

Continuing Review Process

Overview:

ProIRB assists you in keeping track of study expiration dates. Think of managing your studies that are due for their continuing review (renewal, annual review, etc.) as a 3-step process.

Step One: Send a letter to the Investigator requesting a Progress or Final Report and place study on agenda

Step Two: Enter a CPA once the Progress or Final Report is received

Step Three: Post the IRB Meeting Action

A Quick Step Summary is followed by more detailed instructions. Images referenced as Figure 1, etc. are included at the end of the instructions.

Quick Step Summary:

Step One: When ready to check for study expiration dates and then decide which meeting date agenda to assign them to, *click* the **Due for Continuing Review** button on the Main Menu.

- a. *Highlight* the particular meeting date for which you are preparing an agenda.
- b. Each study you choose must be placed on the agenda one at a time. To do so, move the cursor over the small gray box to the left of the row until it turns into a right-facing arrow; then *click* to highlight the entire row.
- c. *Click* the **Place on Agenda and Print Letter** button. *Select* the meeting date on which you want to place the study (if other than the one that is already highlighted). *Click* **OK** to dialog box message.
- d. Use the Letter Manager to prepare and send a letter requesting a Progress or Final Report. *Click* the **Send/Print** button to print out letter (and record to the database that a letter was created).
- e. *Click* the **Return** button to return to the Studies Due for Renewal screen. Notice the information that has now been entered for you by ProIRB.

Step Two: When you later receive the Progress or Final Report, enter a Change in Procedure (CPA) and assign it to the same meeting date agenda on which you placed the study for continuing review in Step One above.

- a. If expediting the renewal, use the Date of Change box to *enter* the actual date you are expediting the Progress or Final Report if you are allowing it to be expedited prior to the full Board meeting date. In this manner, when you post the IRB Meeting Action via Main Menu / Post IRB Meeting Actions button, the new Expiration Date will then be recalculated from the date entered in this box rather than the meeting date itself.
- b. Also, if expediting the renewal, *place* a check mark in the box labeled "Expedite" (blue color).

Step Three: After the Board meeting, *click* the **Post IRB Meeting Actions** button from the Main Menu. *Select* the appropriate Meeting Date / *click* **OK**.

- a. Post an **Action Taken** for each Renewal item on the agenda by *selecting* the most appropriate action from the list, "Approved", "Renewed", "Closed to Enrollment", or "Expedited", depending upon your Board's preference. Notice that the Expiration Date is recalculated based on the meeting date if a "standard" Renewal, but based upon the date entered in the CPA's Date of Change box if an "expedited" Renewal.
- b. The study will now be placed in the list of rows in the Studies Due for Renewal screen with the newly calculated Expiration Date, ready for the whole renewal process to again be completed at its next continuing review cycle.

More detailed instructions start below.

Step One: Send Letter And Place Study On Agenda:

1. To display studies due for continuing review, *click* the **Due for Continuing Review** button on the Main

Menu.

The Studies Due for Renewal screen is displayed (see Page 5, Figure 1), presenting a list of all scheduled meeting dates for the IRB at the top of screen. *Selecting (highlighting)* a meeting date will cause ProIRB to search the database and list, row by row, all of those studies that are due for renewal (that are due to expire) on or before the selected meeting date **plus** those studies due to expire up to **one day** prior to the **next** meeting date. This is to assure that you place studies on the **selected** meeting date's agenda (or any other meeting date you choose) so that your Board reviews those studies before they expire.

For example, say you have a 2/19/03 meeting date and the next meeting date is on 3/19/03. With the 2/19/03 meeting date highlighted, you notice a study in the list that is due to expire on 3/18/03 (one day prior to the 3/19/03 date). You will want to make sure that you place that study on no later than the 2/19/03 meeting date agenda or it will have expired by the time the Board meets again on the 3/19/03 date. In this manner, you can prepare for and assign studies to be seen on a particular meeting date's agenda (and also send a letter to the Investigator) any number of months in **advance** that you want to. (Occasionally, a study's expiration date will fall exactly on the next meeting date following the one you have highlighted. Select that next meeting date just to assure you don't miss a study that needs to be seen at an earlier meeting before it expires).

TIP: Remember, ProIRB calculates a study's expiration date based on the Renewal Cycle. Since you can assign a study due for continuing review to any meeting date agenda you choose, we strongly suggest you keep a study's Renewal Cycle at 12 months on the Study Input and Edit form unless your Board truly does want to review a study more frequently and have its expiration date changed accordingly.

TIP: You cannot type dates or place check marks in any of the columns on this screen. ProIRB enters this information for you.

TIP: *Click* the **Renewal Listing** button to produce a summary-type report that can be printed and/or used for planning purposes.

