IRBWISE™

Guide and Handbook

This Manual was developed by IRB Solutions, Inc. and adapted by the Office of Compliance at the University of Puerto Rico Medical Sciences Campus.

Revised 01/2005

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Introduction

Procedure to Request IRB Review for a Research Project

What do I Need?

1. You need to have an e-mail account from the University of Puerto Rico Medical Sciences Campus (student or employee account). If you don't have it, you can request it at the Office for Information Systems in the second floor of the Main Building.
2. If you already have an e-mail account you should fill the attached document titled **IRB WISE ACCOUNT REQUEST PERSONAL INFORMATION** and take it to the Office of Compliance. You will receive a password to access the IRBWise® system within the next ten days.
3. Once you have the password, follow the manual instructions to submit your research proposal.

Note: It is recommended that you take the Human Subjects Training Certificate during this process. You will need to submit copy of your certificate electronically.

What should I include in my electronic submissions?

All documents to the IRB should be submitted electronically through the IRBWise® System. In the submission you should also:

1. Answer all the questions in the IRBWise® System, especially the required ones.
2. Submit your **COMPLETE** proposal.
3. Submit Informed consent documents in Spanish and English (if applicable). An English version of the Informed Consent Document is required if the project received Federal Funding.
4. Assent Forms (for minors, if applicable).
5. Survey Instrument, Questionnaire or data collection forms (if applicable).
6. Human Subjects Training Certificate
7. Curriculum Vitae
8. Advertisements that will be used in the project.
9. If the research project will be conducted in a facility other than the Medical Sciences Campus, a letter of authorization from the other institution is required.
10. If you are requesting a waiver authorization from the IRB you should include an Informative letter to the participants.

Important: If the Principal Investigator is a student the research project must be electronically "signed off" by the Faculty Advisor **AND** the Department Director. If it's a Faculty member, the research project must be electronically "signed off" by the Department Director.

What Documents Should I Submit in an Amendment?

The amendments are considered any changes to the research protocol or the Informed Consent Documents. In the IRB Wise all the following documents should be submitted as amendments:

1. Investigator Brochures
2. Package Inserts
3. Closure Letters
4. Letters to the Participants
5. Informational Documents
6. Advertisements (should be reviewed by the Press Office before submission to IRB).
7. Audit reports or any other sponsor reports
8. Any other document related to the research project.

What Documents Should I Submit in a Continuing Review?

All the Research projects approved by the IRB have an expiration date of one year or less. The continuing review should also be submitted through the IRBWise® System. In the request for continuing review you should submit:

1. English and Spanish Informed Consents and/or Assent Documents that will expire (stamped version).
2. New Informed Consent Documents and/or Assent Documents
3. All documents that needs to be changed or revised since the last approval.

Adverse Events

The following documents should be submitted through through the IRBWise® System:

1. Serious Adverse Events
    a. Off site
    b. On site
2. Adverse Events
    a. Off site
    b. On site

Note: All the Adverse events should be submitted with the attached report of event.

Important: The UR MSC IRB is subject to a meeting calendar and submission deadlines. All the proposals should be submitted by the meeting submission deadline. If your protocol is submitted and signed off after the submission deadline will be considered for the next IRB meeting.

1.0 Overview

Human Subject Investigations

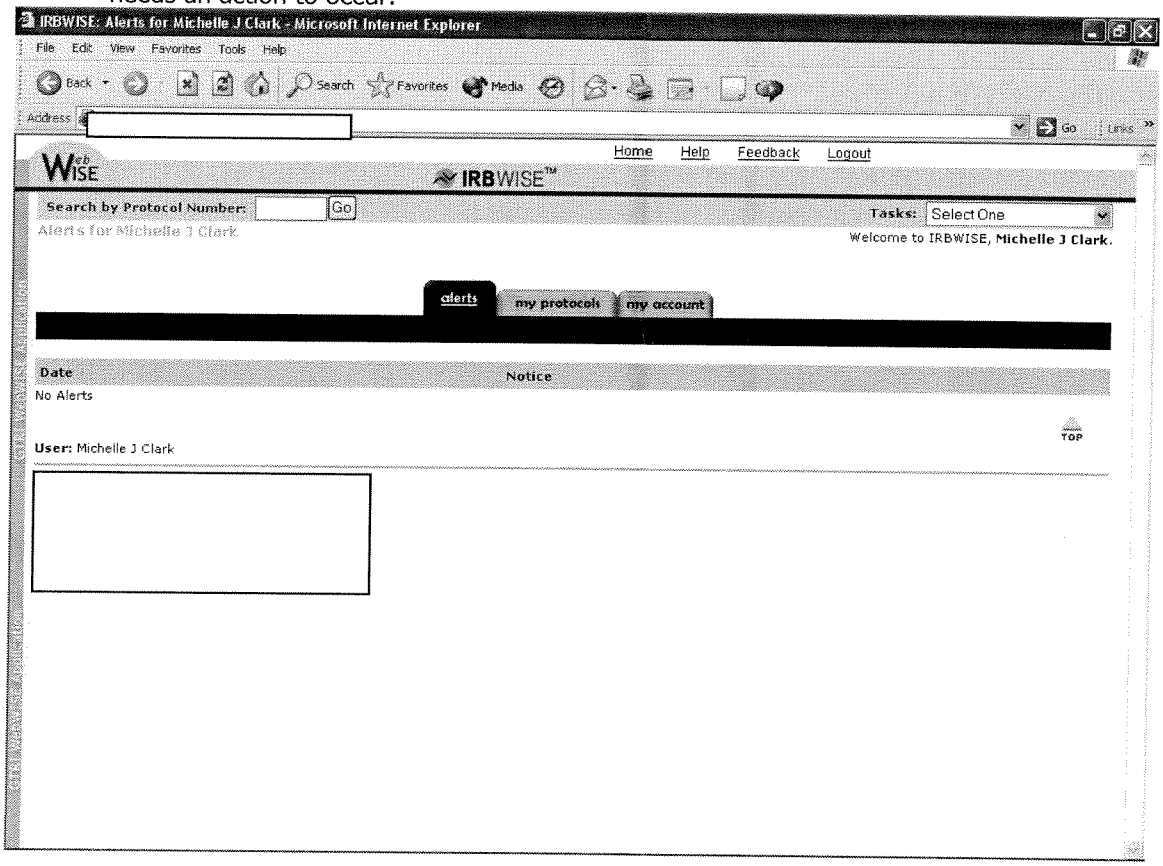
When submitting a protocol to the IRB, use ***IRBWISE***, a new web-enabled Institutional Review Board (IRB) management and tracking system. This system is designed for online submission of human subject investigation applications (protocols), submitting and monitoring continuing reviews and amendments, as well as communicating with the IRB Administrators.

For Investigators and Administrators

1.1 Personalized Home Page

The Alerts section allows for the Office of Research Compliance to directly communicate with researchers about their protocols (i.e., time for continuing review; incomplete application, etc.) The information in the Alerts section will typically need the PI to take some type of action to respond.

An email notification will also be sent to your university email account for an item that needs an action to occur.

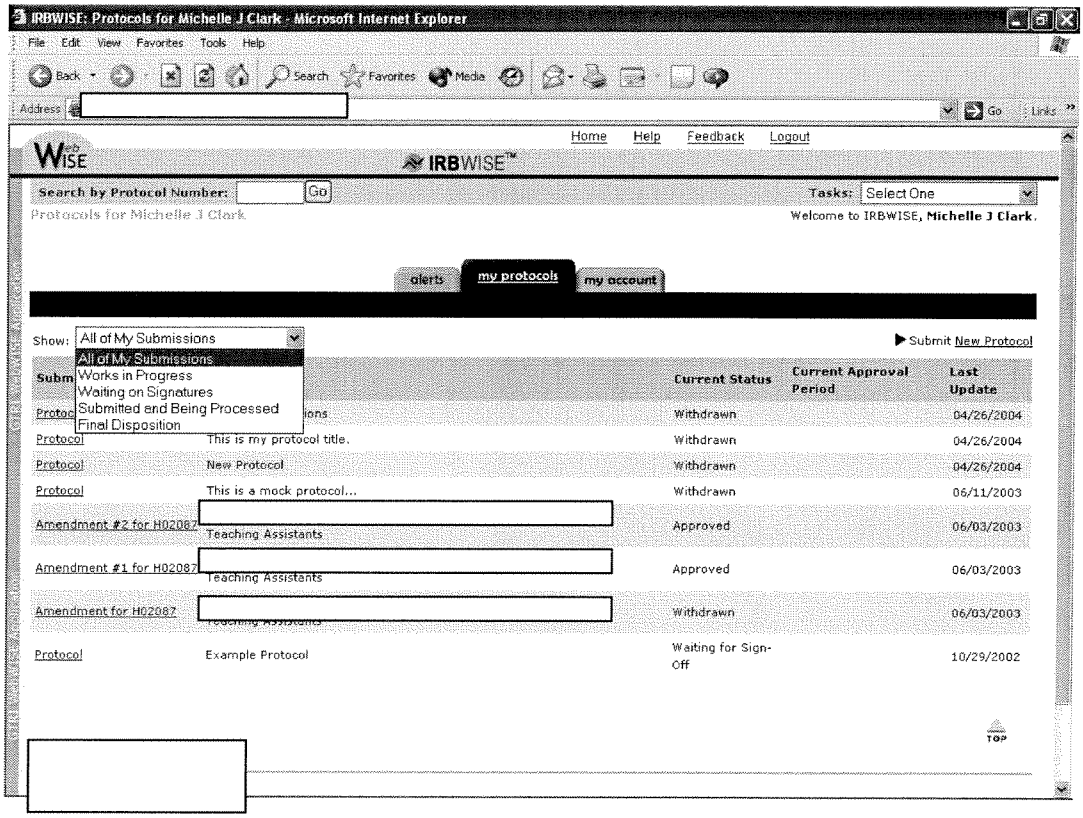


My Protocols contain all protocols of the researcher.

The system allows for the user to sort their protocol submission in multiple ways. You may view (1) All Protocols, (2) works in progress, (3) waiting on signatures, (4)Submitted and Being Processed, and (5) Final Disposition.

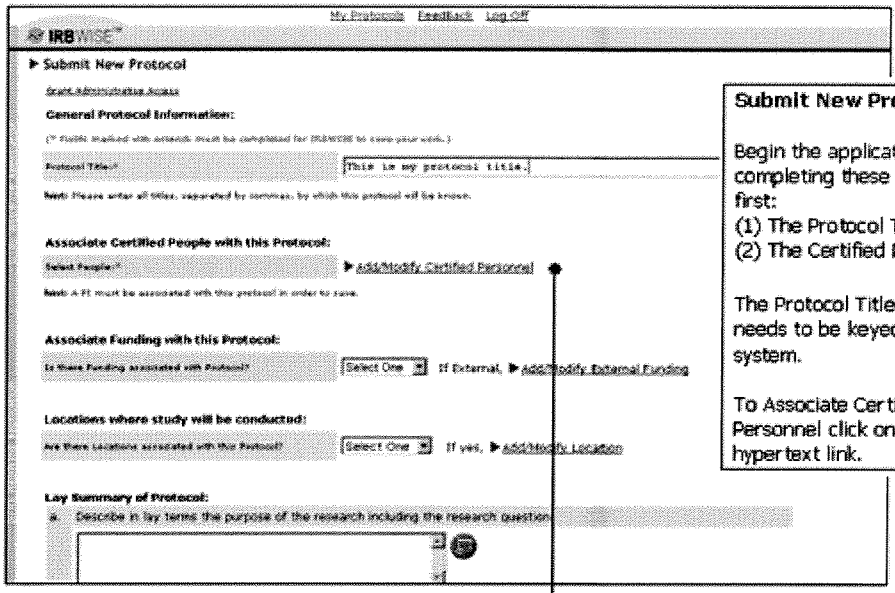
The IRBWise system provides the user with a "snap shot" of each of the protocols including the submission type, approval dates, protocol title and current status.

Note: New protocol applications that have been accepted for processing by the IRB are assigned protocol numbers.



For Investigators

1.2 New Protocol Application



Submit New Protocol:

Begin the application by completing these two items first:
(1) The Protocol Title and
(2) The Certified Personnel.

The Protocol Title simply needs to be keyed into the system.

To Associate Certified Personnel click on the hypertext link.

Associate Personnel:

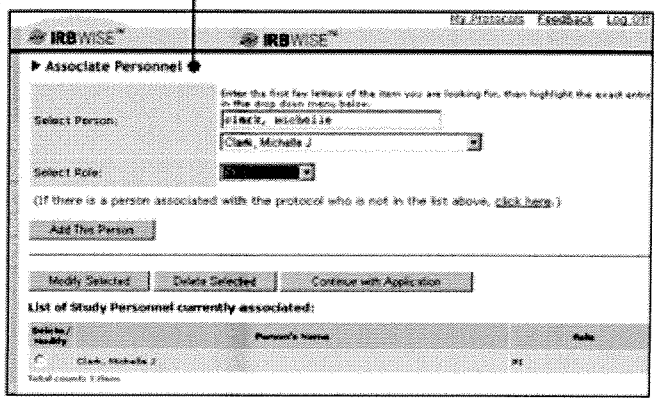
This section is intended to be used for essential personnel working with the protocol.

In the first text box, begin adding a person by keying in the person's last name. Once the person's name appears in the drop down box below, then select the name of the person.

Next Select the Role of the person (PI, CO-PI, etc.)

Then click on the **Add This Person** button.

You'll notice that Michelle Clark has been added as a PI on this protocol.

