



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.

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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 IRB Wise[®] 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 IRB Wise[®] System. In the submission you should also:

1. Answer all the questions in the IRB Wise[®] 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 IRB Wise[®] 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 IRB Wise[®] 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

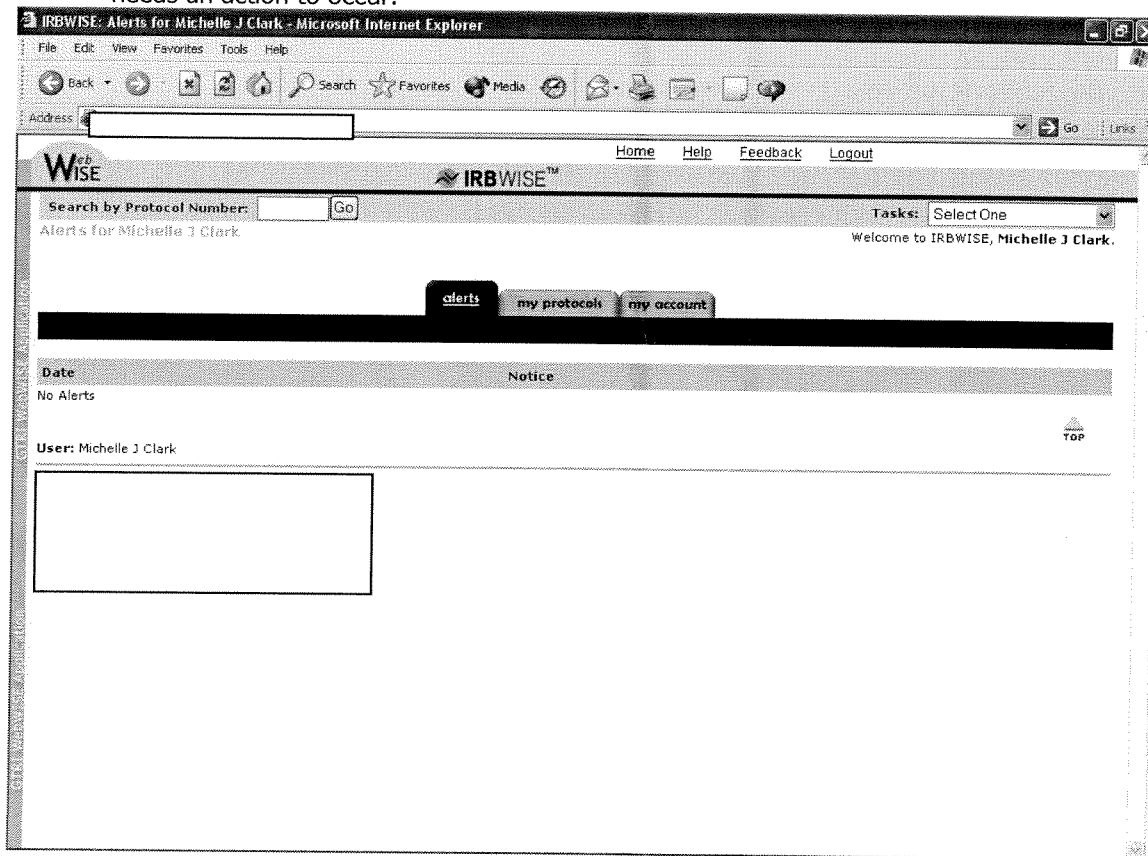
When submitting a protocol to the IRB, use ***IRBWISE***, a new web-enabled Institutional Review Board (IRB) management and tracking system. This system is designed for online submission of human subject investigation applications (protocols), submitting and monitoring continuing reviews and amendments,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



IRBWISE User Guide

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.

The screenshot shows the IRBWISE web application in a Microsoft Internet Explorer browser window. The page title is "IRBWISE: Protocols for Michelle J. Clark". The browser's address bar is empty. The page has a navigation bar with links for Home, Help, Feedback, and Logout. Below the navigation bar, there is a search bar labeled "Search by Protocol Number:" and a "Go" button. To the right of the search bar, there is a "Tasks:" dropdown menu set to "Select One" and a welcome message: "Welcome to IRBWISE, Michelle J. Clark." Below the search bar, there are three tabs: "alerts", "my protocols" (which is selected), and "my account". A "Show:" dropdown menu is open, showing options: "All of My Submissions", "Works in Progress", "Waiting on Signatures", "Submitted and Being Processed", and "Final Disposition". The "All of My Submissions" option is selected. To the right of the dropdown menu, there is a "Submit New Protocol" link. Below the dropdown menu, there is a table with the following columns: "Subm", "Protocol", "Current Status", "Current Approval Period", and "Last Update". The table contains the following data:

Subm	Protocol	Current Status	Current Approval Period	Last Update
Protocol	This is my protocol title.	Withdrawn		04/26/2004
Protocol	New Protocol	Withdrawn		04/26/2004
Protocol	This is a mock protocol...	Withdrawn		06/11/2003
Amendment #2 for H02082	Teaching Assistants	Approved		06/03/2003
Amendment #1 for H02082	Teaching Assistants	Approved		06/03/2003
Amendment for H02082	Teaching Assistants	Withdrawn		06/03/2003
Protocol	Example Protocol	Waiting for Sign-Off		10/29/2002

At the bottom of the page, there is a "TOP" link and a "Log Out" link.

For Investigators

1.2 New Protocol Application

IRBWISE™ My Protocols Feedback Log Off

► **Submit New Protocol**

Grant Administration Access

General Protocol Information:

(* Fields marked with asterisks must be completed for IRBWISE to complete work.)

Protocol Title:

Note: Please enter all titles, separated by commas, by which this protocol will be known.

Associate Certified People with this Protocol:

Select People: [► Add/Modify Certified Personnel](#)

Note: A PI must be associated with this protocol in order to save.

Associate Funding with this Protocol:

Is there funding associated with Protocol? If External, [► Add/Modify External Funding](#)

Locations where study will be conducted:

Are there locations associated with this Protocol? If yes, [► Add/Modify Location](#)

Lay Summary of Protocol:

a. Describe in lay terms the purpose of the research including the research question.

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.

IRBWISE™ My Protocols Feedback Log Off

► **Associate Personnel**

Enter the first few letters of the item you are looking for, then highlight the exact entry in the drop down menu below.

Select Person:

Select Role:

(If there is a person associated with the protocol who is not in the list above, [click here.](#))

List of Study Personnel currently associated:

Select/Modify	Person's Name	Role
<input type="checkbox"/>	Clark, Michelle J	PI

Total counts: 1 item

IRBWISE User Guide

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

The image displays two screenshots of the IRBWISE web application interface. The left screenshot shows the 'Submit New Protocol' form. It includes sections for 'General Protocol Information', 'Associate Certified People with this Protocol', 'Associate Funding with this Protocol', and 'Locations where study will be conducted'. A red star icon is placed next to the 'Grant Administrative Access' link. The right screenshot shows the 'Grant Access to Protocol' form. It includes a note about granting administrative access, a search bar for selecting a person, and a form for entering the information for the person (First Name, Middle Name, Last Name, Address, City, State, Zip).