2. To place a study that is due for continuing review on a meeting date's agenda:

- a. *Highlight* the particular meeting date for which you are preparing an agenda.
- b. Row by row, look for those studies that have no date showing in the On Agenda column.

TIP: *Check* the box labeled "Check to show only those Studies not already on an Agenda" to limit the studies displayed to those that are due (or past due) for renewal and have not yet been placed on an agenda. This reduces the clutter and allows viewing only those items that need attending.

- c. Each study must be placed on the agenda one at a time. To do so, move the cursor over the small gray box to the left of the row until it turns into a right-facing arrow; then *click* to highlight the entire row.
- d. *Click* the **Place on Agenda and Print Letter** button. *Select* the meeting date on which you want to place the study (if other than the one that is already highlighted). A dialog box will prompt you that "Study #...has been assigned to the meeting date you just selected". *Click* **OK**.

TIP: If you want to place the study on an agenda, but not send a letter, click the **Place on Agenda Only** button.

TROUBLESHOOT: If you later realize that you selected a meeting date in error, you will have to *click* the **Preliminary Agenda Items** button from the Main Menu, *highlight* the row with that Renewal item, then *click* the **Delete Agenda Item** button (only the Administrator can perform this delete operation). Then start over with step 2 to place on the correct meeting date.

3. The Letter Manager now displays, ready for you to prepare and send the standard ProIRB® letter named Continuing Review Notice (see Page 6, Figure 2). (NOTE: If you had created a letter template(s), the Which Template to Use?? screen would first appear for you to choose a specific template before the Letter Manager displays).

- a. The Response Required box is checked by default to indicate that you will be looking for a response to the letter you will be sending (in this case, receipt of a Progress or Final Report).
- b. The dates showing in the boxes next to the Response Required check box serve as prompts for when you expect to get the response you want. You can *fill in* or *change* these dates to suit your needs.
- c. You may also *change* the Letter Date if you would like a different date to print on the letter.
- d. Check the box to whom you are going to send the letter (usually the PI box).
- e. Click **Send/Print** button. Click **OK** to dialog box stating, "An Entry has been made to the Follow-up Manager".

TIP: You can always *click* the **Preview** button first to see how the letter will appear and even print it from preview by *clicking* **File menu**, then **Print**. However, if you print from preview, be aware that ProIRB will not record into the database the fact that you printed the letter. Only through using the Send/Print button is the letter recorded to the Follow Up Manager.

TROUBLESHOOT: Only if using the standard ProIRB letter, change the top (and only the top) margin of the letter to accommodate letterhead stationery while in Preview mode by *clicking* **File menu / Page Setup**. The setting will be remembered for future Continuing Review Notice letters. Remember, the wording in the body and closing of this letter can be modified via **Administration / Codes and Tables / Letter Wording and Letter Closings** buttons.

4. Click the **Return** button to return to the Studies Due for Renewal screen. Notice the information that has now been entered for you by ProIRB:
 - a. The meeting date to which you assigned the continuing review is in the "On Agenda" column.
 - b. A check mark is in the "Letter?" column to indicate that a letter was printed.
 - c. The date of the letter you just printed is in the "Sent" column.
5. If at this time you wish to view how a continuing review you entered appears on the agenda:
 - a. Click the **Return** button in the Studies Due for Renewal screen to return to the Main Menu.
 - b. Click the **Preliminary Agenda Items** button / *select* the meeting date in question / *click* the **Prepare Agenda** button / *click* your preference, then, as to **Preview Small** or **Large Fonts** button.
 - c. Each continuing review is placed in the RENEWAL section of the agenda. Notice the words "No Progress Report" after Reason on Agenda.

Step Two: Enter A CPA Once Progress Or Final Report Is Received:

1. When you receive a Progress or Final Report, enter a Change in Procedure (CPA) on the agenda. To do so, *open* the appropriate study (you are in the Study Input and Edit form) / *click* **View or Add CPAs** button / *click* **Yes** to "Do you wish to ADD a new CPA?" dialog box if previous CPAs have already been entered for this study.
2. Information to *enter* into the CPA screen, if **not expedited**:
 - a. Date Received.
 - b. Date of Change – think of as an "effective date" or "date that the change occurred" (hopefully found somewhere on the paper document from which you are getting the information to enter here). Could be the same as Date Received.
 - c. *Highlight* "Progress Report" (or "Final Report", if applicable) in the Type of Change box.
 - d. Although not required, you may *type* into the Other 1 box any additional information about the Report that you choose to enter and have appear on the agenda. The Other 2 box can be used for even more information, but this information will **not** appear on the agenda.
 - e. *Place* a check in the Signed box and *enter* Date Signed (by PI), if you wish, as simply further information.
 - f. The Place on Meeting Agenda (in red color) box should already be pre-checked, but look to make sure.
 - g. Click the **Save Data** button.
 - h. *Select* the same meeting date to which you assigned the continuing review.