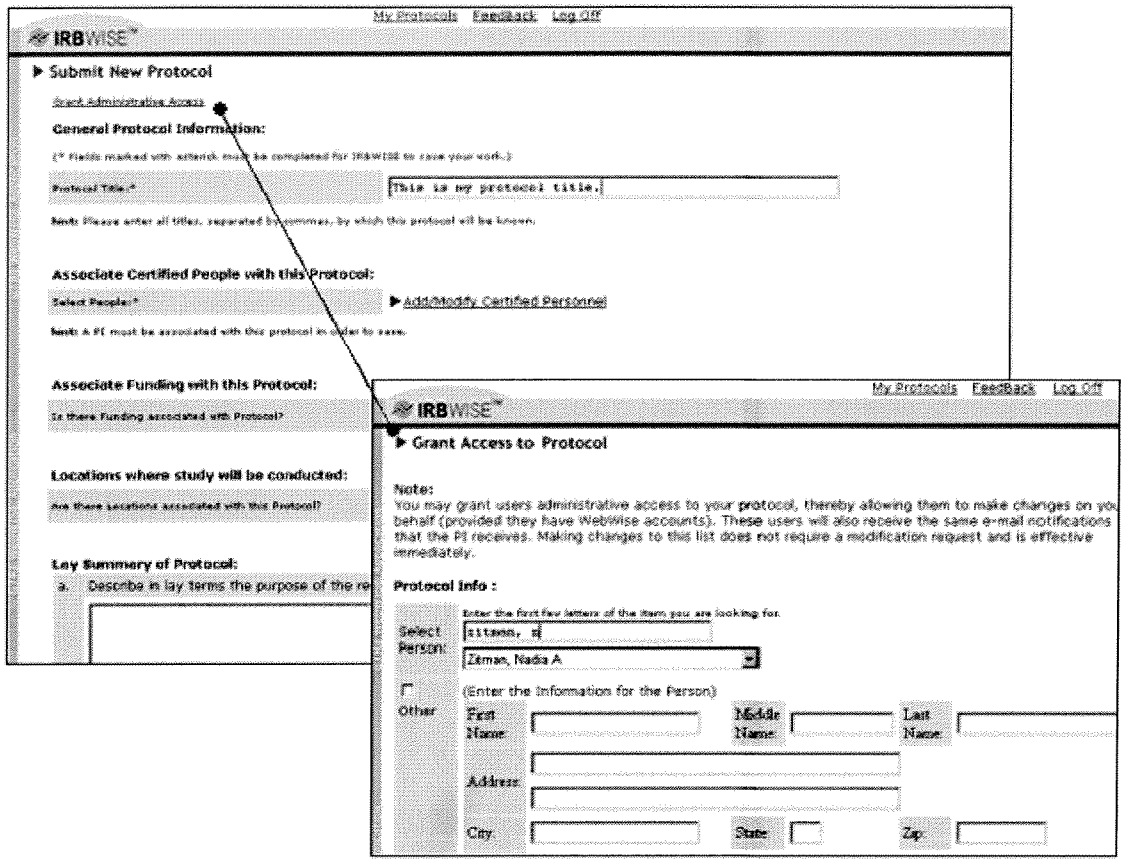


If a person's name does not show up in the drop down menu, you may need to add them to the system. This person must fill the **IRB WISE ACCOUNT REQUEST PERSONAL INFORMATION** and send it to the Office of Compliance. In the account request you will need to submit the following information:

- The person's name
- Organization/ Company
- Phone #
- E-mail Address
- Address
- Proof of completion of Human Subject Training

The individual will be added to the system by the IRB office.

1.2.1 Grant Access to Protocol



Administrative Access may be granted to certain users. The "rights" associated with this access allow these people to receive the same email notifications that the PI receives as well as allowing them to make any changes to the protocol on a PI's behalf. Making any changes to this list does not require a modification request and is effective immediately. Whoever initiates the protocol application is automatically assigned the "Admin Access."

Note: If the PI or CO-PI initiates the protocol application they may want to assign these rights to an administrative assistant. If an administrator initiates an application for a PI then they are automatically assigned administrative access.

To add a person for this role, simply follow the same steps that we used in the previous section (Associate Certified People).

Browser "Reload" Information:

Be sure to click on the "**SAVE**" button before *reloading or refreshing* a new browser page. Data will be lost if you try to refresh the page without saving the data first.

1.2.2 Associate Funding Sources

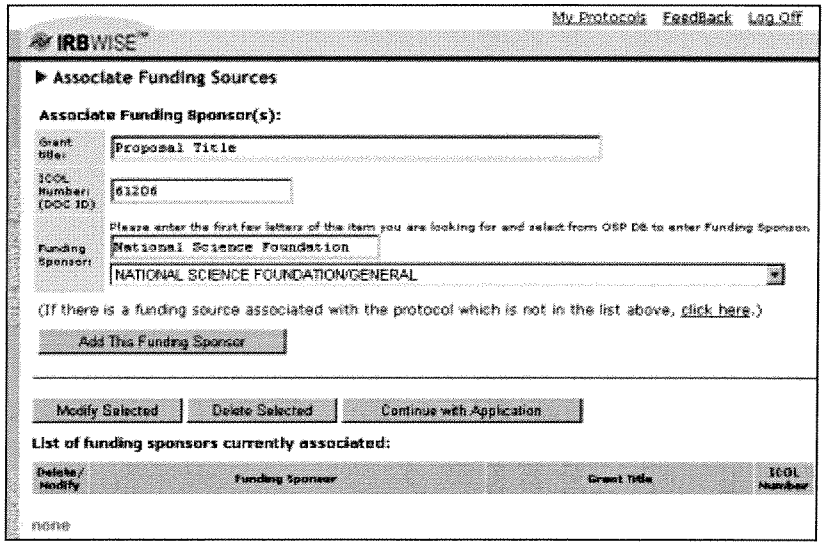
The next application question asks if you have external funding. If you answered YES to the question, the following pop-up window will appear. Please answer the questions as fully as possible.

This window requests information on the external funding agency (sponsor). Typically, the Protocol Title and Grant Title are different; please indicate the title of the Grant as well as the DOC ID number that the Office of Sponsored Programs has assigned to it. It is a requirement for the office to match up proposals with their associated protocols.

The funding sponsor database can be searched by simply typing in the name of the sponsor. Once the sponsor's name appears in the drop down box below, select the name of the sponsor.

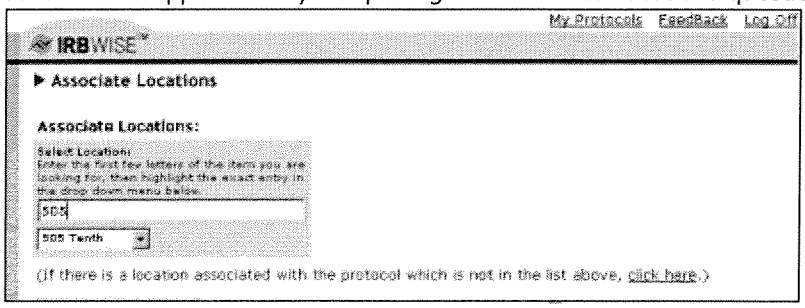
Once that is completed, click on the **Add This Funding Sponsor** button. If the agency does not appear to be in the database, you can add a new funding sponsor.

Click on **Continue with Application** to go back to the main screen.



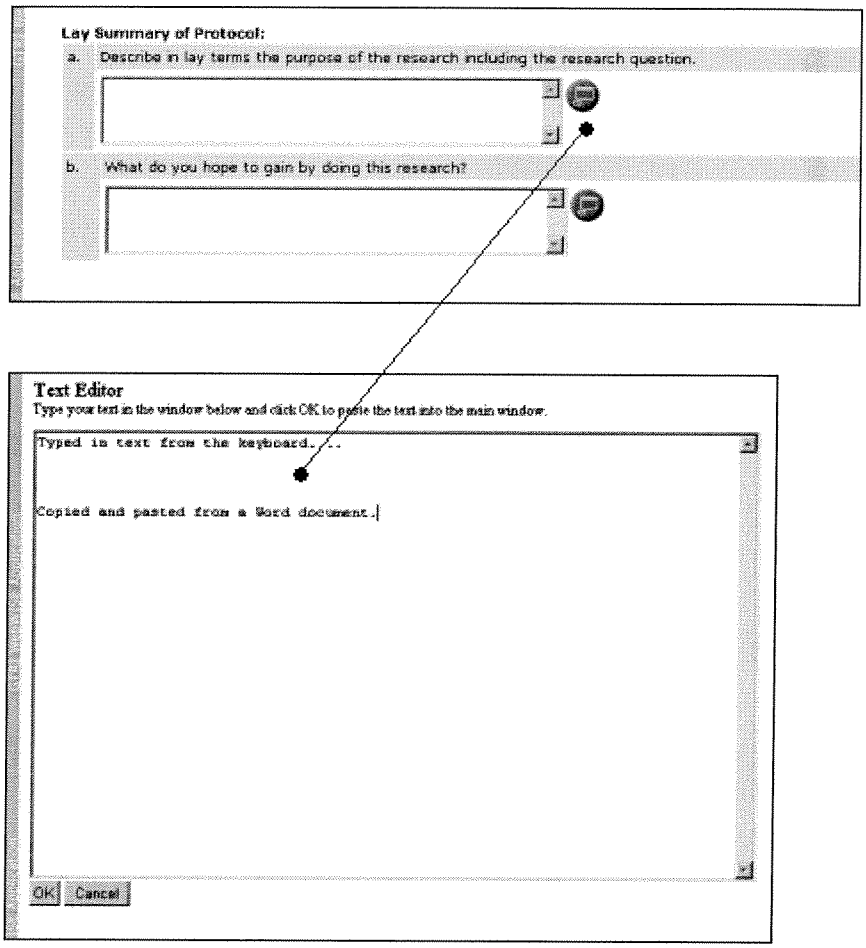
1.2.3 Associate Locations

Continue the application by completing the *Associate Locations* question.

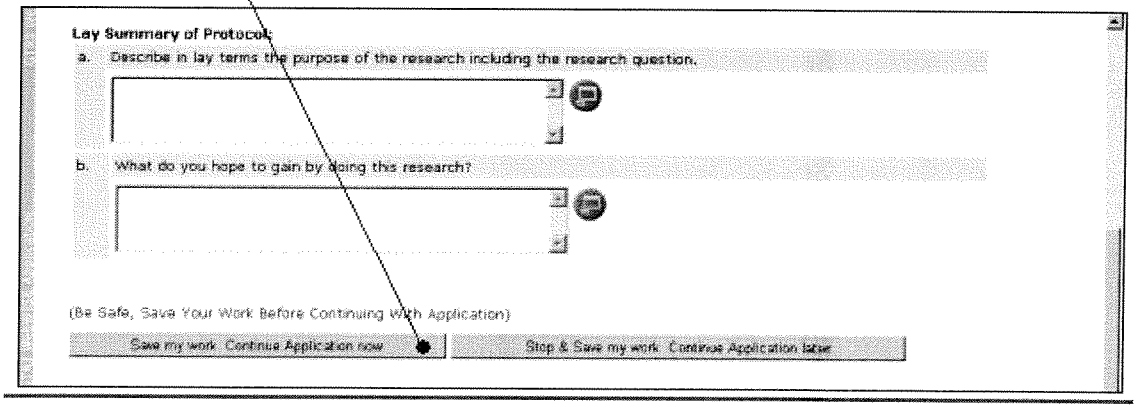


1.2.4 Lay Summary

In this next section, the lay summary of the protocol must be added. You can type directly in the text boxes or you can "copy and paste" the information from a Word/Word Perfect/PDF document. The purple image to the right of the text box opens up a larger text editor that allows you to see more of the text as you are typing. This section can hold up to one page of text.

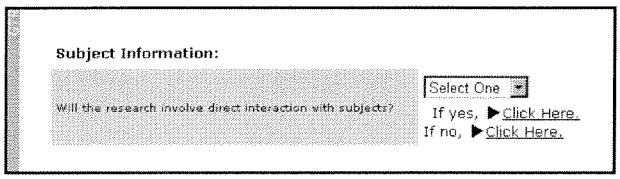


Be sure to **SAVE** your protocol information. You can Save and Continue with the rest of the application – or you can Save and Stop Working on the application (and continue at another time).



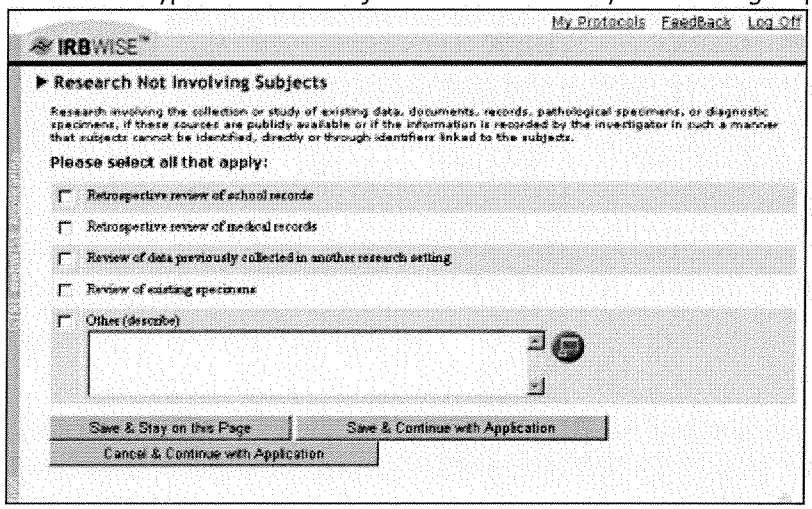
1.2.5 Subject Information

Will the research involve direct interaction with subjects?



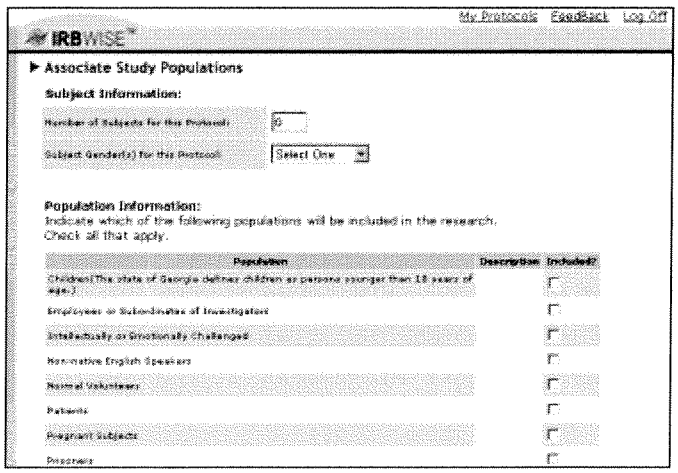
If the answer is NO:

Indicate the type of human subject information that you are using as part of the research.



If the answer is YES:

Explain who the subjects are, how many people are involved in the protocol, the gender of the participants, inclusion/exclusion criteria, recruitment issues, how informed consent will be obtained, and how data will be kept confidential. You will also be asked to indicate what research category best fits your research.



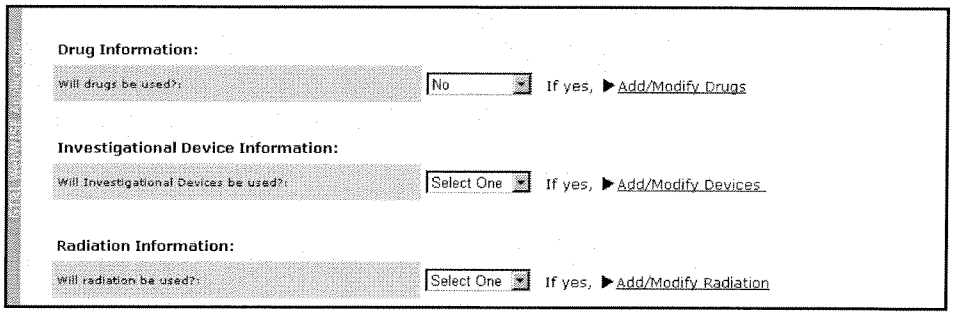
1.2.6 Drug, Investigational Device & Radiation Information

Each of these sections will ask specific questions regarding the research being conducted.