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.

The screenshot shows the 'Associate Funding Sources' form in the IRBWISE system. At the top, there are links for 'My Protocols', 'FeedBack', and 'Log Off'. The form title is 'Associate Funding Sources'. Below it, the section 'Associate Funding Sponsor(s):' contains several input fields: 'Grant Title' (with 'Proposal Title' entered), 'DOC Number (DOC ID)' (with '61204' entered), and 'Funding Sponsor' (with 'National Science Foundation' entered). A dropdown menu below the sponsor field shows 'NATIONAL SCIENCE FOUNDATION/GENERAL'. A note says '(If there is a funding source associated with the protocol which is not in the list above, click here.)'. Below this is an 'Add This Funding Sponsor' button. At the bottom of the form are three buttons: 'Modify Selected', 'Delete Selected', and 'Continue with Application'. Below the buttons is a section titled 'List of funding sponsors currently associated:' followed by a table with columns 'Delete/Modify', 'Funding Sponsor', 'Grant Title', and 'DOC Number'. The table is currently empty, showing 'None'.

1.2.3 Associate Locations

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

The screenshot shows the 'Associate Locations' form in the IRBWISE system. At the top, there are links for 'My Protocols', 'FeedBack', and 'Log Off'. The form title is 'Associate Locations'. Below it, the section 'Associate Locations:' contains a 'Select Location:' label and a text input field with '500' entered. A dropdown menu below the input field shows '500 Tenth'. A note says '(If there is a location associated with the protocol which is not in the list above, click here.)'.

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.

Lay Summary of Protocol:

a. Describe in lay terms the purpose of the research including the research question.

b. What do you hope to gain by doing this research?

Text Editor
Type your text in the window below and click OK to paste the text into the main window.

Typed in text from the keyboard...

Copied and pasted from a Word document.

OK Cancel

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).

Lay Summary of Protocol:

a. Describe in lay terms the purpose of the research including the research question.

b. What do you hope to gain by doing this research?

(Be Safe, Save Your Work Before Continuing With Application)

Save my work Continue Application now Stop & Save my work Continue Application later

1.2.5 Subject Information

Will the research involve direct interaction with subjects?

Subject Information:

Will the research involve direct interaction with subjects?

Select One

If yes, [Click Here](#).

If no, [Click Here](#).

If the answer is NO:

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

IRBWISE™ My Protocols Feedback Log Off

► Research Not Involving Subjects

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please select all that apply:

☐ Retrospective review of school records

☐ Retrospective review of medical records

☐ Review of data previously collected in another research setting

☐ Review of existing specimens

☐ Other (describe):

Save & Stay on this Page Save & Continue with Application

Cancel & Continue with Application

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.

IRBWISE™ My Protocols Feedback Log Off

► Associate Study Populations

Subject Information:

Number of Subjects for this Protocol: 0

Subject Gender(s) for this Protocol: Select One

Population Information:

Indicate which of the following populations will be included in the research. Check all that apply.

Population	Description	Included?
Children (The state of Georgia defines children as persons younger than 18 years of age.)		<input type="checkbox"/>
Employees or Subordinates of Investigator		<input type="checkbox"/>
Intellectually or Emotionally Challenged		<input type="checkbox"/>
Non-native English Speakers		<input type="checkbox"/>
Normal Volunteers		<input type="checkbox"/>
Patients		<input type="checkbox"/>
Pregnant Subjects		<input type="checkbox"/>
Prisoners		<input type="checkbox"/>

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.

The screenshot shows a web form with three sections:

- Drug Information:** A label "will drugs be used?:" followed by a dropdown menu set to "No". To the right is the text "If yes, ► [Add/Modify Drugs](#)".
- Investigational Device Information:** A label "Will Investigational Devices be used?:" followed by a dropdown menu set to "Select One". To the right is the text "If yes, ► [Add/Modify Devices](#)".
- Radiation Information:** A label "Will radiation be used?:" followed by a dropdown menu set to "Select One". To the right is the text "If yes, ► [Add/Modify Radiation](#)".

Associate Key Words

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

The screenshot shows a form titled "Associate Key Words with this Protocol:". Below the title is a hint: "hint: This is not a required field, it is for the PI's own benefit." The form contains two lists of key words:

- List of Possible Key Words:** A list box containing "AIDS", "HIV", and "asthma".
- List of Selected Key Words:** An empty list box.

Between the two lists are two buttons: ">>" and "<<". Below the lists is a checkbox labeled "Other" followed by a text input field. At the bottom, a hint states: "hint: The words you enter here will not appear in the table above. To enter more than one, simply separate them by a comma."

1.2.7 Associate/Upload Documents

Click on the Upload Documents link listed below.

The top screenshot shows a sidebar menu titled 'Documents Associated with this Protocol:' with a link 'Upload Documents' and a hint 'Click Here to View List of Suggested Documents'. Below the menu are buttons: 'Save my work Stay On This Page', 'Stop & Save my work Continue Application later', 'Save Copy to my IRBWISE account', and 'Submit Application for review'.

The bottom screenshot shows the 'Associate New Document' form. It includes a note: 'Note: Protocol/Project Description must be uploaded/associated for IRB to accept your application. (* Fields marked with asterisk are mandatory.)'. The form has the following fields:

- 'Enter title of the document: *' with the value 'Consent Form March 2002'.
- 'How will you be sending this document?' with radio buttons for 'Via paper copy' and 'Electronically'. The 'Electronically' option is selected, and a file path 'C:\Documents and Settings\N_Clerk\GTRO\Desk' is entered next to it.
- 'Document Type: *' with a dropdown menu showing 'Consent Form'.

At the bottom, there is a link 'Click Here to View List of Suggested Documents' and a button 'Upload/Associate This Document'.

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:

Save my work Stay On This Page	Stop & Save my work Continue Application later
Save Copy to my IRBwise account Submit Application for review	

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.

IRBWISE™

My Protocols Feedback Log Off

Review Protocol

Please review your application, then, at the bottom of this page, answer the 'Conflict of Interest' and 'Endorsement' questions and submit your application

Protocol

As Of: March 20, 2002 08:13 AM

Title: This is my protocol title.

Principal Investigator: Clark, Michelle J

Committee Assigned:

Review Types:

Originally Approved:

Current Status: New

Admin Assigned:

Last Activity: March 19, 2002 - Created

Current Approval Period:

Protocol Details

Research Team:

Name	Role
	1
	CO-PI

Research Subjects:

Question	Answer
Will the research involve direct interaction with subjects?	Yes
Number of Subjects for this Protocol:	0
Subject Gender(s) for this Protocol:	

Verify the information on this review screen as it is your protocol application.

