

Customize and Use Standard ProIRB Letters

Overview:

ProIRB is installed with a "standard" collection of letters included. These letters are actually Access reports designed to look as close to an MS Word document as possible. (If you find the standard letters unacceptable, you always have the option to create your own letter templates via our MS Word interface).

The standard letters consist of 3 sections:

The Format
The Wording
The Closing

- The Format of a letter consists of its basic layout and the information that is "passed" or "transferred" to the letter from data you have entered into the Program (e.g., protocol title, approval date, etc.). The user cannot change this section except for the letter's top margin to accommodate letterhead stationery.
- The Wording of a letter consists of the text within the paragraph(s) of the "body" of the letter. This wording will appear in every letter of its type and can be customized by a user within the Administration screen.
- The Closing of the letter consists of the closing word(s) of your choice and the sender's name and title, all of which can be customized by a user within the Administration screen. (NOTE: These are the "default" closings, but you can override the closing information for a specific letter through the Letter Manager. The "override" will remain in effect until you indicate you wish the default closing to be restored.)

If you have more than one IRB, you must first select a specific IRB from the Main Menu before customizing its letter wording and closings following the instructions below. Each IRB, therefore, can have different wording and closings specific for it. If the same letter wording and closings are to be used for all of your IRBs, you must select each IRB one by one and make the changes.

Close any other MS Word documents you may have open and be working on before working with letters in ProIRB. While every attempt has been made to provide accurate instructions, the appearance of screens and dialog boxes and the order in which they appear may vary depending upon the Microsoft Office version and/or email client used.

To Set Up To Use A Standard ProIRB Letter (Instead Of A Letter Template):

- From Main Menu, *click* **Administration** button, then **Template Locations** button under Templates. For any one "type" of letter, you must choose either to use the standard letter for that type or create your own letter template(s) for that type. Make sure the white box to the right of a letter "type" is blank if you wish to use a standard letter. (NOTE: If there **is** a folder path location in the box, *highlight* the path, and then *press* the **Delete** key on your keyboard).
- See Page 3, Figure 1 for an example of a user who has chosen to use the standard ProIRB letter to send Invoice, General, and Consent Deficiency "type" letters because the white box is blank, but create her own template(s) for the remaining "types" because the white box contains a folder path location.

To Customize Letter Wording:

- From Main Menu, *click* **Administration** button, then *click* **Letter Wording** button under Codes and Tables to display the AvailableLetterParagraphs screen (see Page 3, Figure 2).
- Think of each Letter Name as a "type" of letter. Change the preloaded sample text to your preferences for each Letter Name by *clicking* your mouse cursor anywhere in the text area to right of the Letter Name. A

scroll bar and arrows will appear for you to use. Use the Enter key on your keyboard to create new paragraphs.

- **TRICK:** Even better, though, is to *hold down* the Shift key on your keyboard and *press* the F2 key. This enlarges that text area into a Zoom screen to make it easier to work within. However, you will need to hold down the Control key while pressing the Enter key on the keyboard if you wish to create new paragraph(s) while in the Zoom screen. Ignore the Font button. While it may appear you can change font settings, any settings you make will not, in fact, be changed or saved.
- *Click* the **X** in the blue title bar of AvailableLetterParagraphs screen to close out.

To Customize Letter Closings:

- From Main Menu, *click* **Administration** button, then *click* **Letter Closings** button under Codes and Tables to display the MaintainLetterClosings screen (see Page 4, Figure 3).
- *Type* your preferences in the Closing, Sender Name, and Title boxes for each Letter Name type. *Click* the **X** in the blue title bar to close screen.
 - **TIP:** The information given above in To Customize Letter Wording still applies, EXCEPT that scroll arrows will **not** appear. You may still use Shift/F2 to enlarge box, but remember to use Control/Enter to create new paragraph(s).

To Use A Standard Letter:

A standard letter is accessed depending upon what activity or screen correlates with that letter "type".