FDA approval is required for Investigational Drug (IND) use. Information regarding the Manufacturer, Generic Name, Trade Name, IND Name, IND Holder (sponsor or PI), as well as any brochures on the Drug needs to be submitted.

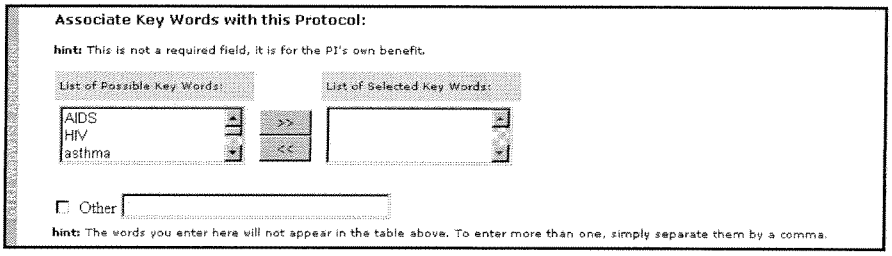
An Investigational Device (IDE) will require similar information to the IND but also requires information on the IDE Category and IDE Risk level.

Research that includes Radiation is required to gain approval from the Radiation Safety Committee and obtain an authorization number.



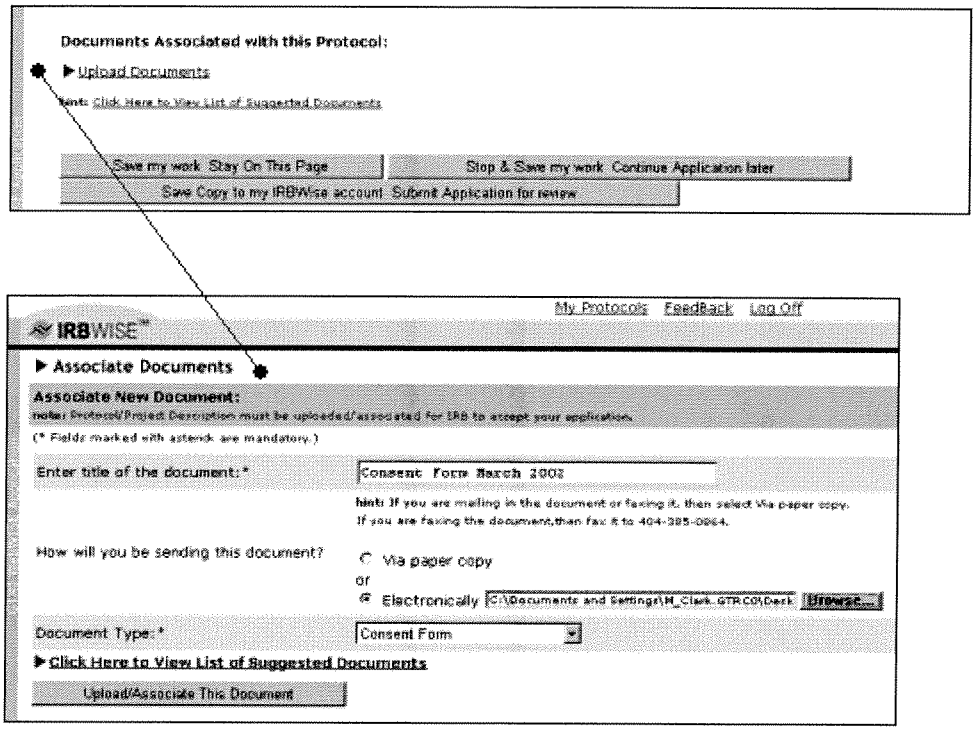
Associate Key Words

This field is not required but is an option given to the PI.



1.2.7 Associate/Upload Documents

Click on the Upload Documents link listed below.



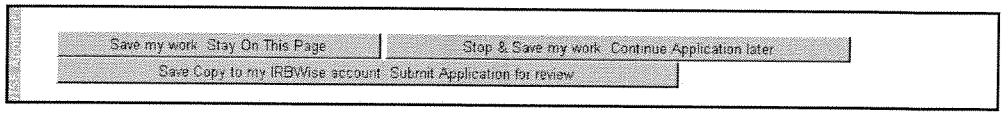
To upload documents

1. Type in the Title of the Document that you want assigned to it (i.e., Consent Form March 2002)
2. Select the method of delivery (if paper copy – send via campus mail or other delivery method, otherwise submit electronically (Word, Word Perfect, or PDF file).
3. Next, select the type of document that you are uploading (Consent Form, Advertisement, Abstract, Project Description, etc.)
4. Then Click on the **Upload This Document** Button.

The system will indicate if the file was uploaded successfully. Continue to upload all files that you want associated with the protocol. Typical documents to be uploaded are as follows, the Abstract, Survey Instrument, Advertisements, Consent, Inclusion/Exclusion Criteria (for subject enrollment), and the Proposal Project Description.

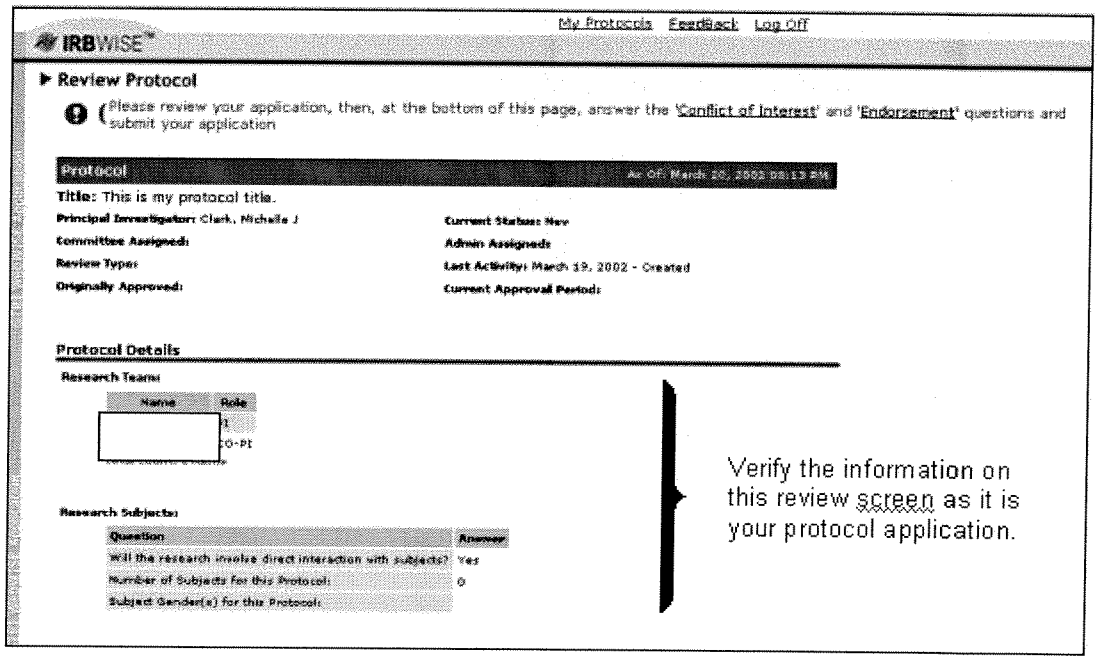
Note: If submitting something to the IRB via paper copy, it is important to still upload the information indicating that the information will be sent to the IRB.

Save Application:



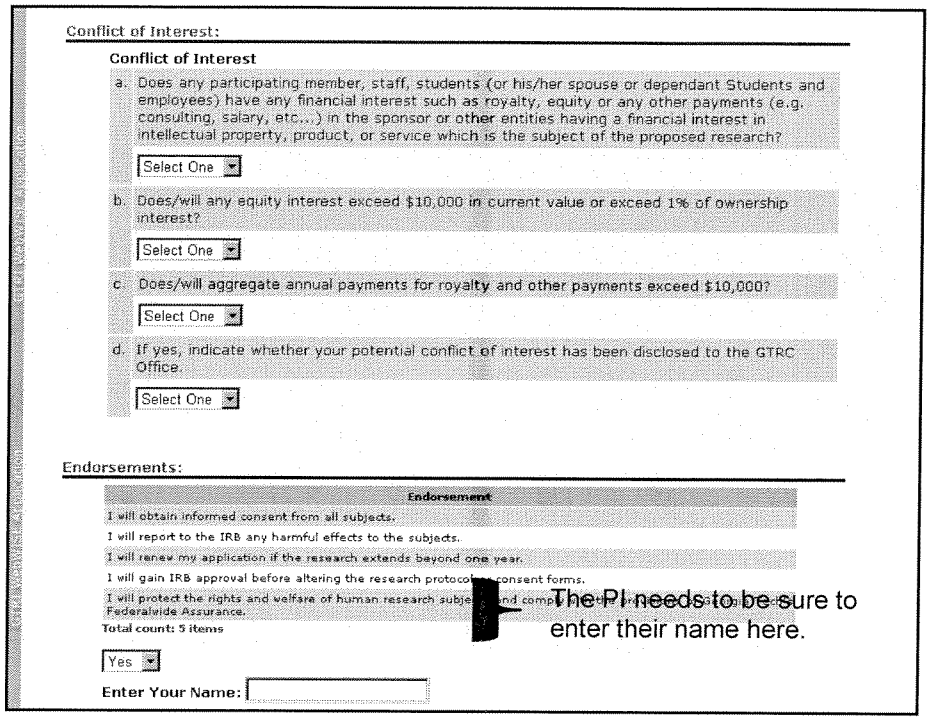
This final section allows users to choose whether to save their work but to stay on this same page; to save their work but will exit out of the application; or to save their work and continue will the submission process.

We chose to **Save & Submit** and are continuing with the submission process. This screen is a "review" of the information that you have input into the system.



1.2.8 Conflict of Interest & Endorsements

At the bottom of the review screen, the Principal Investigator must answer the sections on Conflict of Interest and Endorsements. Once the PI agrees to the Endorsements, they will need to type in their name which signifies an e-signature.



1.2.9 Sign-Off Process

Approvals:

The appropriate approvals ("e-signatures") are necessary to obtain before the application may be processed. Select the appropriate method by clicking on a radio button. Then if necessary, select the Chair or Dean who will need to approve the protocol.

If a *Faculty Member (PI)* then...

Forward the application to their Chair, Director or Dean (Person to whom the PI reports to) for approval. Once approved by the Chair, Director or Dean, the application will be sent to the IRB for review.

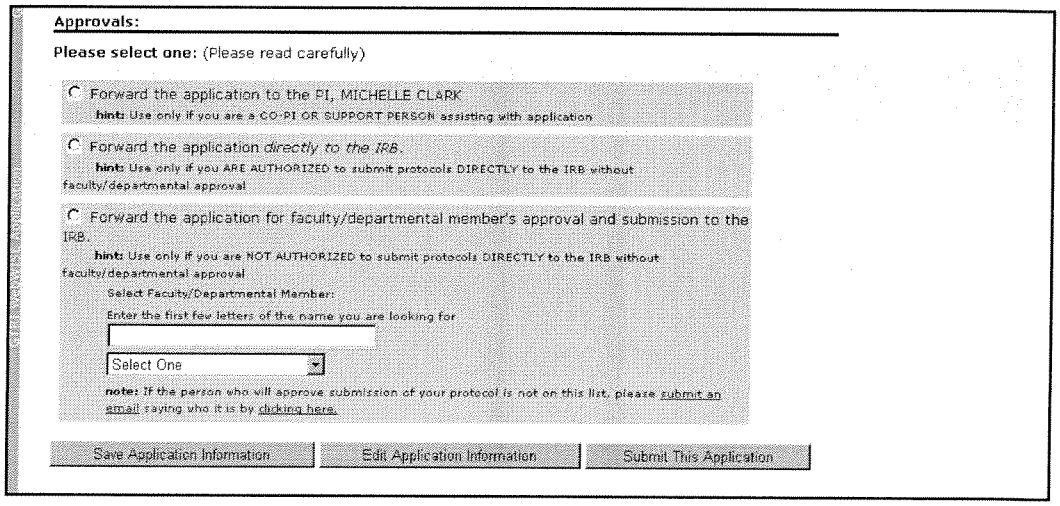
If an *Administrative Assistant* then...

Forward the application to the PI to answer the conflict of interest question, the endorsement statements/signature and then to submit the application to their Chair, Director or Dean (Person to whom the PI reports to). Once approved by the Chair, Director or Dean, the application will be sent to the IRB for review.

If a *Student PI* then...

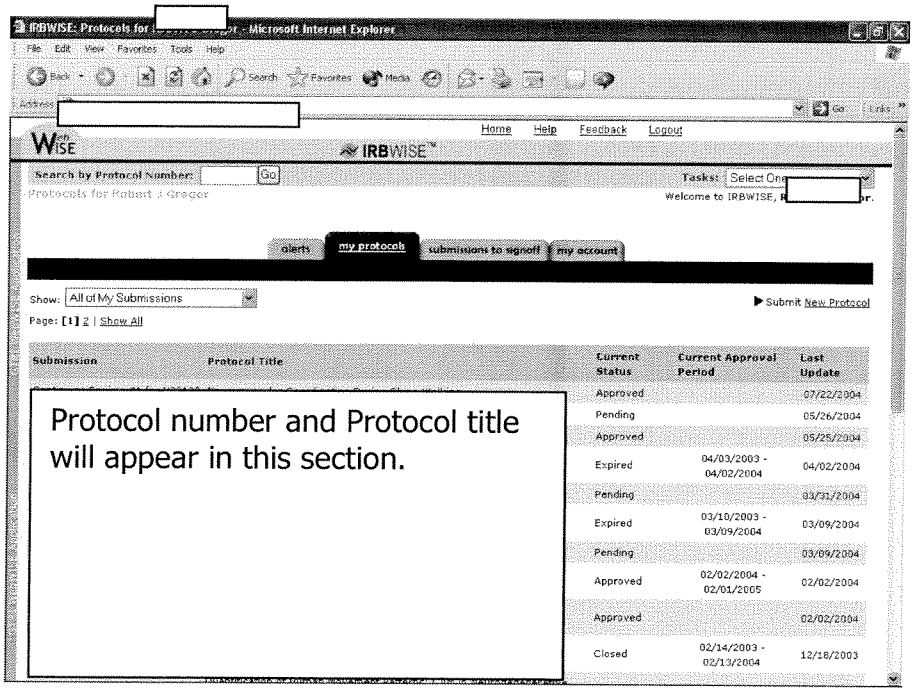
Forward the application to the faculty sponsor for approval who will then forward the application to the Chair, Director or Dean of the department. Once approved by the Chair, Director or Dean, the application will be sent to the IRB for review.