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.

Conflict of Interest:

Conflict of Interest

a. Does any participating member, staff, students (or his/her spouse or dependant Students and employees) have any financial interest such as royalty, equity or any other payments (e.g. consulting, salary, etc...) in the sponsor or other entities having a financial interest in intellectual property, product, or service which is the subject of the proposed research?

Select One

b. Does/will any equity interest exceed \$10,000 in current value or exceed 1% of ownership interest?

Select One

c. Does/will aggregate annual payments for royalty and other payments exceed \$10,000?

Select One

d. If yes, indicate whether your potential conflict of interest has been disclosed to the GTRC Office.

Select One

Endorsements:

Endorsement

I will obtain informed consent from all subjects.

I will report to the IRB any harmful effects to the subjects.

I will renew my application if the research extends beyond one year.

I will gain IRB approval before altering the research protocol or consent forms.

I will protect the rights and welfare of human research subjects and comply with the Federalwide Assurance.

Total count: 5 items

Yes

Enter Your Name:

The PI needs to be sure to enter their name here.

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.

Approvals:

Please select one: (Please read carefully)

☐ Forward the application to the PI, MICHELLE CLARK
hint: Use only if you are a CO-PI OR SUPPORT PERSON assisting with application

☐ Forward the application directly to the IRB.
hint: Use only if you ARE AUTHORIZED to submit protocols DIRECTLY to the IRB without faculty/departmental approval

☐ Forward the application for faculty/departmental member's approval and submission to the IRB.
hint: Use only if you are NOT AUTHORIZED to submit protocols DIRECTLY to the IRB without faculty/departmental approval

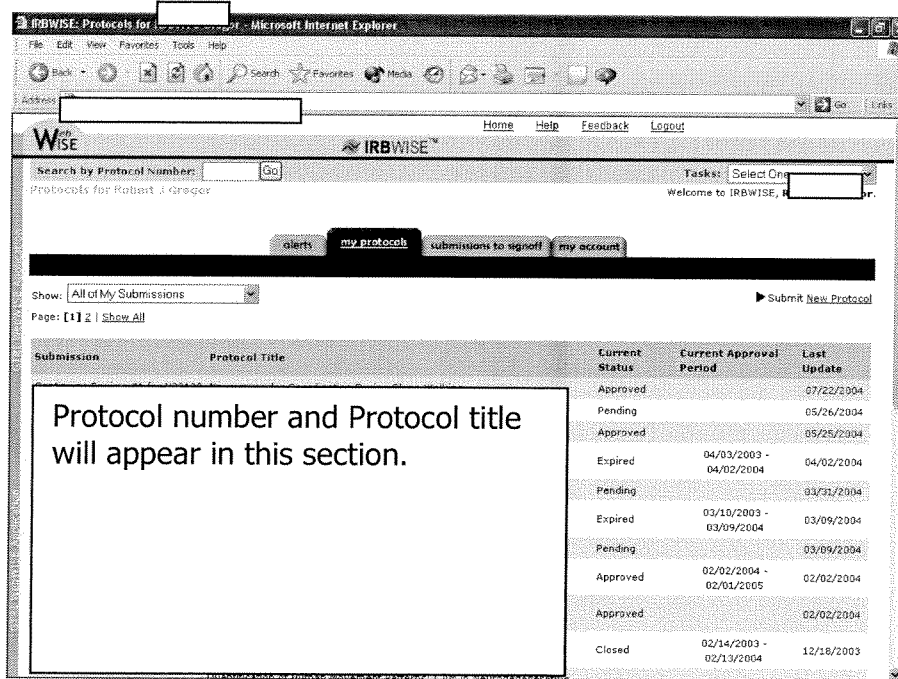
Select Faculty/Departmental Member:
Enter the first few letters of the name you are looking for

Select One

note: If the person who will approve submission of your protocol is not on this list, please [submit an email](#) saying who it is by [clicking here](#).

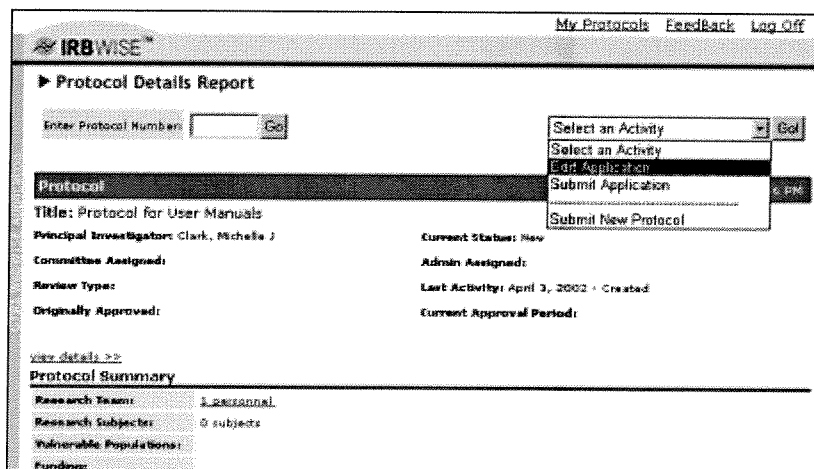
1.2.10 Pre-Submission Protocols

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



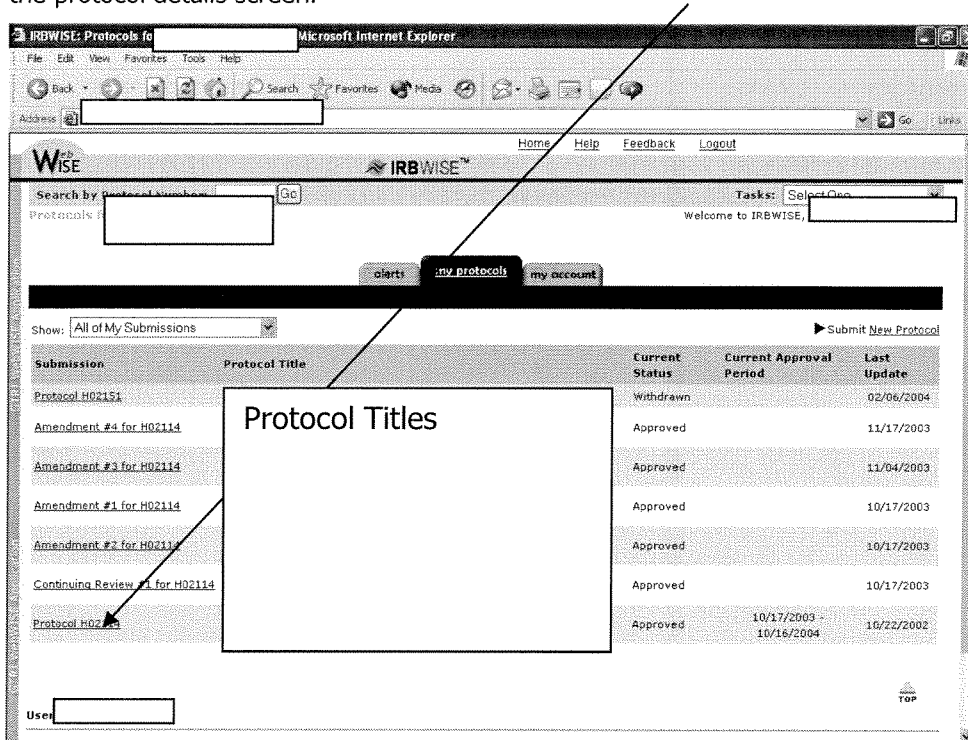
Only protocols which have not been submitted for approvals can be edited in this pre-submission process. Click on the hyperlink that states "view" with the status of "new."

