

User's Manual

Version 10.03.02

Contents

Introduction
My Account Information
Profile3
Change Password3
Biosketch, CV, Pubs
Training History6
Medical Licenses
Signature
Notes9
Announcements
Operating Procedures
View Correspondence
All Department Reports
Department Reports

Introduction

The **My Assistant** menu group in iRIS[™] is available to all users. It contains various aspects of your account information, announcements, operating procedures, and a variety of other helpful items (depending on how your system is configured).



My Account Information

My Account Information allows users to quickly access and update personal information, change passwords, add or view any posted training records, medical licenses or CVs, upload a .jpg image of the users signature (used when signing off on Outcome letters), complete a financial disclosure, set signoff ability, and view vaccination history. The availability of these tabs is dependent on how your system is configured; do not be alarmed if your screen is missing one or more menu items. Some screenshots may also vary depending on what features are turned on or off and whether any labels have been renamed by your System Administrator.

When you first click on the My Account Information link, a new page will open listing your personal contact information

iRIS 10.03.02

				\frown
My Account - Su	san Investigator			Back
				Save Changes
Profile	* Last Name:	Investigator	First Name: Susan * Middle Name:	
Change Password	Suffix:		Personal Question:	
Contact Management	Prefix:		Personal	
Proposal Info	* Job Title: F	Physician	Contact Information (* fields requir	ed)
Other System IDs	Status: A	Active	* Email Address:	Email Address
Biosketch, CV, Pubs	Degree:	\checkmark	* Phone:	
Training History	Is Faculty:	🔍 Yes 🔍 No	* Cell Phone:	-
Medical Licenses	* Employee ID:		* Fax:	
Signature	Specialty:	Add Remove	Personal URL:	
Diselectron			*Mailing Address: 123 Missouri Court	
Disclosures	Relationship to the Institution	○ Affiliated ○ Non-Affiliated		\sim
Signoff Availability	Representational	O Scientist		\sim
Vaccination History	Representative of		Physical Address:	
Notes	specific entity:	Add Remove		\sim

Profile

The Profile tab is where you can view and edit your personal information.

You can change any of the information listed in the screenshot above except for your Department (or Site) association on this screen and your Job Title. This information must be approved and changed by your iRIS[™] Administrator. Additionally, some fields like the phone number, email, employee ID, and others may be read-only if your system operates with an LDAP user directory.

It is now possible to turn off and on the visibility of many of the fields on the Profile tab via system properties, as well as set whether or not they are required. These properties are available under System User Profile Settings.

Two configurable fields are also now available. These fields can be configured under System Administration > List Configuration and Maintenance > System Setup > Setup System Labels. The Configurable Fields appear under the List of Labels for System on the System Label screen.

Remember to click on the **Save Changes** button whenever you make changes to this page. Otherwise, when you exit this page, your changes will not be applied. (Some fields may be designated as required as described above and you cannot Save Changes until they are entered.)

Note: It is important to have your current e-mail address listed. iRIS[™] sends out important notifications regarding your projects. If you do not have your correct email address, you will not receive these notifications.

Note: The System Administrator has the ability to add customized links to the My Assistant tab. The property system.use_custom_menus, within System Administration -> System Configuration -> System Default Settings allows the System Administrator to turn on or off this feature. These links may either be Internal or External. The Internal links will link directly to a page within iRIS.

Change Password

Click on the Change Password tab to change your password.

My Account - Su	an Investigator	R Back
		Save Changes
Profile		
Change Password	*Old Password:	
Contact Management	*New Password:	
Proposal Info	*New Password Verify:	
Other System IDs		
Biosketch, CV, Pubs		

This will open a page similar to the one shown in the screenshot above. In order to change your password, you must supply your **Old Password**, enter in the desired **New Password**, and verify the desired New Password in the appropriate fields. Click **Save Changes** to complete the change in your password. Your instance of iRIS may have settings that do not allow you to use the last few passwords you have used in the past.

Biosketch, CV, Pubs

You can upload and view your Biosketch, CV, and Publications from this tab.

My Account - Susan Investigator							
	_						
Profile Curriculum Vitae (CV) or Biosketch • Add CV or Biosketch							
Change Password	Remove	Edit	Document Type	Version Date	Title		View Document
Contact Management Proposal Info	8		Curriculum Vitae (CV)	10/27/2016	cv		
Other System IDs	IDs Publications • Add Publication						
Biosketch, CV, Pubs	Remove	Edit	Publication Type	Publication date	Publication Title		View Attachment
Medical Licenses	No Public	o Publication has been added.					

The above screenshot is what your Biosketch, CV, and Publications page may look like. From this page you will be able to upload your professional experience and other relevant work you have conducted. This tab will contain any Curriculum Vitae/Biosketch/Publications you may have stored in iRIS. All three of these documents can be added by you or your System Administrator.