Be sure to click on the **Submit This Application** button.



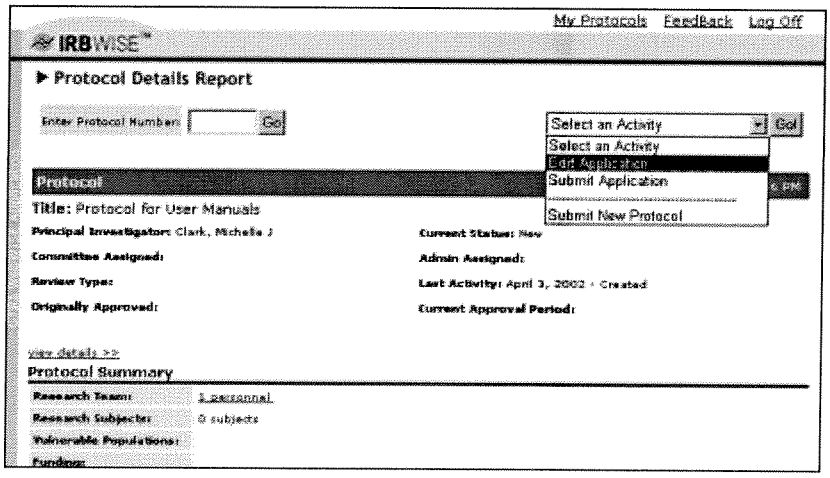
1.2.10 Pre-Submission Protocols

Protocols can be partially completed and then saved without being submitted. These protocols reside in the **My Protocols** section.



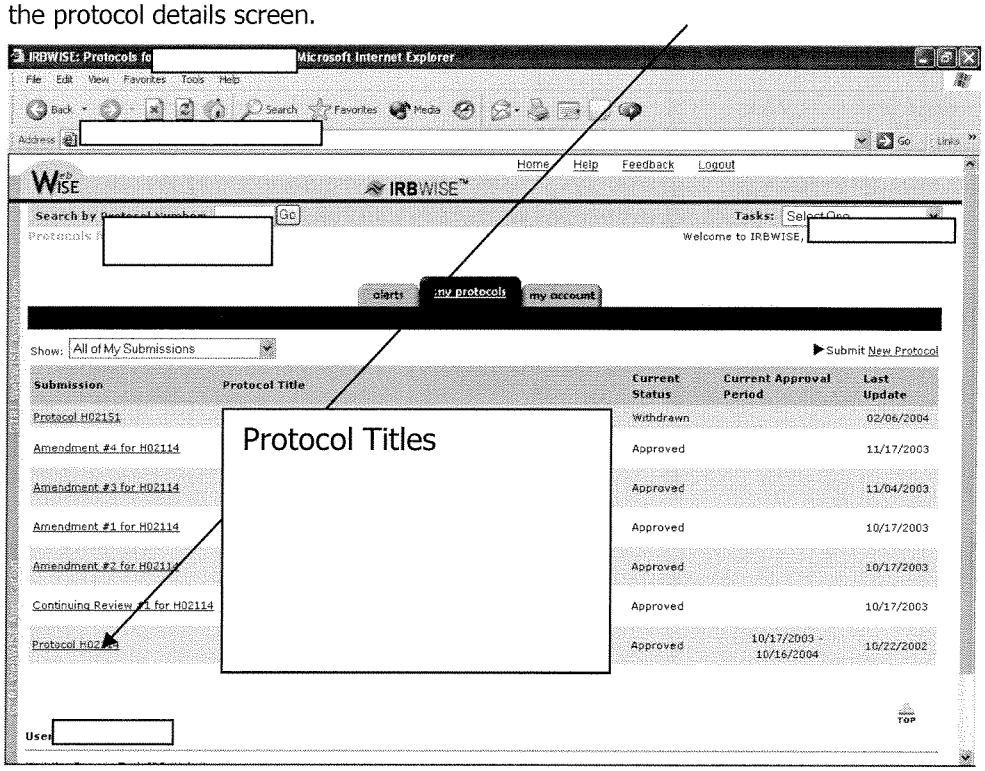
Only protocols which have not been submitted for approvals can be edited in this pre-submission process. Click on the hyperlink that states "view" with the status of "new."

The next screen displays the protocol information that has been completed. To edit the information, click on the drop-down box and select **Edit Application** and click the **GO** button.

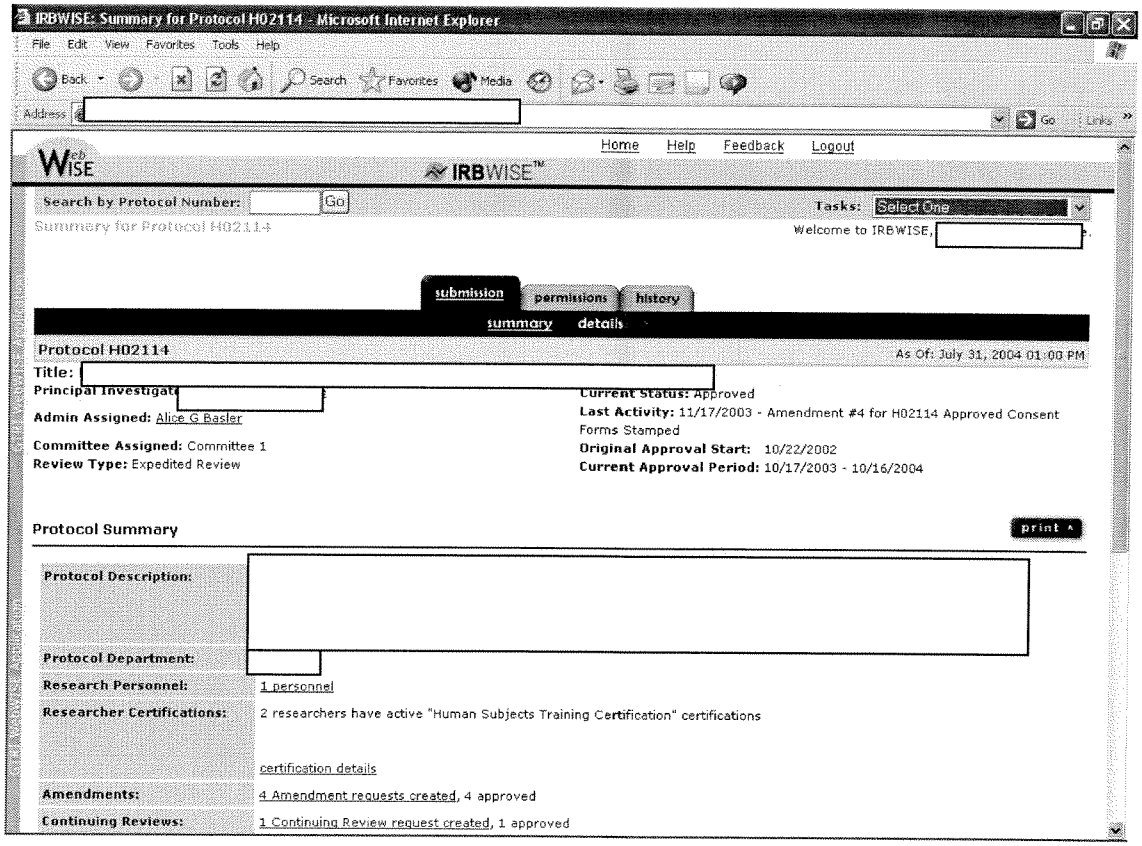


2.0 Submitting an Amendment

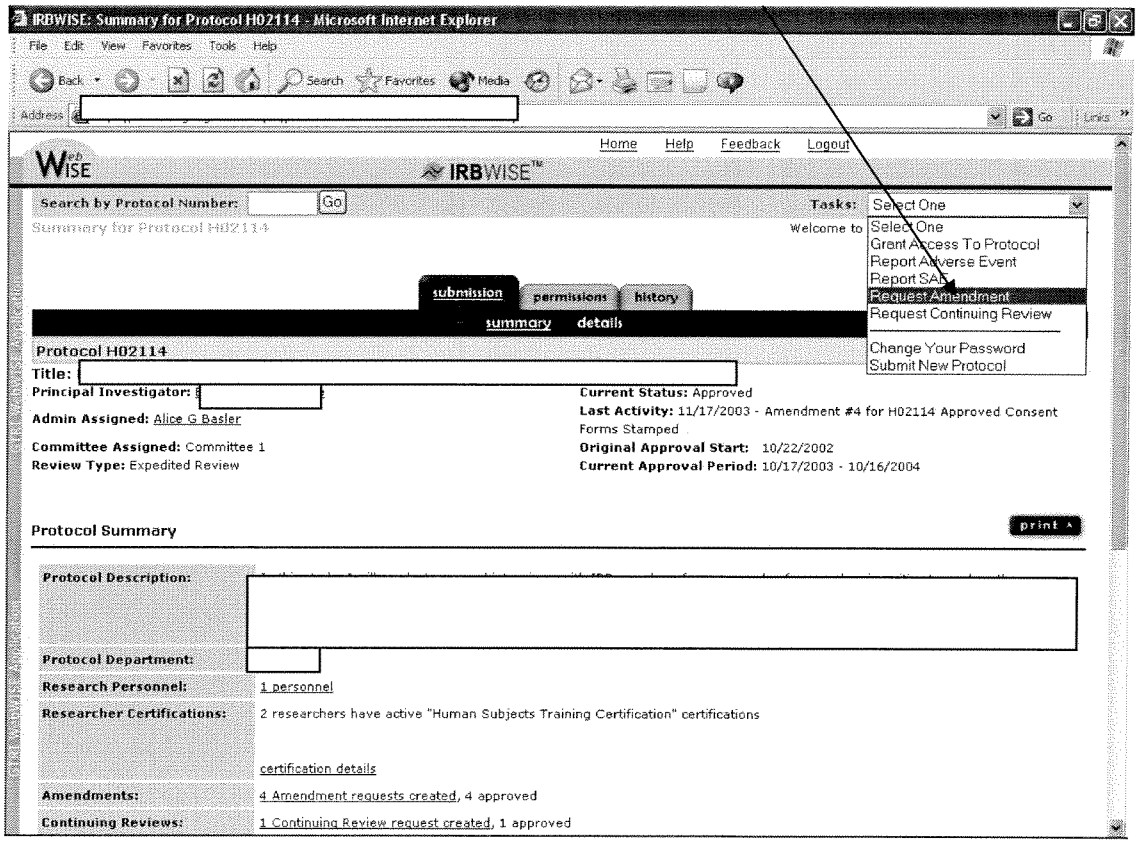
To submit an amendment, you must begin with an approved protocol which is located in the **My Protocols** tab. Click on the protocol number that contains the hypertext link. This will bring up the protocol details screen.



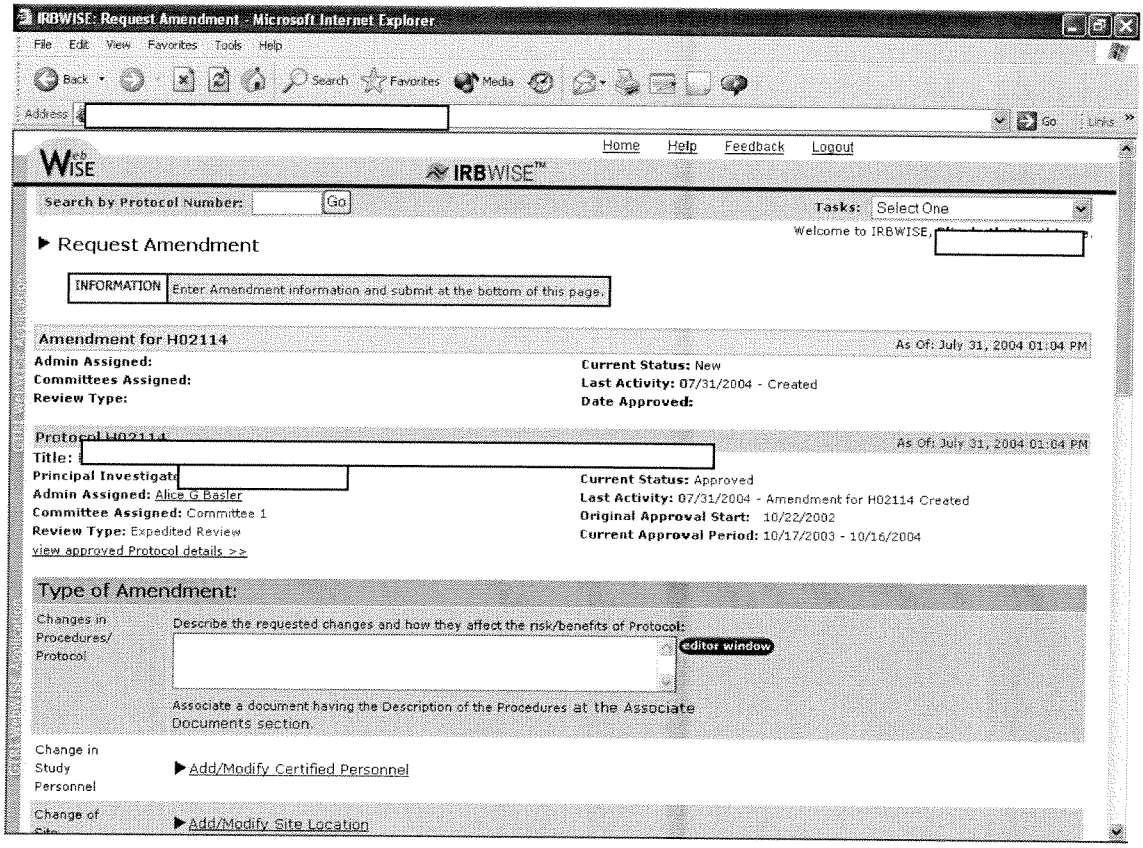
The screen below is the protocol details for Protocol Number H02114 which contains the protocol summary.