- i. Click **OK** to dialog box reminding you to which meeting date the study is assigned / click **OK** to "Data Saved".
- j. **IMPORTANT:** Before clicking OK to dialog box "Please record the following CPA Internal# to your document...", write that Internal# on your paper document (Report) that will be filed. This is an important feature of ProIRB that serves for cross-reference and internal auditing purposes.
- k. The Follow-Up Letter Maintenance screen displays (see Page 6, Figure 3). If more than one letter is listed in this screen, find the one you are specifically looking for. Place a check mark in the "Rec'd?" column. Today's date will be automatically entered, but you can *highlight* the date and type in another if needed. Completing this screen indicates your receipt of the Progress or Final Report in response to the letter you sent under **Step One: # 3** above. Think of it as "closing out the loop" for the Continuing Review Notice letter that was recorded to the Follow up Manager. Click the **Return** button.
- l. NOTE: The CPA Number (Internal#) has been entered for you; the For Meeting Date box now has an entry for the date of the agenda to which you assigned the Report; and a change in color to light turquoise has occurred to the words "New Change in Procedure" to indicate you have just entered this new CPA.
- m. From this screen, you may click the **Return** button to get back to the Main Menu or click the **Add New CPA** button if you have other types of CPAs to enter for this specific study.
- n. If you were to now check how this item appears on the agenda, you would see that the words "No Progress Report" have been replaced with the words "Progress Report" after Reason on Agenda within the RENEWAL section.

TIP: If, prior to an IRB meeting date, you haven't received the Progress or Final Report you were expecting, you may consider keeping the continuing review on the agenda just so the Board can see that a Report has not been received (for the record, so to speak). You can then table the continuing review item to another meeting date until you do receive the Report.

TIP: In ProIRB, the word Report (as in Progress Report) is associated with **annual** continuing reviews. If your board wishes to review a study more frequently (let's say quarterly) and requests a "Progress Report" each quarter, make the following changes: From Main Menu, click **Administration** button / Codes and Tables / click **CPA Types** button. In the CPA Type column, add a type named Quarterly Review, or Interim Review, or (your choice) – anything that doesn't include the word "Report". In the Category column, choose Procedure and make sure a check mark is placed in the Agenda? column. Now, if you enter a CPA for a review, other than the one for an annual "Progress Report", ProIRB will not recalculate the Expiration Date at this time.

- 3. Information to enter into the CPA screen, if **expedited** (differences from those above in **Step Two: #2**):
 - a. Use the Date of Change box to enter the actual date you are expediting the Progress or Final Report if you are allowing it to be expedited prior to the full Board meeting date. In this manner, when you post the IRB Meeting Action via Main Menu / Post IRB Meeting Actions button, the new Expiration Date will then be recalculated from the date entered in this box rather than the meeting date itself.
 - b. Place check mark in the box labeled "Expedite" (blue color).
 - c. In addition to *highlighting* Progress or Final Report under Type of Change, you may also choose to *highlight* either "Expedited" or Expedited Approval" in the Pre-Meeting Action Taken box if this isn't too much redundant information for you on the agenda.
 - d. If you now click the **Preliminary Agenda Items** button from the Main Menu, notice a check mark has been placed in the EXP column to indicate the Progress Report (Renewal) was expedited.
 - e. If you then click **Prepare Agenda** button to see how this item appears on the agenda, you will see it under the EXPEDITED section (rather than the RENEWAL section). Reason on Agenda will read "Renewal – Progress Report" and Agenda Details will show the Expedited Date (taken from the date you entered in the Date of Change box in the CPA screen). If you had also selected "Expedited" or "Expedited Approval" in the Pre-Meeting Action Taken box, that wording would also show after the word Action on the same line.

TIP: Remember, if you have entered both expedited **and** non-expedited items for any one study, the expedited item(s) will not now appear in the EXPEDITED section of the Agenda, but will be grouped together in the highest hierarchy section for the non-expedited item(s). For example, if

you had expedited a Progress Report (Renewal), it would appear in the EXPEDITED section of the Agenda. However, if you had also entered an SAE for the same study, both items will now appear under the ADVERSE EVENT section of the Agenda.

Step Three: Post the IRB Meeting Action:

1. Click the **Post IRB Meeting Actions** button from the Main Menu. *Select* the appropriate Meeting Date / *click* **OK**.