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.



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

The screenshot shows a web browser window titled "IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer". The browser's address bar is empty. The web application has a header with "Web WISE" and "IRBWISE™" logos, and navigation links for "Home", "Help", "Feedback", and "Logout". Below the header is a search bar with the text "Search by Protocol Number:" and a "Go" button. To the right of the search bar is a "Tasks:" dropdown menu set to "Select One" and a "Welcome to IRBWISE," message with a small input field. The main content area has tabs for "submission", "permissions", and "history". Below these tabs are links for "summary" and "details". The "summary" tab is active, showing details for "Protocol H02114" as of "July 31, 2004 01:00 PM". The details include: "Title:" (redacted), "Principal Investigator:" (redacted), "Admin Assigned: Alice G Basler", "Committee Assigned: Committee 1", "Review Type: Expedited Review", "Current Status: Approved", "Last Activity: 11/17/2003 - Amendment #4 for H02114 Approved Consent Forms Stamped", "Original Approval Start: 10/22/2002", and "Current Approval Period: 10/17/2003 - 10/16/2004". Below this is a "Protocol Summary" section with a "print" button. The summary is presented in a table-like format with labels and values.

Protocol Description:	
Protocol Department:	
Research Personnel:	1 personnel
Researcher Certifications:	2 researchers have active "Human Subjects Training Certification" certifications certification details
Amendments:	4 Amendment requests created, 4 approved
Continuing Reviews:	1 Continuing Review request created, 1 approved

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

IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media

Address: Go Links

Web WISE IRBWISE™

Home Help Feedback Logout

Search by Protocol Number: Go

Summary for Protocol H02114

Welcome to

Tasks: Select One

- Select One
- Grant Access To Protocol
- Report Adverse Event
- Report SAE
- Request Amendment**
- Request Continuing Review
- Change Your Password
- Submit New Protocol

submission permissions history

summary details

Protocol H02114

Title:

Principal Investigator:

Admin Assigned: Alice G Basler

Committee Assigned: Committee 1

Review Type: Expedited Review

Current Status: Approved

Last Activity: 11/17/2003 - Amendment #4 for H02114 Approved Consent Forms Stamped

Original Approval Start: 10/22/2002

Current Approval Period: 10/17/2003 - 10/16/2004

print

Protocol Summary

Protocol Description:	<input type="text"/>
Protocol Department:	<input type="text"/>
Research Personnel:	1 personnel
Researcher Certifications:	2 researchers have active "Human Subjects Training Certification" certifications certification details
Amendments:	4 Amendment requests created, 4 approved
Continuing Reviews:	1 Continuing Review request created, 1 approved

IRBWISE User Guide

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

IRBWISE: Request Amendment - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail News RSS Feeds

Address: Go Links

Home Help Feedback Logout

IRBWISE™

Search by Protocol Number: Go Tasks: Select One

Welcome to IRBWISE,

► Request Amendment

INFORMATION Enter Amendment information and submit at the bottom of this page.

Amendment for H02114 As Of: July 31, 2004 01:04 PM

Admin Assigned: **Current Status:** New

Committees Assigned: **Last Activity:** 07/31/2004 - Created

Review Type: **Date Approved:**

Protocol H02114 As Of: July 31, 2004 01:04 PM

Title: **Current Status:** Approved

Principal Investigator: **Last Activity:** 07/31/2004 - Amendment for H02114 Created

Admin Assigned: Alice G. Basler **Original Approval Start:** 10/22/2002

Committee Assigned: Committee 1 **Current Approval Period:** 10/17/2003 - 10/16/2004

Review Type: Expedited Review

[view approved Protocol details >>](#)

Type of Amendment:

Changes in Procedures/Protocol Describe the requested changes and how they affect the risk/benefits of Protocol: [editor window](#)

Associate a document having the Description of the Procedures at the Associate Documents section.

Change in Study Personnel ► [Add/Modify Certified Personnel](#)

Change of Site ► [Add/Modify Site Location](#)

Type of Modification:

Changes in Procedures/Protocol: Describe the requested changes and how it affects the risk/benefits of Protocol. I've changed the consent form and added Nadia Zitman as a Co-PI.

Change in Study Personnel: [Add/Modify Certified Personnel](#)

Change of Site: [Add/Modify Site Location](#)

Change in Enrollment: Current approved#:15 resulting total to

Change in Consent Form: [Add/Modify Consent Form](#)
Explain the reason for changing the Consent form:

Advertisement: [Add/Modify Advertisements](#)

Check All That Apply:

☐ Newspaper Ad

☐ Radio Announcement

Name of Paper:

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*.

IRBWISE™

Associate Personnel

This modification request will not take effect until it is approved by the board.

Select Person: Enter the first few letters of the name you are looking for, then highlight the exact entry in the drop down menu below.
Zitman

Select Role:

(If there is a person associated with the protocol who is not in the list above, click here.)

IRBWISE™

Mr. Protocol Feedback Log Off

Associate Documents

This modification request will not take effect until it is approved by the board.

Associate Documents

(* Fields marked with asterisk are mandatory.)

Enter title of the document: * Example Consent Form March 2002

How will you be sending this document? ☐ Via paper copy or ☒ Electronically

Document Type: *

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

IRBWISE User Guide



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 with the submission process.

Save my workContinue Application now	Stop & Save my WorkContinue Application Later
Save Copy to my IRBwise account & Submit application for review	

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

[My Protocols](#) [FeedBack](#) [Log Off](#)

IRBWISE™

► Review Modification

Protocol H020046 As Of: March 26, 2002 03:45 PM

Title: Example Protocol

Principal Investigator: Kimble, Sebastian C.