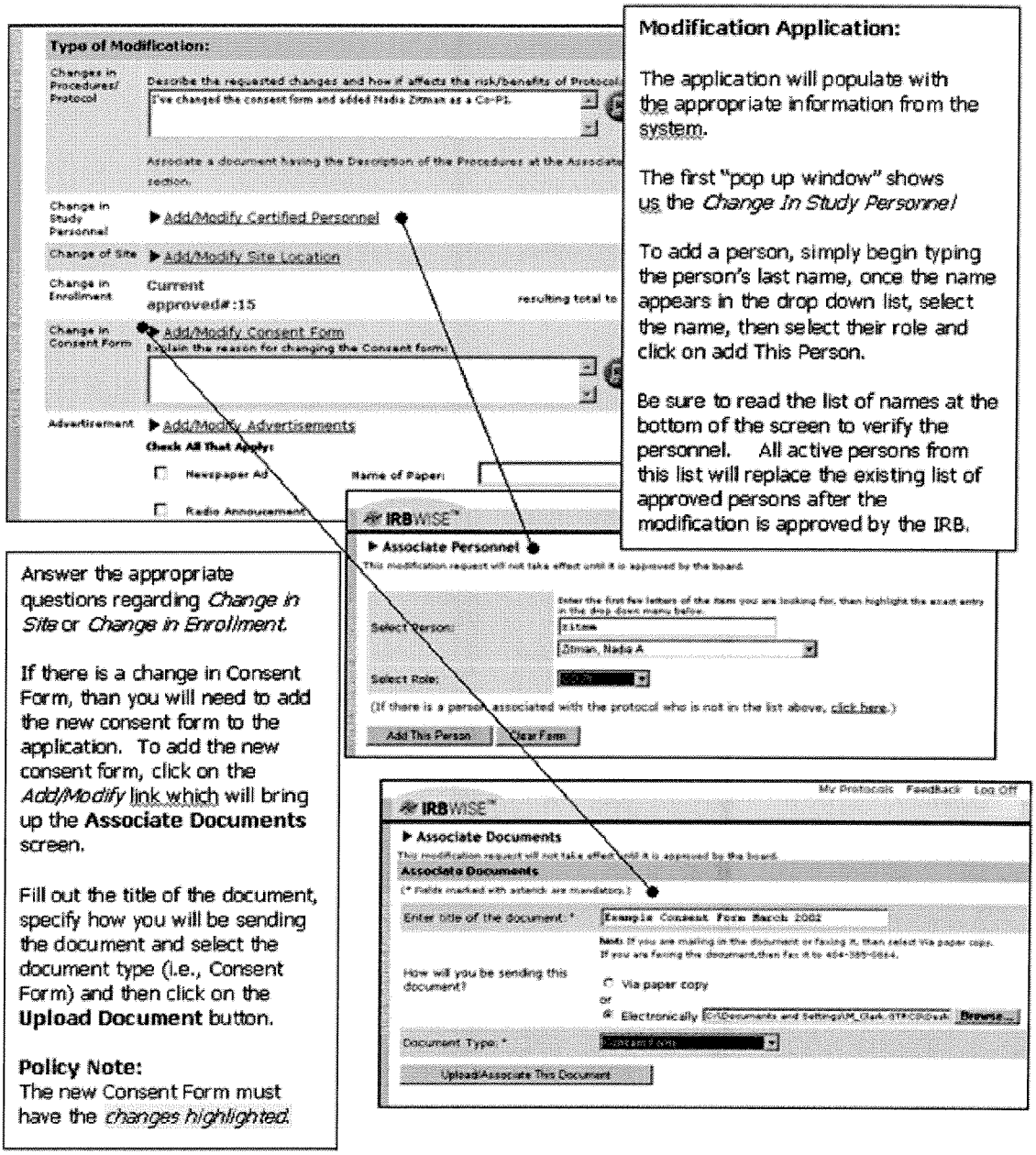


Click on the drop down box and select **Request Amendemnt**.



The top of the Request Amendment screen contains the basic protocol information. The bottom portion of the screen contains the application for the amdment request.





Modification Application:

The application will populate with the appropriate information from the system.

The first "pop up window" shows us the *Change In Study Personnel*

To add a person, simply begin typing the person's last name, once the name appears in the drop down list, select the name, then select their role and click on add This Person.

Be sure to read the list of names at the bottom of the screen to verify the personnel. All active persons from this list will replace the existing list of approved persons after the modification is approved by the IRB.

Answer the appropriate questions regarding *Change in Site* or *Change in Enrollment.*

If there is a change in Consent Form, than you will need to add the new consent form to the application. To add the new consent form, click on the *Add/Modify* link which will bring up the **Associate Documents** screen.

Fill out the title of the document, specify how you will be sending the document and select the document type (i.e., Consent Form) and then click on the **Upload Document** button.

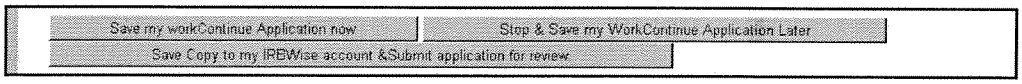
Policy Note:
The new Consent Form must have the *changes highlighted.*

Continue with the Amendment Application by adding or modifying the appropriate sections.

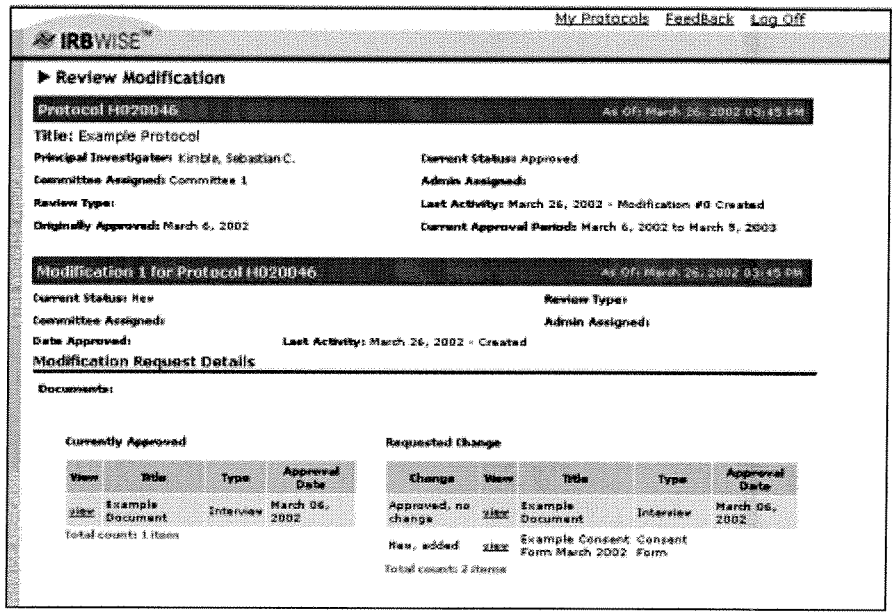
This icon will open up a larger window for text editing.

Be sure to answer any questions regarding the justification of the requested changes.

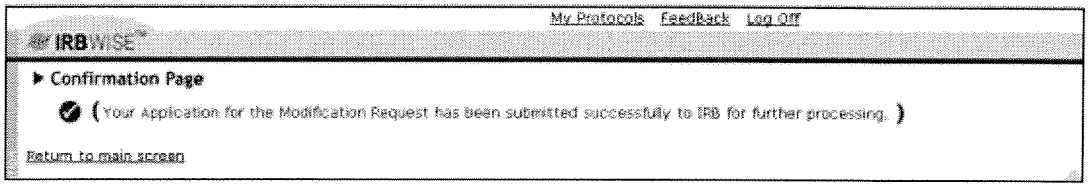
This section allows users to choose whether to save their work but to stay on this same page; to save their work but will exit out of the application; or to save their work and continue will the submission process.



In this case, the amendment application has been submitted. The details of the application are summarized on the next screen.



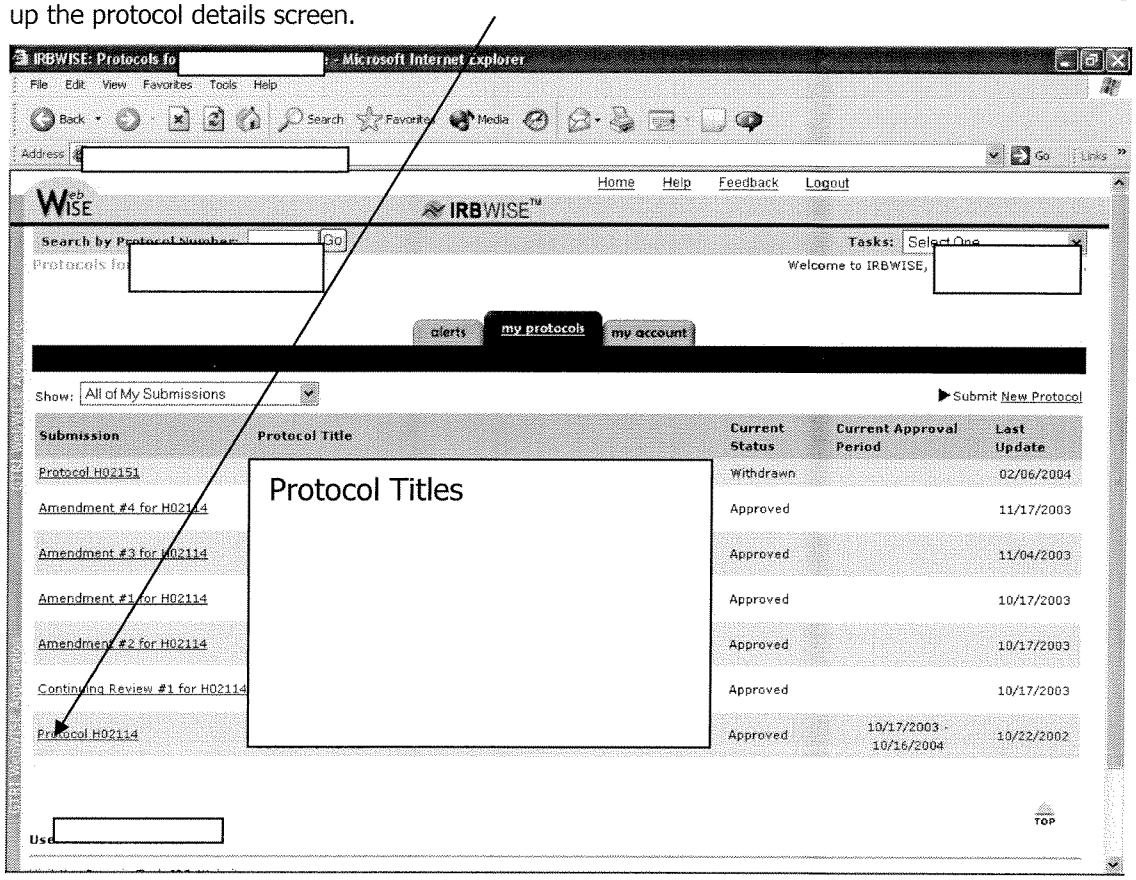
NOTE: If you need to add anything additional at this point. DO NOT click on the back browser to add info – this will create a second Amendment. Instead, click on the HOME button (on the top navigation) and then select the amendment in the Amendment in the system.



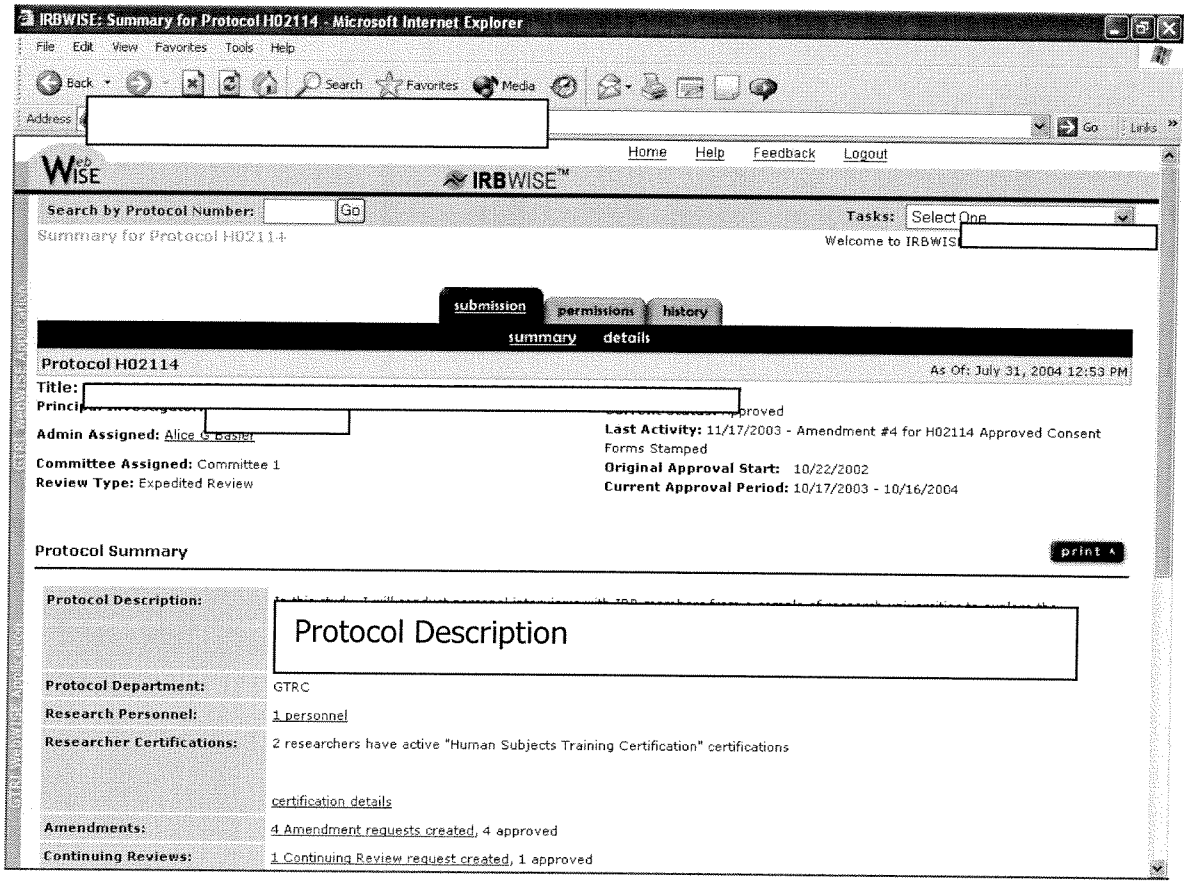
You should receive a confirmation of a successful submission. Please note that this transaction does not indicate a complete application or approval of the Amendment. You may still receive requests for additional information from an IRB administrator.

