrong?
- Have you signed a user agreement? To receive system emails, you must be an active user; to be activated, you must sign a user agreement.
- Are you listed in the "Other Personnel" section of the Personnel Information? If you are, you will not receive emails for the study.
- Has your email address changed? If it has, it needs to be updated in each individual study on which you are named. (This change must be submitted on an Amendment Form under "Other Change.")
- If none of these situations apply to you, contact the IRB Administrative Office so that we can let the vendor know about your problem.

How do I know what an approval email is for?
The IRB Office has recently made changes to the subject line and content of the emails to name the form that has been submitted. But if you have submitted multiple Miscellaneous Forms, Deviation Forms or Report Forms, you will still need to log in to eProtocol and access the Event History to determine which form was approved.

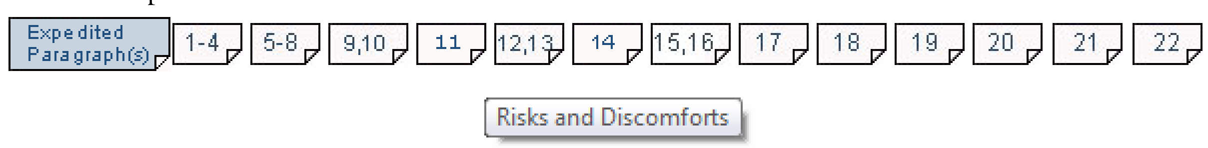
Finding IRB-Approved Documents

IRB-approved consent and assent forms will always appear under the heading "IRB Office Document(s)" in Section 22 of the Protocol Information. Please do not delete any documents from this heading; they are essential to maintain the history of the protocol. But if multiple versions of the approved consent form(s) appear, always use the most recently approved document.

Note: The IRB requires that subjects sign copies of consent forms that bear the IRB's approval stamp.

Navigating in eProtocol

- As a general rule, eProtocol works best when you are using Mozilla Firefox as your browser. Check with your IT department if you are unsure whether or not you can download it. (It's free to download; simply google "Firefox.")
- Don't wait more than a minute for pages or pop-ups to load. If the system is responding slowly, close the window ("X" out of it); then try again.
- When completing the Amendment or Continuing Review Form, don't click the "Next" arrows. If you need to make changes to a certain section (e.g., the Personnel Information" section), use the left navigation bar instead.
- Avoid using your browser's navigation arrows; rely on the system's navigation.
- The easiest way to navigate in the Protocol Information section is to click the numbered page icons that appear at the top of the page. By hovering your cursor over the icon, you can see a short description of the contents.



- Use the "Search Protocol" feature for a fast way to view the forms you've submitted for a study.

Printing Forms in Internet Explorer

If you are unable to print forms while using Internet Explorer as your browser, follow these steps:

- Open Internet Explorer.
- Click "Tools" at the top of the screen.
- Click "Internet Options" at the bottom of the drop-down menu.
- Click the "Security" tab on the pop-up.
- Click the "Custom level" button at the bottom of the pop-up.
- Scroll down through the alphabetical listing to "Downloads"--about a third of the way down the list.
- Under the heading "Automatic prompting for file downloads," click "Enable."
- Click "OK" at the bottom of the pop-up page.
- Then click "OK" again at the bottom of the "Internet Options" pop-up.
- Close out of Internet Explorer.
- Restart Internet Explorer, and access the document.

Responding to the IRB's Comments

The IRB communicates its stipulations through the Comments feature in eProtocol.

- On your Home Page, click the link under "Protocol Event" in the row of the study you wish to access. (The link is called "Comments Received (Cycle X)" or "Comments Sent (Cycle X)."
- The IRB's Comments will appear.
- Enter any responses to the comments that you wish to make.
- Important: Access the section of the protocol affected by the comment and make the appropriate changes there as well.
- Access the Comments when all the requested revisions are complete.
- Then click the "Submit to IRB" button at the top of the page.
- Click "Yes" when the pop-up appears.
- A message will appear, stating that the form and your responses have been submitted to the IRB, and you will be redirected to the Home Page.

Using the Event History Feature

From the Event History (accessed by clicking the last button in the left navigation bar), you can see the entire history of the protocol. All underlined words are links.

Event History

Date	Status	View Attachments	Letters
05/08/2009	PROTOCOL CREATED		
05/08/2009	SUBMITTED	View Attachments	
05/08/2009	PANEL ASSIGNED		
05/08/2009	APPROVED		
12/28/2009	AMENDMENT FORM CREATED		
12/30/2009	SUBMITTED	View Attachments	
01/05/2010	APPROVED	View Attachments	Approval Letter
01/11/2010	AMENDMENT FORM CREATED		
01/12/2010	SUBMITTED	View Attachments	
01/18/2010	REVIEWER(S) ASSIGNED		
02/03/2010	SUBMITTED (CYCLE 1)	View Attachments	
02/12/2010	SUBMITTED (CYCLE 2)	View Attachments	
02/26/2010	APPROVED	View Attachments	Approval Letter
03/01/2010	CONTINUING REVIEW FORM CREATED		
03/01/2010	SUBMITTED	View Attachments	
03/16/2010	REVIEWER(S) ASSIGNED		
03/30/2010	APPROVED		Approval Letter

- To view the form itself (e.g., an Amendment), click either “SUBMITTED” or “APPROVED” in the “Status” column.
- Attachments submitted or approved with the form may be accessed through the “View Attachments” links.
- Approval letters for new studies, Amendments, and Continuing Reviews are generated by the system and accessible by clicking the link in the fourth column. (Note: The example above is from a migrated study; therefore, it has no letter for the first approval listed in the system.)