Remove a Document – To delete the CV/Publications record from iRIS, click the **W** button in the Remove Column.

Edit a Document – Clicking the 📉 icon in the Edit column opens up the specific, editable details for the document.

View Document – The icon of the document opens a new window that will display the uploaded document.

Add a New CV or Biosketch – Click on the Add CV or Biosketch button to open a new page similar to the one shown in the screenshot below.

					Save Uploaded file to IRIS
Profile Change Password Contact Management	Edit the Document You Selected				
Proposal Info Other System IDs	*Document Type:	 Curriculum Vitae (CV) Biosketch 			
Biosketch, CV, Pubs	*Title:				
Training History	Version Date:				
Medical Licenses		Upload			
Signature	Load the document into iRIS:	Name	View the Document	Download the Document	
Disclosures		No Document has been uploaded.]
Signoff Availability					

In the above screen shot you can determine which document type you wish to upload. In this particular case, we will be uploading a **Curriculum Vitae(CV)** so we will select the corresponding button.

Title –The title of the CV (*required field).

Version Date – The version date of the CV.

Load the document into iRIS – Click on the **Upload** button to upload your CV document into iRIS. The document must be either .doc or .rtf file format in order for iRIS to accept the upload.

After you upload a document, the page will refresh and a Word icon will populate to the left of the CV information When you are finished adding the information for the CV, click **Save Uploaded file to IRIS** button and you will be returned to the previous screen.

Click **Add Publication** and the following screen will appear. Each publication entry can have a Publication Type, Publication Title, and Publication Date. The publication document itself can be loaded as an attachment. Additionally, each publication listing can be associated to a particular project or study and/or certain keywords.

My Account - Admini	istrator										🖪 Back	c
											Save Char	nges
Profile Change Password Biosketch, CV, Pubs Education History	Publication Type: Publication Title:	Journal Medica	▼ or Ne 1 Jour	w Type	*							
Medical Licenses President Signature Notes	ublication Date :	11/22/201	2	•						File Attachm	ent	
Fil	le Attachment :	Delete No File At	Edit tachmen	t has been added				Title				
									C Add	Study Associ	ation	
St	tudy ssociation :	Delete No Associ	ation has	been added			Stu	dy Title				
									- Add	Keyword		
Ke	eyword :	Delete No Keywo	ord has b	een added			Ke	yword				

Note: If you enter a New Type of publication, once you click **Save Changes**, this new type will be added to the list of Publication Types and other users will have the option to select it as well. Keep this in mind so that you do not enter personal information in the New Type field.

Training History

You can view your training history by clicking on this tab.

My Account - Susan Investigator							
Profile	Training Group - Course		Course Date	Course Expiration	Score		
Contact Management		No training records have	e been added to this user				
Proposal Info							
Other System IDs							
Biosketch, CV, Pubs							
Training History							

The screenshot above is an example of what the Training History page may look like. The items listed in the table may include: the associated **Training Group**, the **Course** title, **Course Date** (the day the training was taken), **Course Expiration** (date the training expires), and the **Score** received for the training. In this screenshot, no training courses have been applied to the user. This information must be approved and changed by your iRIS Administrator.

Medical Licenses

Any Medical Licenses you may have can be found in this tab. You and/or the Administrator can upload this information.

My Account - Su	ısan Inv	/estigato	or					🖪 Back
Profile	Medica	al Licens	es					Add License
Change Password	Remove	Edit/View	License Number	View License	Version Date	License Type	Expiration Date	State of Issue
Proposal Info	8	2	12345		10/01/2016	Medical	10/25/2018	ARKANSAS
Other System IDs								
Biosketch, CV, Pubs								
Training History								
Medical Licenses								

Remove License– To delete a Medical License record, click the 😢 icon in the Remove column.

Edit/View – Click on the kicon in this column to open up the details for the specific license you wish to view. This is where you can find editable details for the Medical License record and make any necessary changes.

View License – Click on the icon in this column to open a document viewer and see the attached document.

Add License – Click on the Add License button to add a document. This will open a new page like the one shown below:

My Account - Su	ısan Investigator				🔳 Back
					Save Changes
Profile					
Change Password	License Type:	Medical 🗸 or New Type			
Contact Management	License Number:	12345			
Proposal Info	Expiration Date :	10/27/2016			
Other Custom IDs	State of Issue :	AL 🗸			
Other System IDs	Version Date:	10/27/2016			
Biosketch, CV, Pubs		Upload			
Training History		Name	View the Document	Download the Document	
Medical Licenses	Load the document into iRIS:		E C		
Signature		tmp_51748_0_License.docx		Download	
Disclosures			п	л	1

License Type – Select the type of license that you are adding from the dropdown menu or, if not listed, you may add a license type by entering the selection in the **New Type** text box.