- *Click* **Send Study Specific Letter** button when in the Study Input and Edit screen.
- *Click* **General Letter Choices** button from Main Menu.
- *Click* **Send Invoice** button when in the Study Input and Edit screen.
- *Click* **Acknowledgment Letter** button when in the Serious Adverse Event screen.
- *Click* **Acknowledgment Letter** button when in the Change in Procedure screen.
- *Click* **Send Correspondence** button when in the Agenda Item Detail screen while entering post-meeting actions.
- *Click* **Consent Checklist** button when in the Study Input and Edit screen, then *click* the **Send Letter** button in the Informed Consent Checklist screen. (NOTE: The Send Letter button is activated only if you had removed a check mark in the Complies? Column for at least one of the items. Otherwise, ProIRB assumes there is no reason for sending a letter if everything is checked and appears to comply.)
- *Click* the **Place on Agenda and Print Letter** button when in the Studies Due for Renewal screen.

When any of the above letters is selected, the Letter Manager displays, with the name appearing for that particular "type" of standard letter, ready for you to prepare the letter for sending.

To Change Top Margin Of Letter:

- *Click* **Preview** button from Letter Manager screen to display how the letter will appear. While in this preview screen *click* **File**, then **Page Setup**, and change the **Top** margin to your preference. Do not change any other margin setting as it may adversely affect how the letter appears. This new Top margin setting will be "remembered" the next time you use this "type" of letter. You will, however, have to separately set each "type" of letter's top margin.

OTHER TUTORIAL REFERENCES:

Letter Templates

Letter Manager

Assign Default Template Locations

ProIRB[®] *by ProIRB Plus, Inc.*

Click the respective button to use your templates

Template Types	Your MS Word Template Locations	
Study Specific Template/Folder	C:\Cc\ProIRB_Dev\Templates\StudyLetters	Use Templates
General Letter Template/Folder		Use Templates
Invoice Template/Folder		Use Templates
SAE Template /Folder	C:\Cc\ProIRB_Dev\Templates\SAELetters	Use Templates
CPA Template/Folder	C:\Cc\ProIRB_Dev\Templates\CPALetters	Use Templates
IRB Action Template/Folder	C:\Cc\ProIRB_Dev\Templates\IRBActionLetters	Use Templates
Consent Deficiency Template/Folder		Use Templates
Continuing Review Template/Folder	C:\Cc\ProIRB_Dev\Templates\ContinuingReviewLetters	Use Templates

Blank out the Path for the Specific Template Type if you wish to use the regular ProIRB (non Template) letter for that specific Letter Type (ie. Continuing Review.)

[Return](#)

Figure 1

AvailableLetterParagraphs	
For IRB = Compiled Institution	
LetterName	Wording
Informed Consent Deficiencies	We have reviewed the Informed Consent you have submitted and have identified the area(s), listed below, where the consent does not meet the standards as set forth by either the FDA or Institutional Review Board of Our Hospital. Please correct and resubmit the Consent form accordingly.
Continuing Review Notice	The records of our Institutional Review Board indicate that the above referenced Study is due for renewal (or closure, if applicable): Please complete the Institutional Review Board Research Progress/Final Report
Invoice for IRB Services	This is to advise you that we have received and are processing your application for initial submission for the above referenced protocol. We are reviewing your completed application including your Informed Consent to make sure it meets our qualifications. In
IRB Action Letter	To advise you that the above referenced Study has been presented to the Institutional Review Board identified above, and the following action taken subject to the conditions and explanation provided below.
CPA Acknowledgment	This is to acknowledge that the Institutional Review Board of Our Hospital is in the receipt of the information identified below and has been reviewed and approved by the expedited method.
SAE Acknowledgment	This letter is to acknowledge that the Institutional Review Board of Our Hospital has received and reviewed the Serious Adverse Event Report identified below. Thank you for keeping the IRB informed.

Figure 2

MaintainLetterClosings			
For IRB = Compiled Institution			
Letter Name	Closing	Sender Name	Title
Informed Consent Deficiencies	Sincerely,	Sally	IRB Coordinator
Continuing Review Notice	Sincerely,	Sally	IRB Coordinator
Invoice for IRB Services	Respectfully yours,	Sally	IRB Coordinator
IRB Action Letter	Sincerely,	Dr. X	Chair, Institutional Review Board
SAE Acknowledgment	Sincerely,	Dr. X	Chair, Institutional Review Board
CPA Acknowledgment	Sincerely,	Dr. X	Chair, Institutional Review Board
Study Specific (comments only)	Sincerely,	Dr. X	Chair, Institutional Review Board
General Letter	Sincerely,	Dr. X, MD	Chair, Institutional Review Board

Figure 3