Quick Tips to Avoid Stips & Save Time

General Tips

- Avoid using non-standard abbreviations in your responses to questions on the forms or in naming documents.
- Avoid submitting documents that are password protected. Passwords complicate matters for the reviewers.
- Double-space between paragraphs in your responses on the forms to make the print view easier to read.
- Every study (both new and migrated) must have a PI Assurance attached in Section 22. Always attach a copy of the PI Assurance to new studies and the first Amendment or Continuing Review Form submitted for a migrated study.
- Notify the IRB of any changes to email addresses so that we can change the user management on our end. Note, however, that each individual study on which the person is named will require a separate update.
- Pay special attention to the names you give attachments. If you include a date in the file name, please make sure it is the same as the date on the document.
- System emails are not sent to non-users; so if a researcher has not submitted a user agreement, he or she will not receive continuing review reminders or other system-generated emails.
- When you inquire about an issue with eProtocol, always be ready to reference the Protocol ID number.

Consent Forms

- Changes to consent forms should be shown using the track changes feature in Word. (PDFs of consent forms will not be accepted.) To access track changes . . .
  - In Word 2003, go to "Tools"; then click "Track Changes."
  - In Word 2007, click "Review" then "Track Changes."
- Double-check "clean" copies of the consent form to ensure that you have accepted all the changes and deleted the IRB's comments, if you are working from the version with the IRB's comments. (To delete comments, right-click on the comment in the margin, and select the "Delete Comment.")
- Note: When the IRB approves a consent form, the study number is added to the header in the upper right corner and the approval stamp to the signature page. Sometimes it is necessary to adjust the spacing or to move the signature lines to a separate page to accommodate the stamp.

Forms

- Proofread your responses. Don't rely on the spell check feature in eProtocol to catch your errors. (This applies even to information you cut and paste from another document. Symbols sometimes transfer in their HTML tags. To ensure that the responses are clear, proofread them.)

- Most stipulations on forms result from a lack of detail in responses.
- Follow these tips for specific forms.
  - Amendment Form
    - Always provide a summary description of the change in the appropriate fields. Whenever a protocol amendment or other change impacts your local site, explain the local context to facilitate the IRB's review.
    - Unless you are submitting a protocol amendment, you should not respond to the question concerning the risk level of the proposed change(s). Do not select any of the radio buttons, for example, if you are requesting an increased enrollment goal.
    - Similarly, do not respond to the question concerning the reconsenting of subjects unless you are proposing changes to the consent form.
    - Provide a description of every item attached for the amendment. (Items attached without any explanation will be returned to you.)
  - Continuing Review Form
    - Enrollment numbers apply to chart reviews as well as interventions or other types of studies. Keep and enter accurate counts of the number of records accessed for a study.
    - "N/A" is not an appropriate response to Item (a) regarding the study's progress. Essentially, you need to summarize what the research team has accomplished on the study since the past continuing review and justify why the study should remain open.
    - The section concerning "Study Trends" requires a *summary* of various events that have occurred since the last continuing review. Avoid simply listing the non-serious adverse events, protocol deviations, etc. that have occurred.
  - Final Report Form
    - In order to submit the Final Report Form, all five questions must be answered "Yes." If the study is being terminated, "yes" responses will not apply. Explain the correct answers in response to the last item on the form.
    - In general, most stipulations on Final Reports involve a lack of detail in response to the final question regarding the study's findings. Although it isn't necessary to write several paragraphs, you should describe two or three of the study's key results or the site's experience conducting the trial.
  - Miscellaneous Form

    Only items for the Board's reference (e.g., annual reports, DSMB reports, sponsor communications regarding enrollment closures, etc.) may be submitted using a Miscellaneous Form. Any item that represents a change to the study (e.g., revised patient information booklets, recruitment materials, Investigator's Brochures, etc.) must be submitted on an Amendment Form.

- Protocol Deviation Form
  - The system automatically enters the study number in the "Identified By" field. Please delete this and enter the name of the person who identified the deviation. (We will be changing this in future updates to the system.)
  - Thorough descriptions of the event and the corrective action plan (items *a* and *c*) are essential. Because you are familiar with the event, a brief description may appear adequate; but a good approach to writing a thorough explanation is to answer who, what, when, where, how, and why about the incident.
- Report Form
  - The system requires that all three boxes—"Unexpected," "Related," and "Serious"—be checked in order to submit the Report Form. If the event you are reporting does not meet one or more of these criteria, explain why you are submitting the report when you are describing the event (e.g., "The sponsor has requested that we notify the IRB of this event even though it is not unexpected.").
  - Include the subject's ID number in your explanation. (A field for the Subject ID will be added in a future update to the form.)
  - The IRB requires that researchers report subject deaths from any cause. It is not necessary to add a statement concerning this policy to your description of the death, nor is it necessary to explain that the system requires you to check all three boxes to report the death. If the death is unrelated to the study, simply state this in your explanation of the death (e.g., "The subject's death is attributed to disease progression and is not related to the study intervention.").