3.0 Submitting a Continuing Review

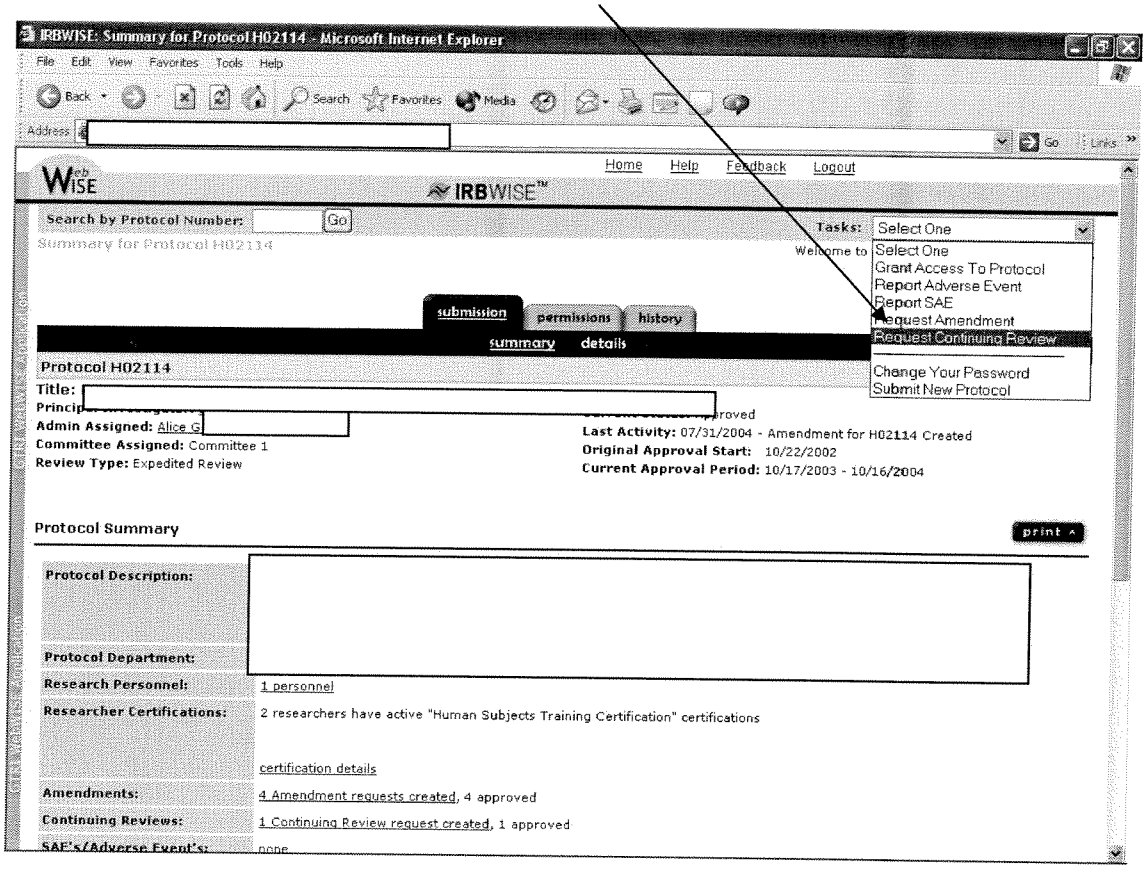
To submit a Continuing Review, you must begin with an approved protocol which is located in the **My Protocols** tab. Click on the protocol number that contains the hypertext link. This will bring up the protocol details screen.



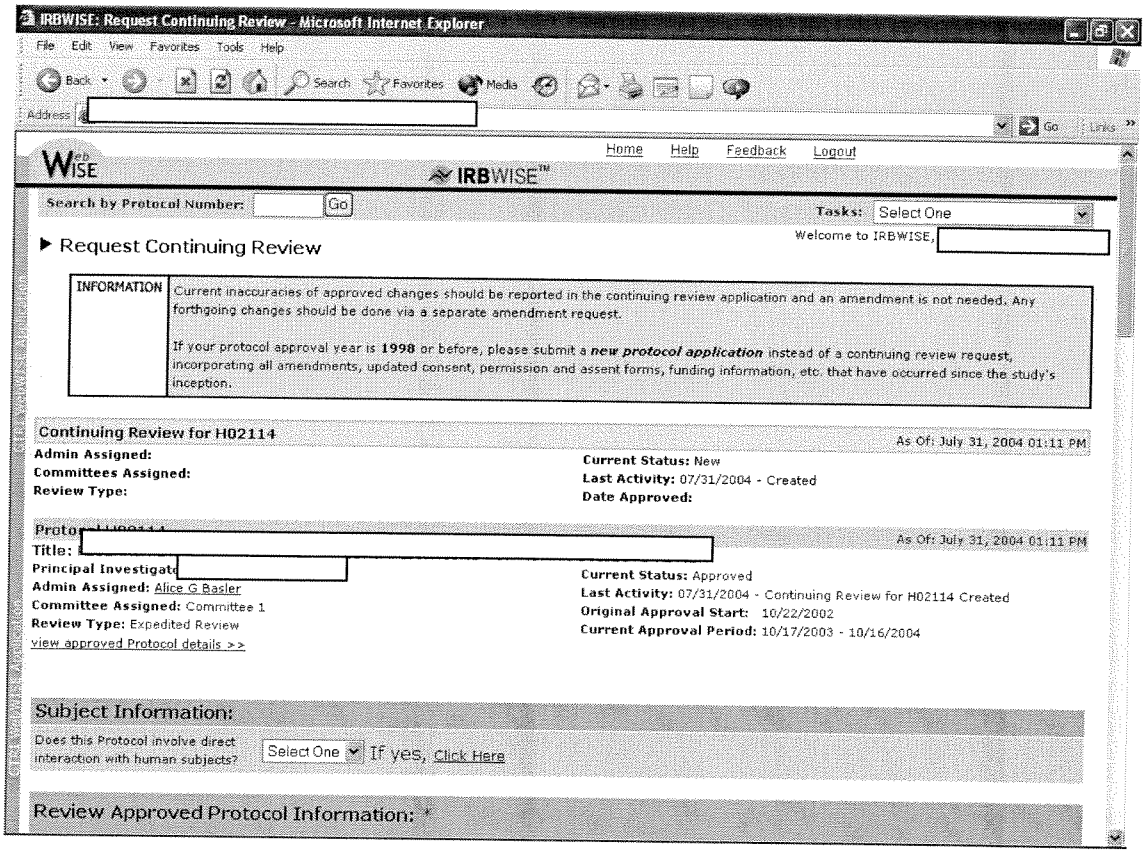
The screen below is the protocol details for Protocol Number H02114 which contains the protocol summary.

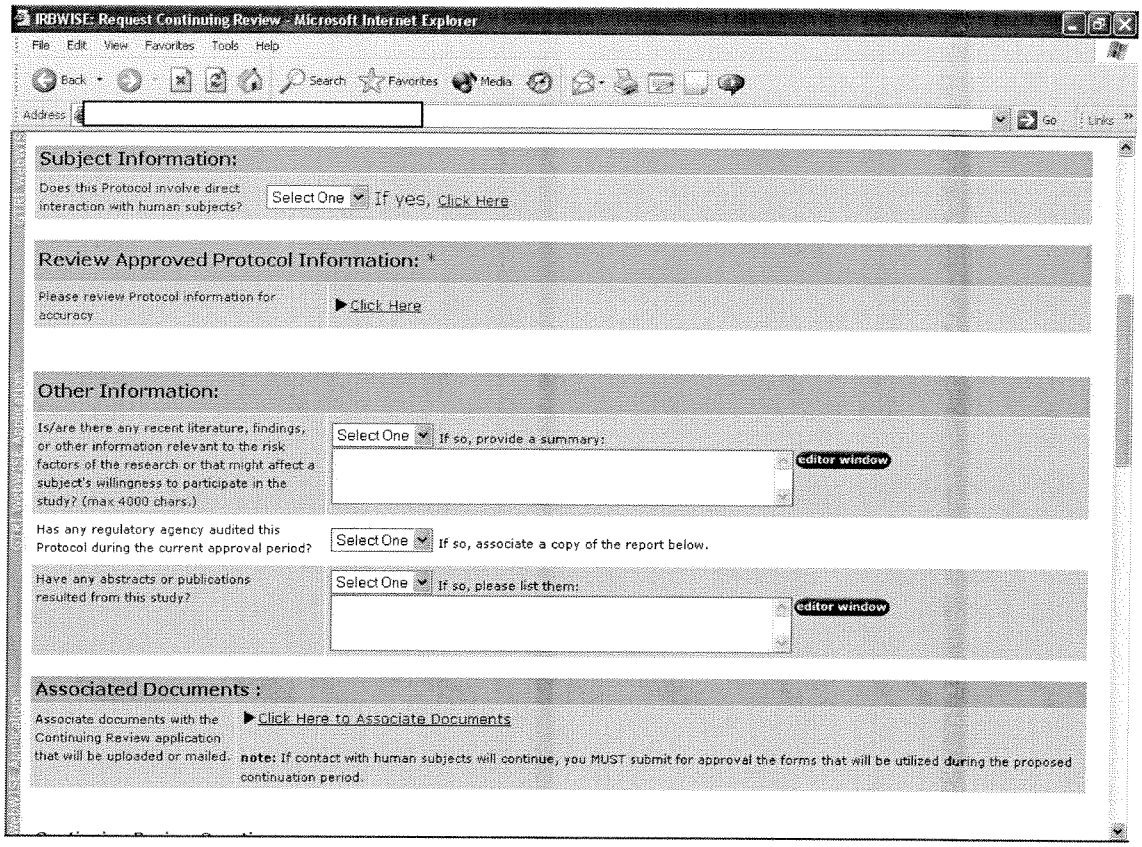


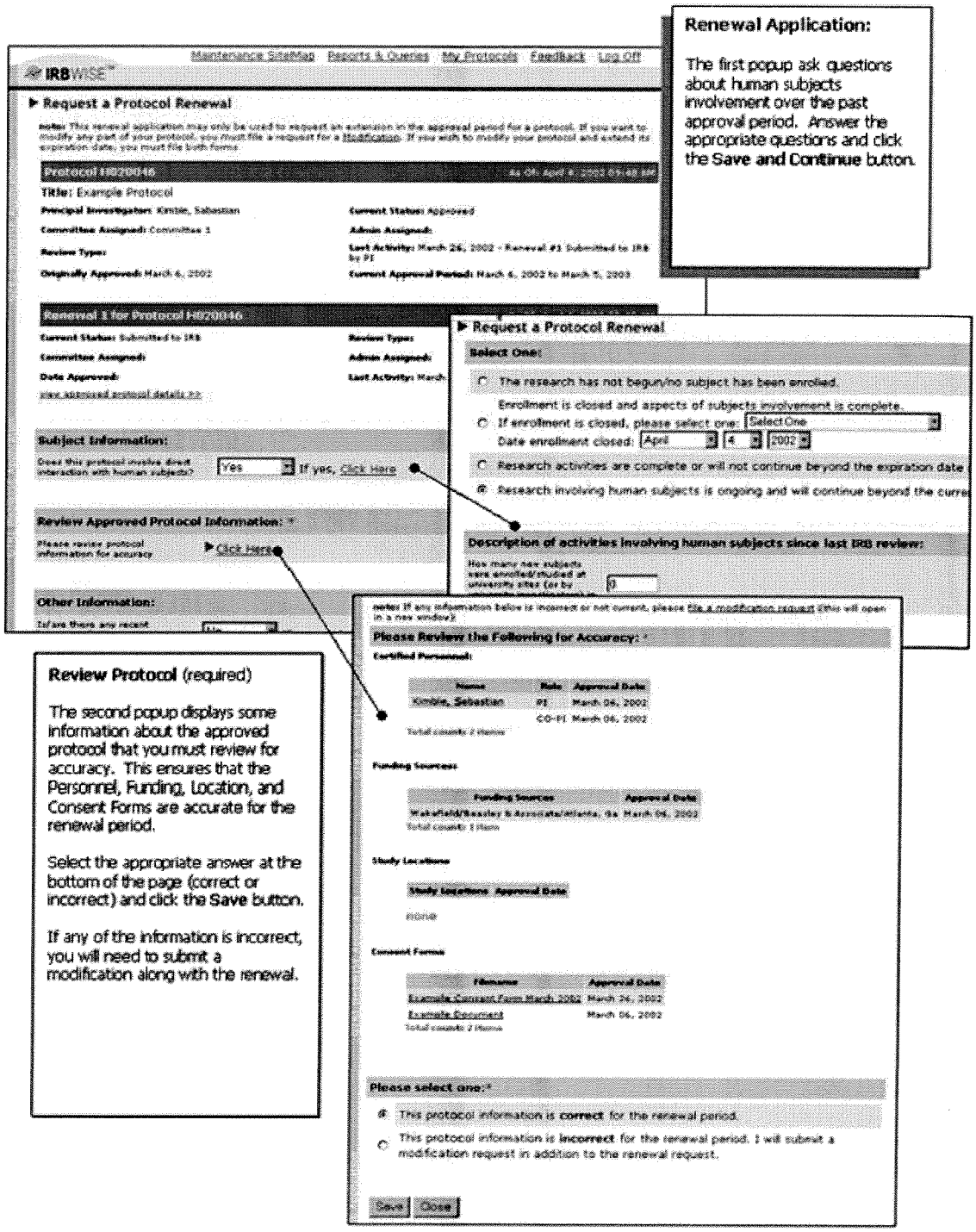
Click on the TASKS menu and select "Request Continuing Review" from the dropdown menu.



The top of the Request a Continuing Review screen contains the basic protocol information. The bottom portion of the screen contains the application for the Continuing Review request.



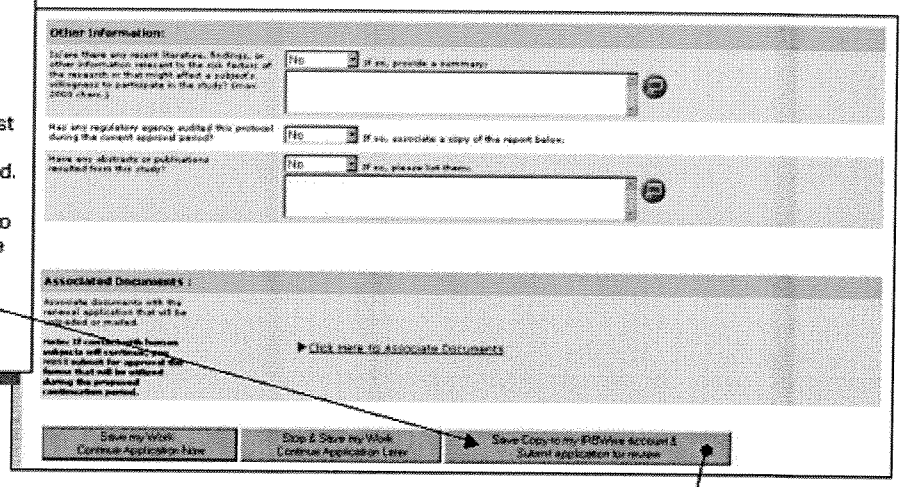

IRBWISE: Request Continuing Review - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites Media
Address
Go Links
Subject Information:
Does this Protocol involve direct interaction with human subjects?
Select One
If yes, Click Here
Review Approved Protocol Information: *
Please review Protocol information for accuracy
Click Here
Other Information:
Is/are there any recent literature, findings, or other information relevant to the risk factors of the research or that might affect a subject's willingness to participate in the study? (max 4000 chars.)
Select One
If so, provide a summary:
editor window
Has any regulatory agency audited this Protocol during the current approval period?
Select One
If so, associate a copy of the report below.
Have any abstracts or publications resulted from this study?
Select One
If so, please list them:
editor window
Associated Documents :
Associate documents with the Continuing Review application that will be uploaded or mailed.
Click Here to Associate Documents
note: If contact with human subjects will continue, you MUST submit for approval the forms that will be utilized during the proposed continuation period.