Committee Assigned: Committee 1

Review Type:

Originally Approved: March 6, 2002

Current Status: Approved

Admin Assigned:

Last Activity: March 26, 2002 - Modification #0 Created

Current Approval Period: March 6, 2002 to March 5, 2003

Modification 1 for Protocol H020046 As Of: March 26, 2002 03:45 PM

Current Status: New

Review Type:

Committee Assigned:

Date Approved:

Last Activity: March 26, 2002 - Created

Admin Assigned:

Modification Request Details

Documents:

Currently Approved

View	Title	Type	Approval Date
View	Example Document	Interview	March 06, 2002

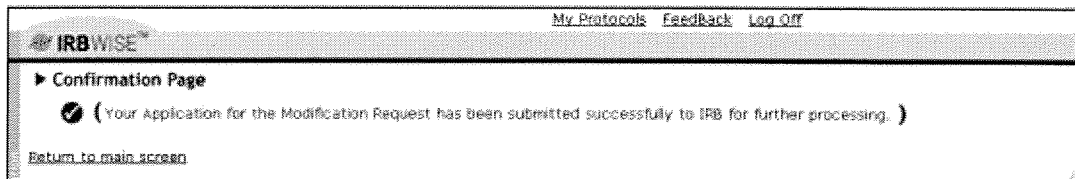
Total count: 1 item

Requested Change

Change	View	Title	Type	Approval Date
Approved, no change	View	Example Document	Interview	March 06, 2002
New, added	View	Example Consent Form	Consent Form	March 2002

Total count: 2 items

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 screenshot shows the IRBWISE web application interface. At the top, there's a navigation bar with links for Home, Help, Feedback, and Logout. Below this is a search bar and a welcome message. The main content area is divided into tabs: alerts, my protocols (selected), and my account. A table titled 'All of My Submissions' displays a list of protocols and their status. A box labeled 'Protocol Titles' is overlaid on the table, and an arrow points from the text above to the 'Protocol H02114' row.

Submission	Protocol Title	Current Status	Current Approval Period	Last Update
Protocol H02151		Withdrawn		02/06/2004
Amendment #4 for H02114		Approved		11/17/2003
Amendment #3 for H02114		Approved		11/04/2003
Amendment #1 for H02114		Approved		10/17/2003
Amendment #2 for H02114		Approved		10/17/2003
Continuing Review #1 for H02114		Approved		10/17/2003
Protocol H02114		Approved	10/17/2003 - 10/16/2004	10/22/2002

IRBWISE User Guide

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

The screenshot shows a Microsoft Internet Explorer browser window displaying the IRBWISE web application. The browser's address bar shows the URL. The application's navigation bar includes links for Home, Help, Feedback, and Logout. A search bar is present with the text "Search by Protocol Number:" and a "Go" button. The main content area is titled "Summary for Protocol H02114" and includes a "Welcome to IRBWISE" message. Below this, there are tabs for "submission", "permissions", and "history". The "summary" tab is selected, showing details for Protocol H02114. The details include the Title, Principal Investigator, Admin Assigned (Alice Q. Casper), Committee Assigned (Committee 1), Review Type (Expedited Review), Last Activity (11/17/2003 - Amendment #4 for H02114 Approved Consent Forms Stamped), Original Approval Start (10/22/2002), and Current Approval Period (10/17/2003 - 10/16/2004). A "print" button is located at the bottom right of the details section. Below the details, there is a "Protocol Summary" section with a "print" button. The "Protocol Summary" section includes a "Protocol Description" field, which is currently empty. Other fields in the summary include "Protocol Department" (GTRC), "Research Personnel" (1 personnel), "Researcher Certifications" (2 researchers have active "Human Subjects Training Certification" certifications), "Amendments" (4 Amendment requests created, 4 approved), and "Continuing Reviews" (1 Continuing Review request created, 1 approved).

IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media

Address: [Redacted] Go Links

Home Help Feedback Logout

IRBWISE™

Search by Protocol Number: [Redacted] Go Tasks: Select One

Summary for Protocol H02114 Welcome to IRBWISE [Redacted]

submission permissions history

summary details

Protocol H02114 As Of: July 31, 2004 12:53 PM

Title: [Redacted]

Principal Investigator: [Redacted]

Admin Assigned: Alice Q. Casper

Committee Assigned: Committee 1

Review Type: Expedited Review

Last Activity: 11/17/2003 - Amendment #4 for H02114 Approved Consent Forms Stamped

Original Approval Start: 10/22/2002

Current Approval Period: 10/17/2003 - 10/16/2004

print

Protocol Summary

Protocol Description: [Redacted]

Protocol Department: GTRC

Research Personnel: 1 personnel

Researcher Certifications: 2 researchers have active "Human Subjects Training Certification" certifications

Amendments: 4 Amendment requests created, 4 approved

Continuing Reviews: 1 Continuing Review request created, 1 approved

IRBWISE User Guide

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

IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail

Address Go Links

Wise IRBWISE™ Home Help Feedback Logout

Search by Protocol Number: Go

Summary for Protocol H02114

Tasks: Select One
Select One
Grant Access To Protocol
Report Adverse Event
Report SAE
Request Amendment
Request Continuing Review
Change Your Password
Submit New Protocol

Welcome to

submission permissions history summary details

Protocol H02114

Title:

Principal Investigator:

Admin Assigned: Alice G. Approved

Committee Assigned: Committee 1

Review Type: Expedited Review

Last Activity: 07/31/2004 - Amendment for H02114 Created

Original Approval Start: 10/22/2002

Current Approval Period: 10/17/2003 - 10/16/2004

Protocol Summary print

Protocol Description:	<input type="text"/>
Protocol Department:	<input type="text"/>
Research Personnel:	1 personnel
Researcher Certifications:	2 researchers have active "Human Subjects Training Certification" certifications certification details
Amendments:	4 Amendment requests created, 4 approved
Continuing Reviews:	1 Continuing Review request created, 1 approved
SAE's/Adverse Event's:	none

IRBWISE User Guide

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.

The screenshot shows the IRBWISE web application in a Microsoft Internet Explorer browser window. The page title is "IRBWISE: Request Continuing Review". The browser's address bar is empty. The page has a navigation bar with links for Home, Help, Feedback, and Logout. Below the navigation bar is a search bar labeled "Search by Protocol Number:" with a "Go" button. To the right of the search bar is a "Tasks:" dropdown menu set to "Select One" and a "Welcome to IRBWISE," message with a redacted box.

The main content area is titled "Request Continuing Review". It contains an "INFORMATION" box with the following text:

Current inaccuracies of approved changes should be reported in the continuing review application and an amendment is not needed. Any forthcoming changes should be done via a separate amendment request.

If your protocol approval year is 1998 or before, please submit a **new protocol application** instead of a continuing review request, incorporating all amendments, updated consent, permission and assent forms, funding information, etc. that have occurred since the study's inception.