The Agenda Item Detail screen is displayed. The left side of the lower half of the screen under the heading Reason Study is on Agenda contains **all** the items that were on that meeting date agenda. *Click* the **Previous** and **Next Record** buttons to navigate through each item until you come to one with Agenda Category of Renewal. If you had expedited the renewal, note that the wording appears somewhat differently - Agenda Category will display "Expedited" and the Reason 1 box displays "Renewal". The right side of the screen under the heading IRB Meeting Action is where you "post" or enter information about each Renewal item (just as you do for every other type of item on the agenda).

2. Posting an Action Taken for each Renewal item on the agenda.

- a. *Select* the most appropriate action from the list, "Approved", "Renewed", "Closed to Enrollment", or "Expedited", depending upon your Board's preference. Notice that the Expiration Date is recalculated based on the meeting date if a "standard" Renewal, but based upon the date entered in the CPA's Date of Change box if an "expedited" Renewal.

TROUBLESHOOT: ProIRB will only recalculate The Expiration Date for you if you choose one of the exact action words above. If you want to select some other Action Taken, you must first choose one of these words (or any other IRB Action Code you created through Administration that have the letters "approv" or "renew" as part of the wording) so that the Expiration Date is first recalculated, **then** make your final Action Taken selection.

- b. Just as you would for every type of item on the agenda, fill in whatever information you deem appropriate in the Action Explanation, Discussion, and Vote sections to complete your posting for each Renewal item. *Click* **Save Data** button.
3. The study will now be placed in the list of rows in the Studies Due for Renewal screen with the newly calculated Expiration Date, ready for the whole renewal process to again be completed at its next continuing review cycle.

OTHER TUTORIAL REFERENCES:

Letter Manager
Follow Up Manager

ProIRB[®] IRB Compiled Institution
by ProIRB Plus, Inc.

Studies Due for Renewal at the Meeting

Check to show only those Studies not already on an Agenda

1/15/2003
 2/19/2003
 3/19/2003
 4/16/2003
 5/21/2003

—Report Received—

IRB#:	Protocol:	Expires:	On Agenda	Exp	Letter?	Sent	Final	Progress	
98-0043	RTOG 97-12, A Phase	1/15/2003		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
98-0046	BRN #2001, A Phase	1/15/2003		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
00-0113	S0000, Selenium and	12/18/2002	11/20/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	10/10/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	10/
00-0115	S0007, Evaluation of 3	12/18/2002	11/20/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	11/16/2002	<input type="checkbox"/>	<input type="checkbox"/>	
00-0115	S0007, Evaluation of 3	12/18/2002	11/20/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	10/11/2002	<input type="checkbox"/>	<input type="checkbox"/>	
00-0116	RTOG 99-01, A Phase	12/18/2002	11/20/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	10/11/2002	<input type="checkbox"/>	<input type="checkbox"/>	
00-0117	RTOG 99-13, A Phase	12/18/2002	12/18/2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>	11/16/2002	<input type="checkbox"/>	<input type="checkbox"/>	

Record: 1 of 101

Figure 1

ProIRB[®] Letter Manager Compiled Institution

Letter Continuing Review Notice

Study# 00-0021
On Meeting Date 1/15/2003
Letter Date 12/1/2002

Response Required
Date Required 1/1/2003
 Date to Follow Up 12/25/2002

Addressee

Sponsor Any Company E-MAIL Mail

PI Last Name--3980, Therese MS, RN, E-MAIL Mail

Coordinator E-MAIL Mail

Reviewers E-MAIL Mail

IRB Members Last Name--4013, David E. PhD, CIP E-MAIL Mail
 Last Name--4014, Joan RN E-MAIL Mail
 Last Name--4016, George MMD E-MAIL Mail

Other Contact E-MAIL Mail

CC: Email CCs

Sponsor

PI

Coordinator

All Reviewers

All IRB Members

Add or Delete CCs

Add Comments to Letter

Closing and Signatory

For this Letter Sincerely, Sally IRB Coordinator

Default Sincerely, Sally IRB Coordinator

Figure 2

ProIRB[®]
by ProIRB Plus, Inc.

Follow Up Letter Maintenance

Follow-Up letters for Study #

Complete the Received Check Box and Date for the Letter this CPA applies to.

-----Received-----

	Date Sent:	To:	Letter	FU Rqd	FU Date	Due By	Rec'd?	Date Rec'd
▶	12/15/2002	PI Post	Continuing Review Notice	<input checked="" type="checkbox"/>	12/21/2002	1/5/2003	<input type="checkbox"/>	
	12/15/2002	PI Post	Invoice for IRB Services	<input checked="" type="checkbox"/>	12/21/2002	1/5/2003	<input type="checkbox"/>	

Figure 3