Renewal Application:
The first popup ask questions about human subjects involvement over the past approval period. Answer the appropriate questions and click the Save and Continue button.
Review Protocol (required)
The second popup displays some information about the approved protocol that you must review for accuracy. This ensures that the Personnel, Funding, Location, and Consent Forms are accurate for the renewal period.
Select the appropriate answer at the bottom of the page (correct or incorrect) and click the Save button.
If any of the information is incorrect, you will need to submit a modification along with the renewal.

Answer the other questions on the renewal application.

Note that if contact with human subjects will continue, you must upload the consent forms that will be used.

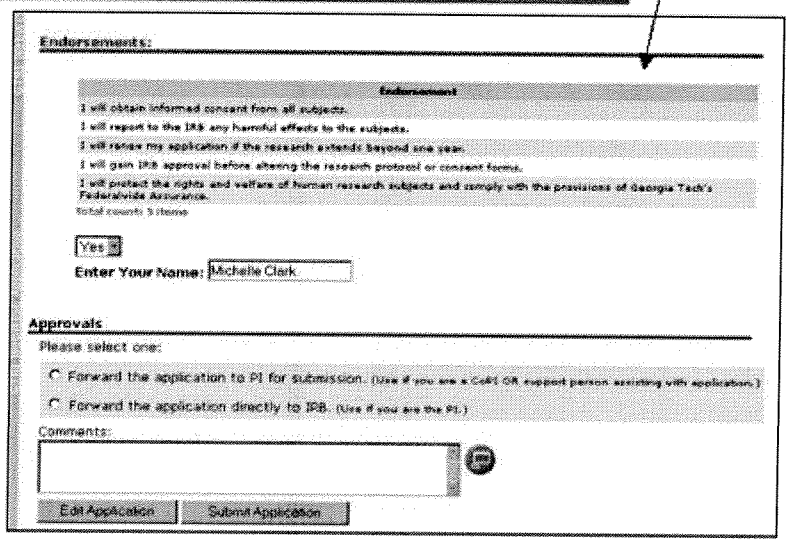
When you are ready to review and submit the renewal application, click the "**Save Copy...Submit Application**" button



Review Renewal:

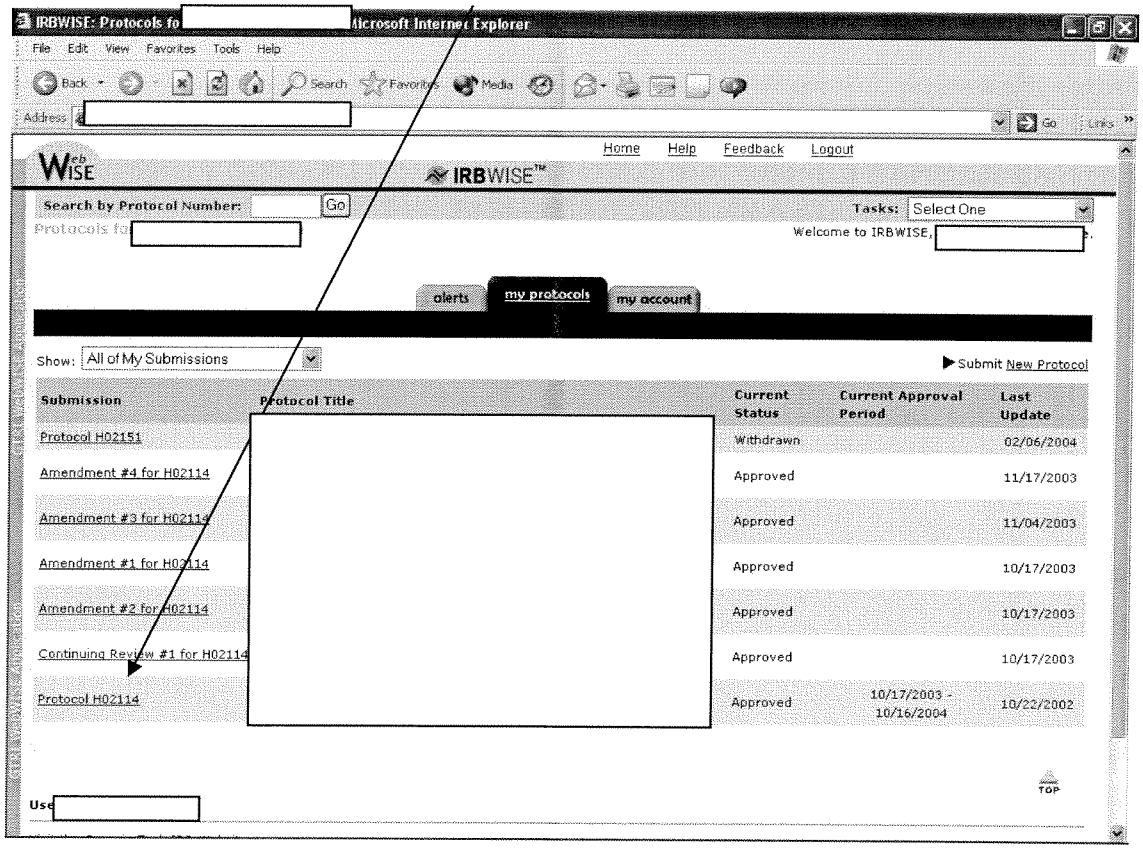
Finally, review your renewal application. Scroll to the bottom of the page and answer the Conflict of Interest and the Endorsement questions for the renewal period. If you need to make changes to your application, click the **Edit Application** button.

When you are ready to submit the application, first select who you will send it to (the PI or the IRB), include any comments about the application, and click the **Submit Application** button

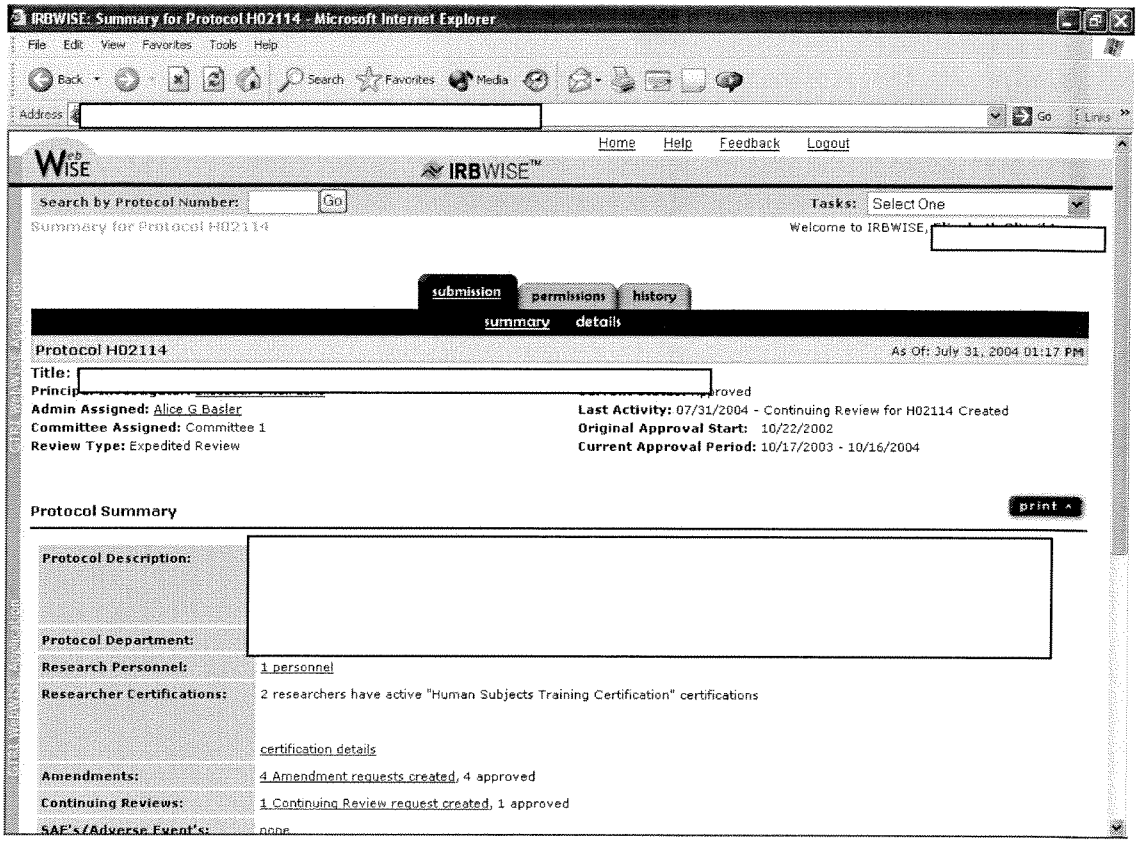


4.0 Adverse Events

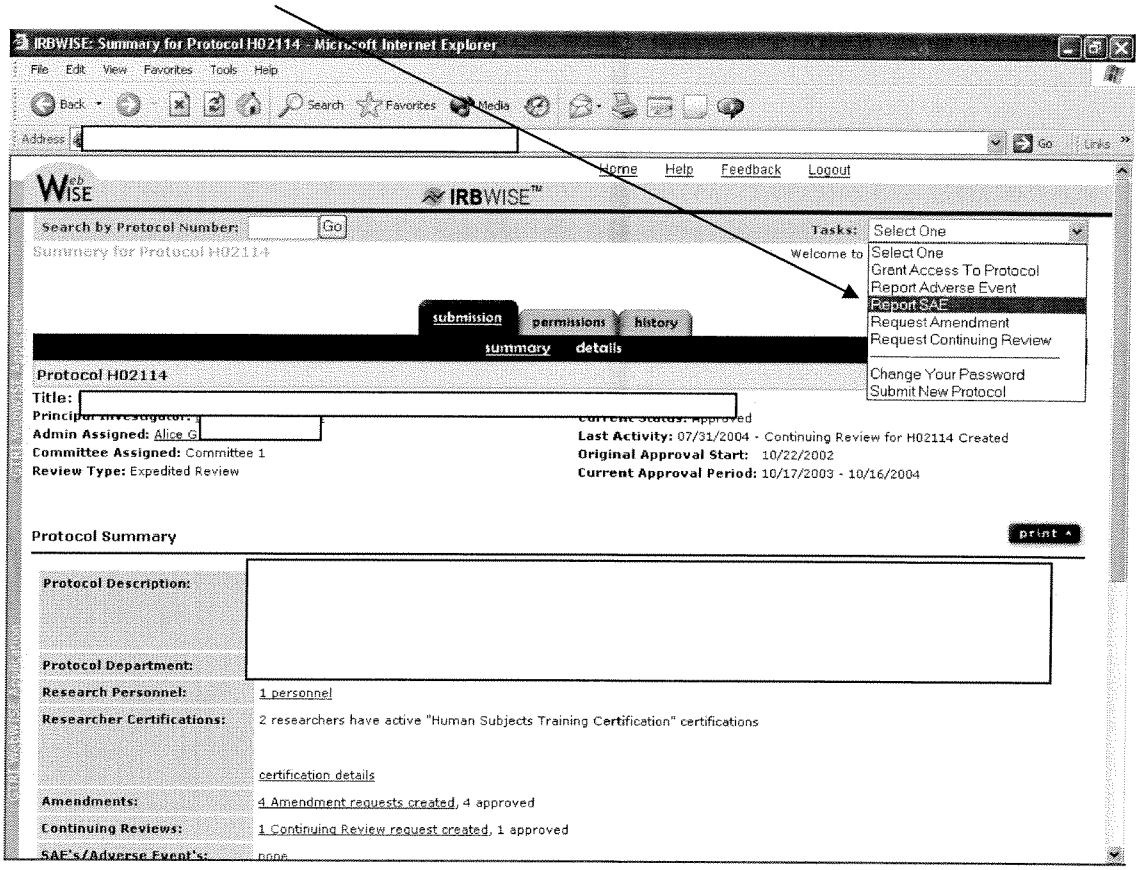
To report an adverse event or a serious adverse events, you must begin with an approved protocol which is located in the **My Protocols** tab. Click on the protocol number that contains the hypertext link. This will bring up the protocol details screen.



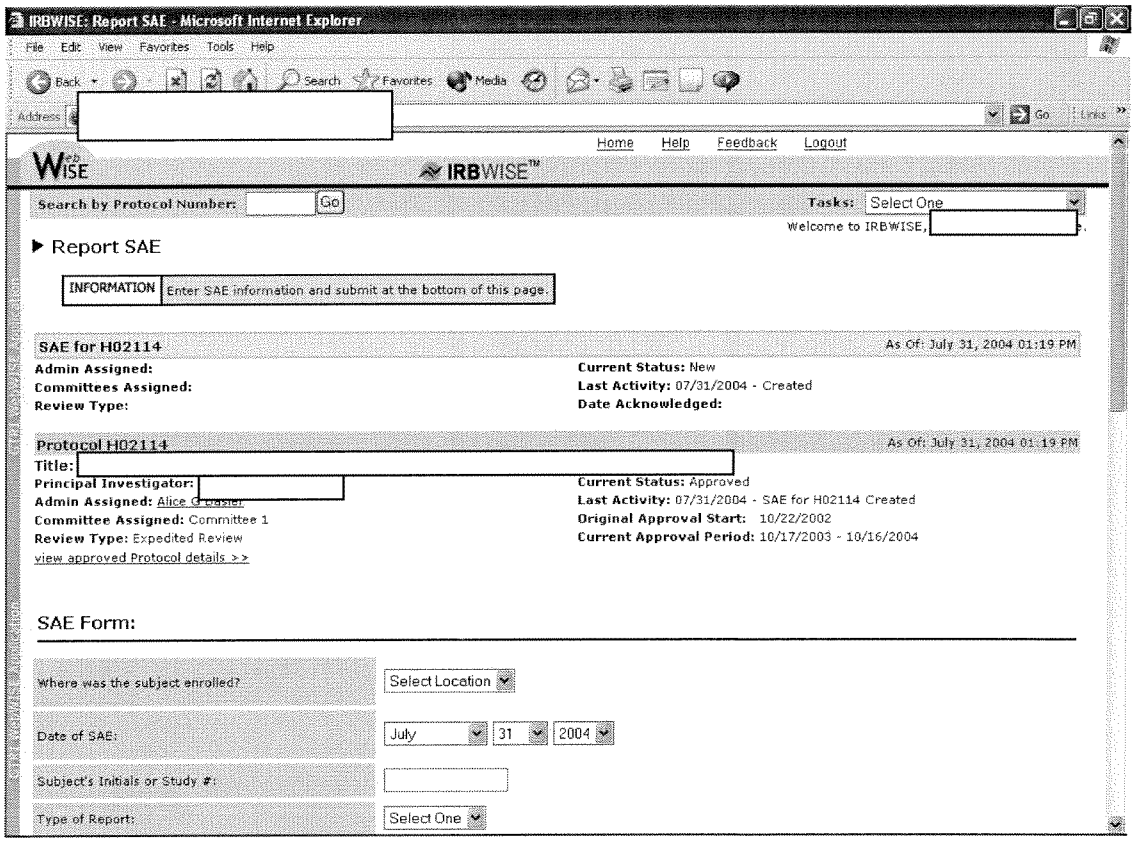
The screen below is the protocol details for Protocol Number H02114 which contains the protocol summary.