Below the information box is a section for "Continuing Review for H02114". It displays the following information:

Admin Assigned:
Committees Assigned:
Review Type:

Current Status: New
Last Activity: 07/31/2004 - Created
Date Approved:

As Of: July 31, 2004 01:11 PM

Below this section is a section for "Protocol H02114". It displays the following information:

Title:
Principal Investigator:
Admin Assigned: Alice G. Basler
Committee Assigned: Committee 1
Review Type: Expedited Review
[view approved Protocol details >>](#)

Current Status: Approved
Last Activity: 07/31/2004 - Continuing Review for H02114 Created
Original Approval Start: 10/22/2002
Current Approval Period: 10/17/2003 - 10/16/2004

As Of: July 31, 2004 01:11 PM

Below the protocol information is a section for "Subject Information:". It contains a question: "Does this Protocol involve direct interaction with human subjects?" with a "Select One" dropdown menu and a link "If yes, Click Here".

At the bottom of the page is a section for "Review Approved Protocol Information: *".

IRBWISE User Guide

IRBWISE: Request Continuing Review - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Media Print Mail

Address Go Links

Subject Information:

Does this Protocol involve direct interaction with human subjects? 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.) If so, provide a summary: [editor window](#)

Has any regulatory agency audited this Protocol during the current approval period? If so, associate a copy of the report below.

Have any abstracts or publications resulted from this study? 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.

IRBWISE™ Maintenance SiteMap Reports & Queries My Protocols Feedback Log Off

Request a Protocol Renewal

Notes: This renewal application may only be used to request an extension in the approval period for a protocol. If you want to modify any part of your protocol, you must file a request for a [Modification](#). If you wish to modify your protocol and extend its expiration date, you must file both forms.

Protocol #020046 as of: April 4, 2002 09:48 AM

Title: Example Protocol

Principal Investigator: Kimble, Sebastian

Committee Assigned: Committee 1

Review Types:

Originally Approved: March 6, 2002

Current Status: Approved

Admin Assigned:

Last Activity: March 26, 2002 - Renewal #1 Submitted to IRB by PI

Current Approval Period: March 6, 2002 to March 5, 2003

Renewal 1 for Protocol #020046

Current Status: Submitted to IRB

Committee Assigned:

Date Approved:

[View approved protocol details >>](#)

Subject Information:

Does this protocol involve direct interaction with human subjects? If yes, [Click Here](#)

Review Approved Protocol Information:

Please review protocol information for accuracy. [Click Here](#)

Other Information:

Is/are there any recent

Renewal Application:

The first popup asks questions about human subjects involvement over the past approval period. Answer the appropriate questions and click the Save and Continue button.

Request a Protocol Renewal

Select One:

☐ The research has not begun/no subject has been enrolled.
Enrollment is closed and aspects of subjects involvement is complete.

☐ If enrollment is closed, please select one:

Date enrollment closed:

☐ Research activities are complete or will not continue beyond the expiration date

☒ Research involving human subjects is ongoing and will continue beyond the current approval period.

Description of activities involving human subjects since last IRB review:

How many new subjects were enrolled/studied at university sites (or by community-based researchers)?

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.

Please Review the Following for Accuracy:

Certified Personnel:

Name	Role	Approval Date
Kimble, Sebastian	PI	March 06, 2002
	CO-PI	March 06, 2002

Total counts: 2 Names

Funding Sources:

Funding Source	Approval Date
Wakefield/Beasley & Associates/Atlanta, GA	March 06, 2002

Total counts: 1 Item

Study Locations:

Study Locations	Approval Date
None	

Consent Forms:

Filename	Approval Date
Example Consent Form March 2002	March 26, 2002
Example Document	March 06, 2002

Total counts: 2 Items

Please select one:

☒ This protocol information is correct for the renewal period.

☐ This protocol information is incorrect for the renewal period. I will submit a modification request in addition to the renewal request.

Notes: If any information below is incorrect or not current, please [file a modification request](#) (this will open in a new window).

IRBWISE User Guide

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

Other Information:

Is there more 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 2000 char.) No ☒ If so, provide a summary:

Has any regulatory agency audited this protocol during the consent approval period? No ☒ If so, associate a copy of the report below:

Have any adverse or publications resulted from this study? No ☒ If so, please list them:

Associated Documents:

Associate documents with the renewal application that will be linked or mailed.

Note: If you through human subjects will continue, you must submit for approval all forms that will be utilized during the proposed continuation period.

[Click here to Associate Documents](#)

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

Endorsements:

Endorsement

I will obtain informed consent from all subjects.

I will report to the IRB any harmful effects to the subjects.

I will renew my application if the research extends beyond one year.

I will gain IRB approval before altering the research protocol or consent forms.

I will protect the rights and welfare of human research subjects and comply with the provisions of Georgia Tech's Federallywide Assurance.

Total records: 5 items

☒ Yes ☐ No

Enter Your Name:

Approvals

Please select one:

☒ Forward the application to PI for submission. (Use if you are a CoPI OR support person assisting with application.)

☐ Forward the application directly to IRB. (Use if you are the PI.)

Comments:

4.0 Adverse Events

To report an adverse event or a serious adverse event, 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 screenshot shows the IRBWISE web application interface. At the top, there is a navigation bar with links for Home, Help, Feedback, and Logout. Below this is a search bar labeled 'Search by Protocol Number:' and a 'Go' button. A 'Tasks:' dropdown menu is set to 'Select One'. A 'Welcome to IRBWISE,' message is followed by a user name field. Below the navigation bar, there are three tabs: 'alerts', 'my protocols' (which is selected), and 'my account'. A 'Show:' dropdown menu is set to 'All of My Submissions'. A 'Submit New Protocol' link is visible. The main content area displays a table of submissions. A red box highlights the 'Protocol Title' column, and a red arrow points to the 'Protocol H02114' link.