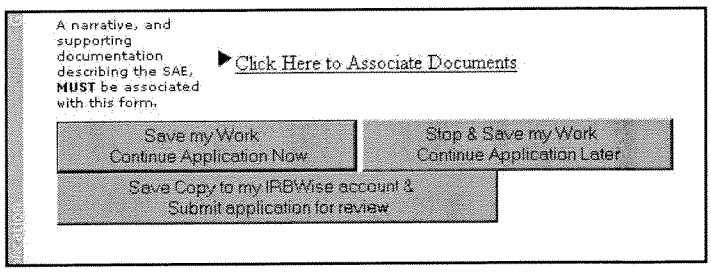
Click on **Report SAE**



The top of the Report SAE (Serious Adverse Event) screen contains the basic protocol information. The bottom portion of the screen contains the application for the SAE report. The Adverse Event screen is similar to the SAE screen.

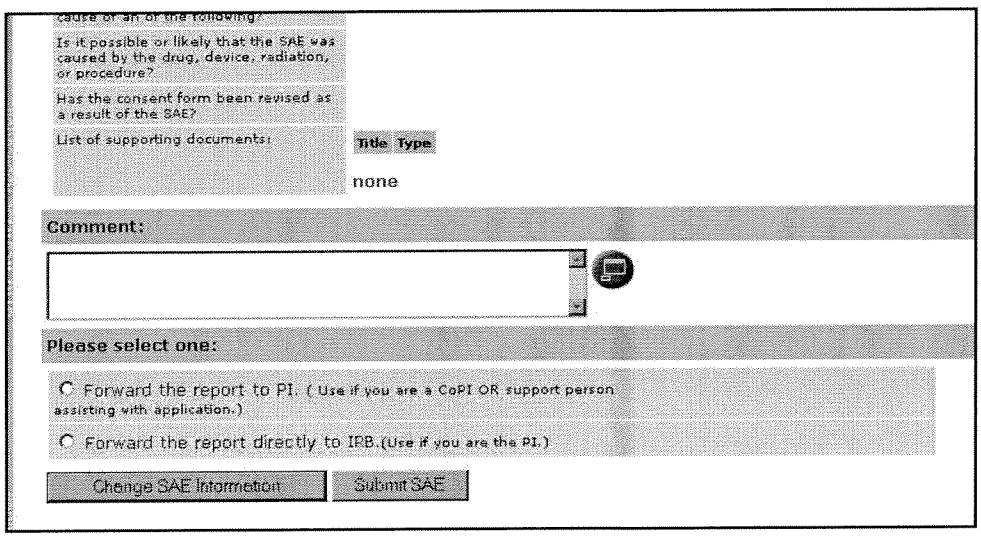


When you are done with the report, click the **Save Copy...Submit Application** button at the bottom of the report.



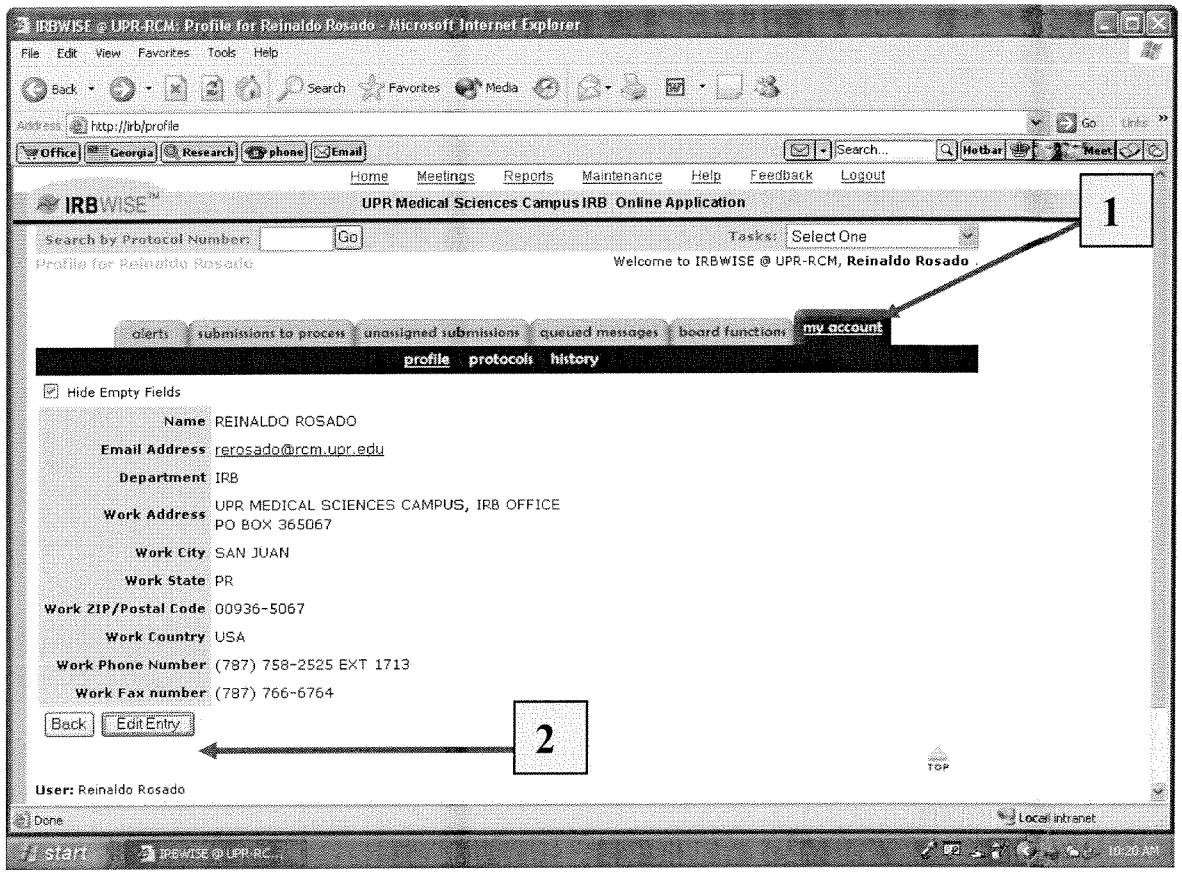
On the final page, review the SAE before you submit it. To edit the report, click the **Change SAE Information** button.

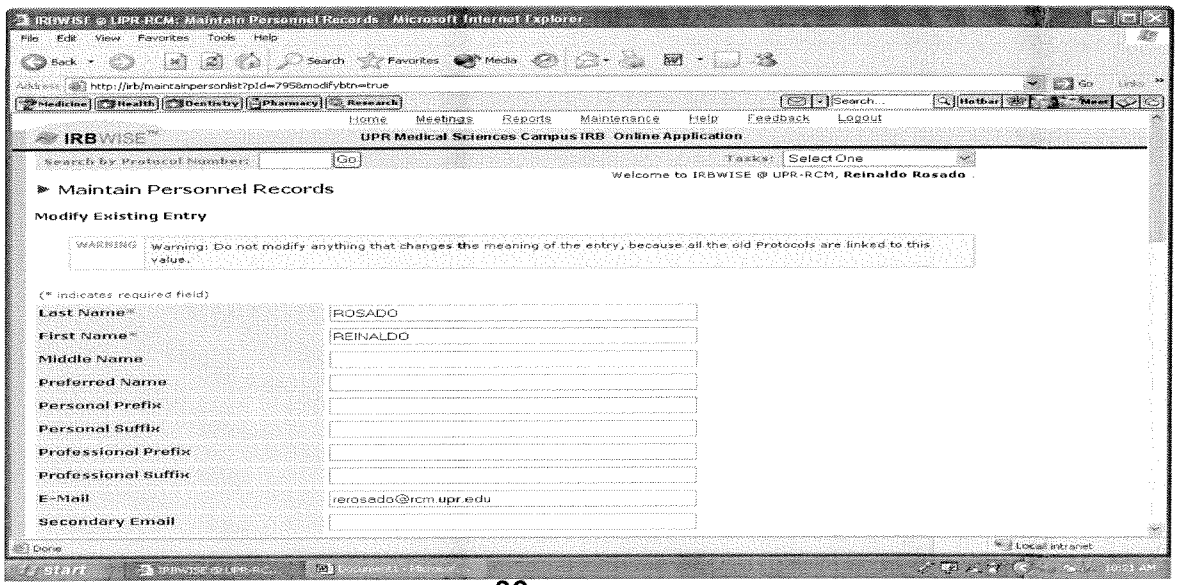
To submit the report, select who you will send it to (the PI or the IRB), enter any comments about the report, and click **Submit SAE.**



How to submit the curriculum vitae and Human Subjects Training Certificate in the IRBWise® System

1. In your homepage of the IRBWise® System go to **"my account"** tab. You will se your profile information.
2. Then go to **"Edit Entry"**. This will take you to the **"Maintain Personnel Records"** section, where you will find your personal information. It is recommended for you to keep you personal information updated. This information will be used by the IRB staff in case they need to contact you.



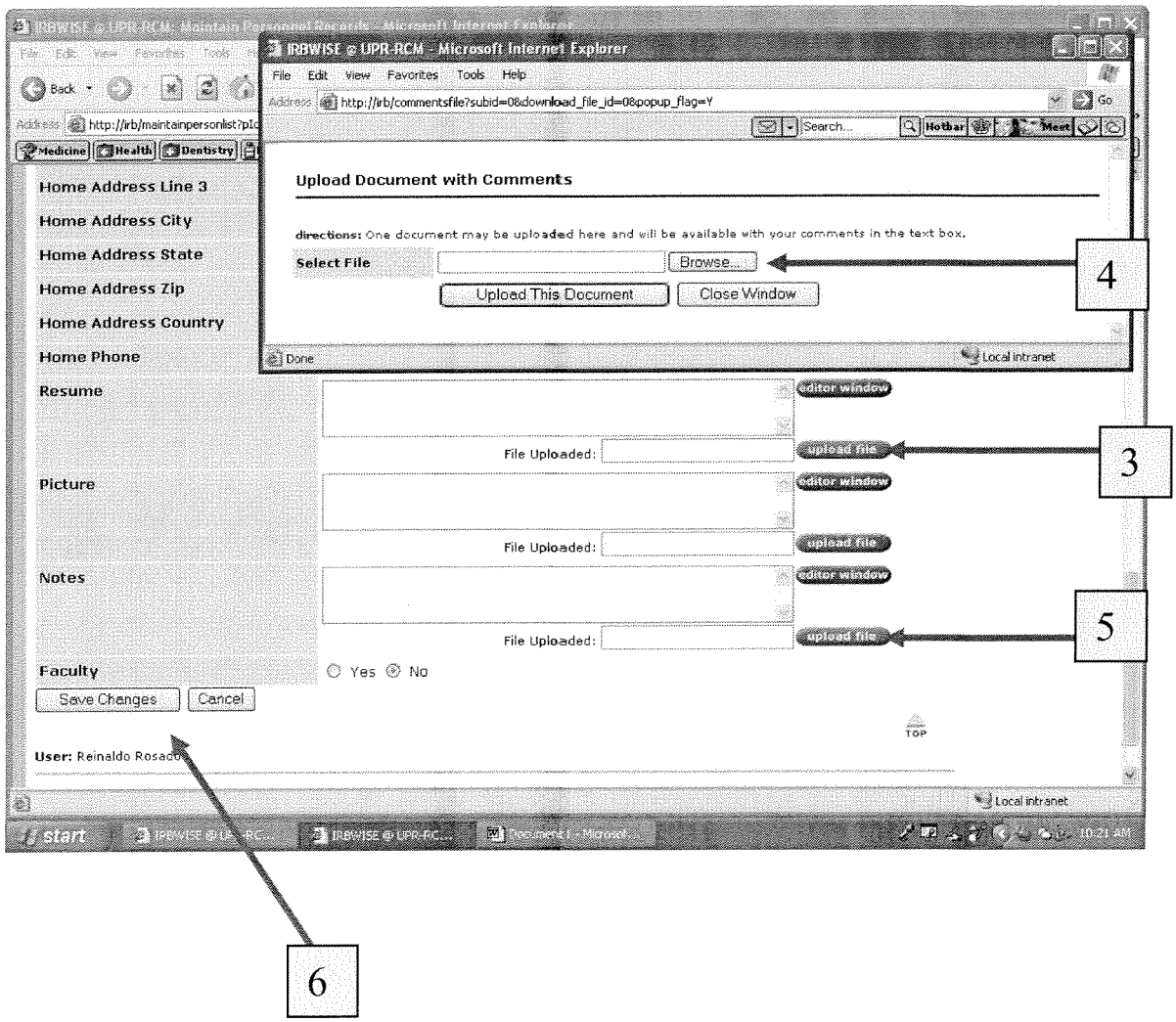


3. In the **"Maintain Personnel Records"** section, go to **"Resume"** and **"upload file"**. A new window will appear titled **"upload document with comments"**.

4. You will click **"browse"** where you will upload the curriculum vitae.

5. In the **"notes"** section repeat steps 3 and 4 and attach the Human Subjects Training Certificate.

6. Once you submit both documents "save changes".



University of Puerto Rico
Medical Science Campus
IRBWise® Account Request
Personal Information

Please complete the following information. Do not leave any item unanswered.
Please submit the completed form to IRB Office 622C, RCM Main Building.

Last Name	
First Name	
Middle Name	
E-Mail	
Address Line 1	
Address Line 2	
City/State	
Zip Code	
Country	
Phone	
Fax	
Faculty	
Faculty Member	
Department	
Account /Password Assigned *(do not write here)*	

Signature _____ Date _____

Miguel Cruz
IRBWise System Administrator

Reinaldo Rosado
IRB ADMINISTRATOR