Submission	Protocol Title	Current Status	Current Approval Period	Last Update
Protocol H02151		Withdrawn		02/06/2004
Amendment #4 for H02114		Approved		11/17/2003
Amendment #3 for H02114		Approved		11/04/2003
Amendment #1 for H02114		Approved		10/17/2003
Amendment #2 for H02114		Approved		10/17/2003
Continuing Review #1 for H02114		Approved		10/17/2003
Protocol H02114		Approved	10/17/2003 - 10/16/2004	10/22/2002

IRBWISE User Guide

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

IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail News RSS

Address: Go

Home Help Feedback Logout

IRBWISE™

Search by Protocol Number: Go Tasks: Select One

Summary for Protocol H02114 Welcome to IRBWISE,

[submission](#) [permissions](#) [history](#)

[summary](#) [details](#)

Protocol H02114 As Of: July 31, 2004 01:17 PM

Title: Approved

Admin Assigned: Alice G Basler Last Activity: 07/31/2004 - Continuing Review for H02114 Created

Committee Assigned: Committee 1 Original Approval Start: 10/22/2002

Review Type: Expedited Review Current Approval Period: 10/17/2003 - 10/16/2004

Protocol Summary [print](#)

Protocol Description:	<input type="text"/>
Protocol Department:	<input type="text"/>
Research Personnel:	1 personnel
Researcher Certifications:	2 researchers have active "Human Subjects Training Certification" certifications certification details
Amendments:	4 Amendment requests created, 4 approved
Continuing Reviews:	1 Continuing Review request created, 1 approved
SAE's/Adverse Event's:	none

IRBWISE User Guide

Click on **Report SAE**

IRBWISE: Summary for Protocol H02114 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail

Address: [URL] Go Links

Home Help Feedback Logout

Web WISE IRBWISE™

Search by Protocol Number: [Input] Go

Summary for Protocol H02114

Tasks: Select One

- Select One
- Grant Access To Protocol
- Report Adverse Event
- Report SAE
- Request Amendment
- Request Continuing Review
- Change Your Password
- Submit New Protocol

Welcome to

submission permissions history

summary details

Protocol H02114

Title: [Input]

Principal Investigator: [Input]

Admin Assigned: Alice G [Input]

Committee Assigned: Committee 1

Review Type: Expedited Review

Current Status: Approved

Last Activity: 07/31/2004 - Continuing Review for H02114 Created

Original Approval Start: 10/22/2002

Current Approval Period: 10/17/2003 - 10/16/2004

Protocol Summary

print

Protocol Description:	[Input]
Protocol Department:	[Input]
Research Personnel:	1 personnel
Researcher Certifications:	2 researchers have active "Human Subjects Training Certification" certifications
	certification details
Amendments:	4 Amendment requests created, 4 approved
Continuing Reviews:	1 Continuing Review request created, 1 approved
SAE's/Adverse Event's:	none

IRBWISE User Guide

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.

IRBWISE: Report SAE - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail

Address [Redacted] Go Links

Home Help Feedback Logout

Web WISE IRBWISE™

Search by Protocol Numbers: [Redacted] Go Tasks: Select One

Welcome to IRBWISE, [Redacted]

► Report SAE

INFORMATION Enter SAE information and submit at the bottom of this page.

SAE for H02114 As Of: July 31, 2004 01:19 PM

Admin Assigned: [Redacted] Current Status: New
Committees Assigned: [Redacted] Last Activity: 07/31/2004 - Created
Review Type: [Redacted] Date Acknowledged: [Redacted]

Protocol H02114 As Of: July 31, 2004 01:19 PM

Title: [Redacted] Current Status: Approved
Principal Investigator: [Redacted] Last Activity: 07/31/2004 - SAE for H02114 Created
Admin Assigned: Alice C. Gasser Original Approval Start: 10/22/2002
Committee Assigned: Committee 1 Current Approval Period: 10/17/2003 - 10/16/2004
Review Type: Expedited Review
[view approved Protocol details >>](#)

SAE Form:

Where was the subject enrolled? Select Location

Date of SAE: July 31 2004

Subject's Initials or Study #: [Redacted]

Type of Report: Select One

IRBWISE User Guide

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

A narrative, and supporting documentation describing the SAE, **MUST** be associated with this form. [Click Here to Associate Documents](#)

Save my Work
Continue Application Now

Stop & Save my Work
Continue Application Later

Save Copy to my IRB Wise account &
Submit application for review

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**.

Cause of an or the following:

Is it possible or likely that the SAE was caused by the drug, device, radiation, or procedure?

Has the consent form been revised as a result of the SAE?

List of supporting documents:

Title	Type
none	

Comment:

Please select one:

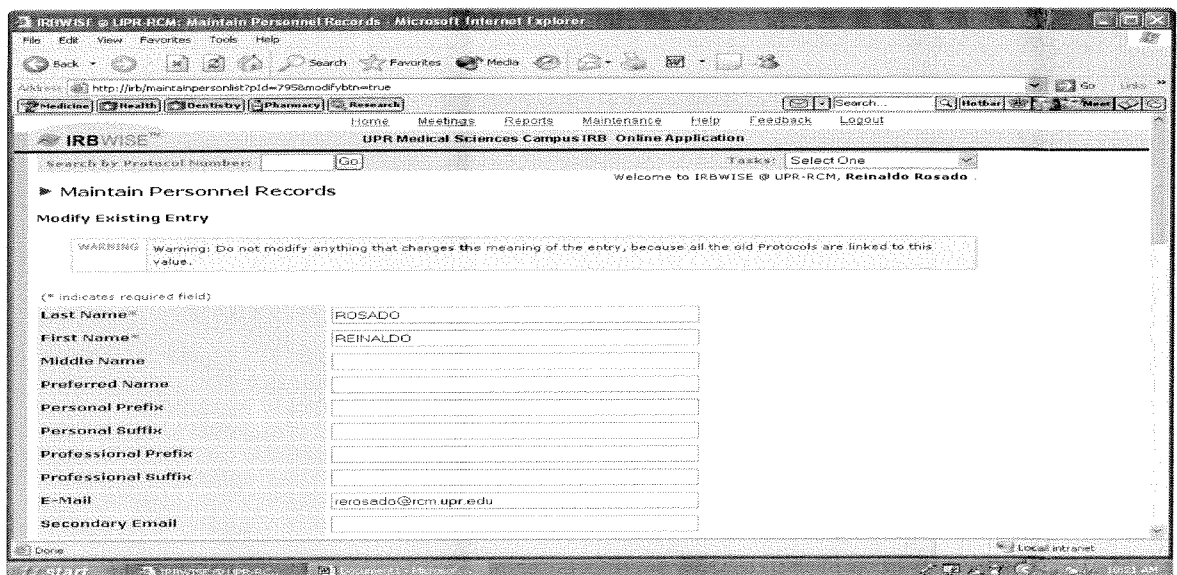
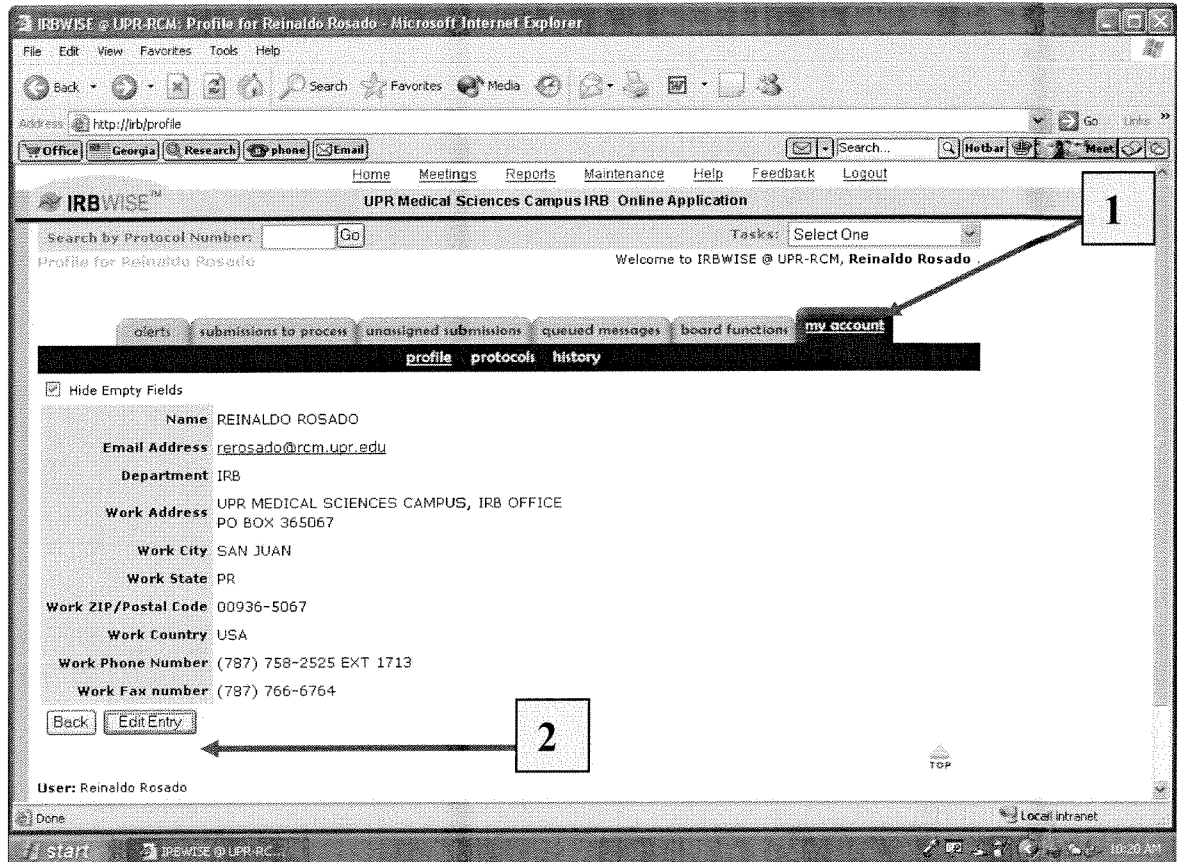
☐ Forward the report to PI. (Use if you are a CoPI OR support person assisting with application.)

☐ Forward the report directly to IRB. (Use if you are the PI.)

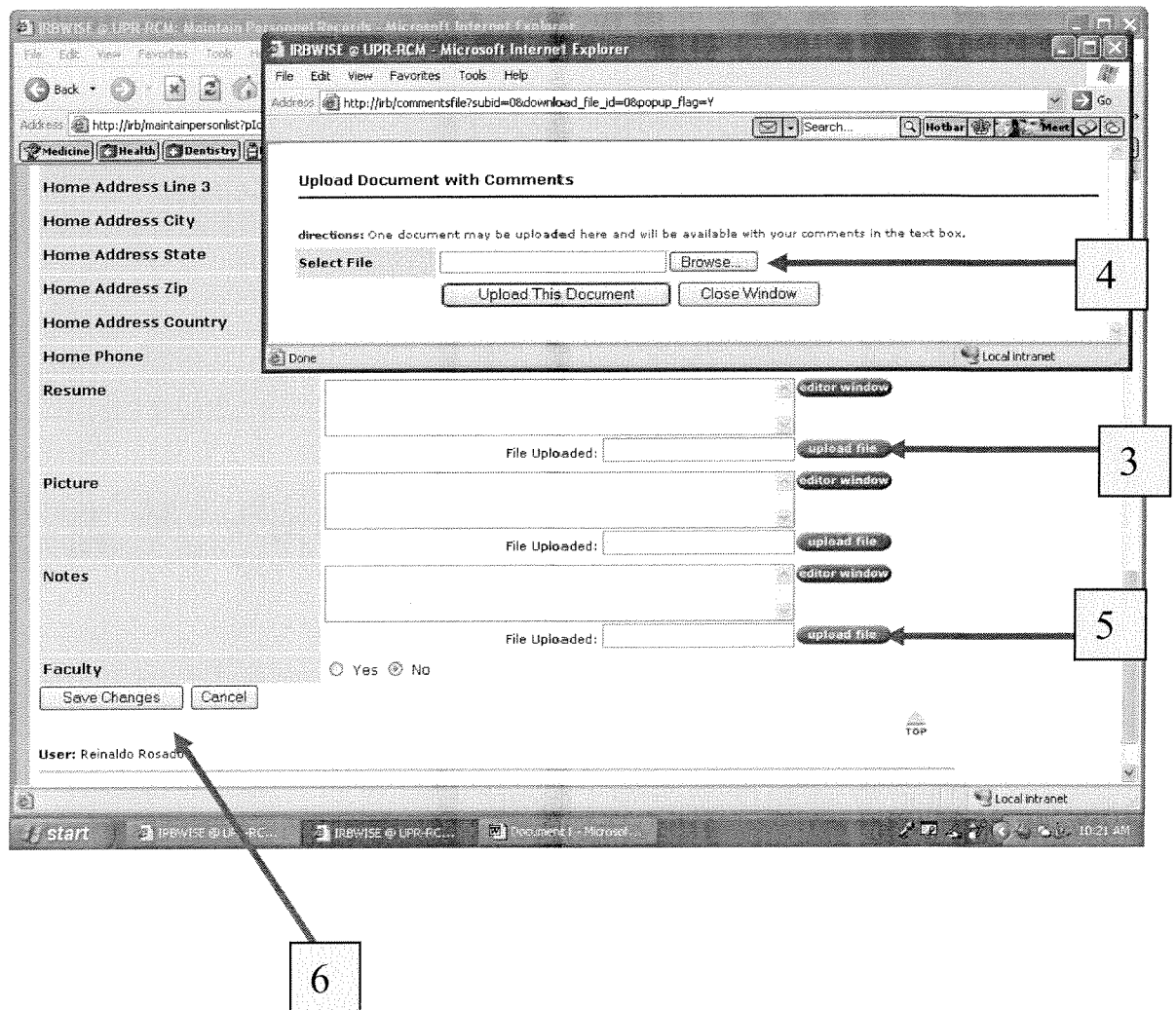
Change SAE Information Submit SAE

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 see 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 your 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
IRB Wise® 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
IRB Wise System Administrator

Reinaldo Rosado
IRB ADMINISTRATOR