Note: If you enter a New Type, once you save your Medical License it will be added to the list of License Types and other users will have the option to select it as well. Keep this in mind so that you do not enter personal information in the New Type field.

License Number – The medical license number.

Expiration Date – The expiration date for this specific medical license.

State of Issue - Select the state that issued your medical license from a dropdown list.

Version Date – The version date of the medical license.

Load the document into iRIS - Click Upload and you can attach a document.

Download the Document – Click Download, and confirm by clicking the OK button. You will be brought to a new page containing instructions on downloading items from iRIS. A yellow bar may populate at the top of your browser. Click the bar and indicate in the menu **Download File...**

Download the License		Back
Instruct Step 1: I vour brow	ions: If your browser blocks pop-ups, then after a few moments a bar similar to the one shown below may appear in wser.	Duck
🐣 To he	ip protect your security, Internet Explorer blocked this site from downloading files to your computer. Click here for options	
Simply cl	lick on the bar and a small drop down list will appear. Click Download File from the list of options. Download File What's the Risk? More information	
Step 2: I this is not to Save i	In a few moments, your browser will prompt you to either Open or Save the file (see example below). Note: t the actual File Download box, it is only a picture. In order to Check-out the document and edit it, you will need it to your workstation.	
	None study, documero-dummy2.doc Type: Heaved Wave Documery, 22.9.8 Download Complete	
	Fine: 64:22:42:146 Uppen Sum Caural While first from the Internet can be updated for space do not oppen or south the Internet for the update do	
To do so, workstati Once you as shown or Close I	, click Save . This will open up a window similar to the one shown below that allows you to choose where in your ion you would like to save the document. J've selected where you will save the document, click Save . After this, the Download Complete box will appear below. From here you can choose to open the document to edit it, open the folder that contains the document, the Download Complete box to edit the document later.	
Step 3: I box that documen To cancel remain in	IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete you click the Download Complete button in iRIS. This allows you to check the document (or upload the t)back into iRIS once you've finished editing it. I the Document Check-out, click Cancel . Note: If you've already saved the file to your computer, the file will a your computer, however you will simply lose the option of checking the document back in.	

This will cause a popup window that will allow you to **Save** the document to your computer. You can choose where to save the document, and then click the **Download Complete** button to return to the Medical License page.

Do you want to open or save License.docx (9.70 KB) from iris-qa?	Open	Save 🔻	Cancel	×

When you finish entering nformation and attaching the required document, click the Save Changes button.

Signature

Users can upload a .jpg of their signature by clicking on this tab, then clicking the **Upload** button.

Profile	Signature
Change Password	Upload
Contact Management	
Proposal Info	
Other System IDs	
Biosketch, CV, Pubs	
Training History	
Medical Licenses	
Signature	

A popup will open, allowing you to browse your computer for the necessary file. Locate the .jpg and upload it to iRIS. There will be no save button on this page after the file is uploaded; it will be automatically saved.

Note: The image that displays on the screen will shrink down to a smaller size when the actual image is applied to a document.

The uploaded signature is used when an electronic signature is applied to an Outcome Letter, or, if configured, to insert department signatures in a PDF version of a submission form. To remove the uploaded signature, click the **Delete** button.

Notes

Any notes you may have can be found in this tab. You and/or the Administrator can upload this information.

My Account - Susan Investigator					🔳 Back
Profile				0	Add a New Note
Change Password	1 resul	t(s) four	id .		
Contact Management	I TOJU	c(s) rour			
Proposal Info	Delete	Edit	Note Content	Added By	Occurrence Date
Other System IDs	8	1	Note test.	Investigator, Susan	10/27/2016
Biosketch, CV, Pubs					
Medical Licenses					
Signature					
Disclosures					
Signoff Availability					
Vaccination History					
Notes					

Add a New Note- Click this button to add a new note.

Edit - The 📉 icon in this column allows you to view or make any necessary corrections to a published note.

Delete Note – Click the 😢 icon in the Delete column to delete a note. Allows the user to delete the requested note.

To add a new note, click the **Add a New Note** button and this screen will populate. The Occurance Date(*required field) must be entered in order to create a new note. Once you have filled in the appropriate text, you will need to click the **Save Note** button. If you do not save the note, the entered text will be lost.

My Account - Sus	an Investigator	🖪 Back
Profile		Save Note
Change Password		
Contact Management	*Occurrence Date:	
Proposal Info		
Other System IDs	□ 栎 响 响 畅 ▲ ₩ & B I 및 ↔ x₂ x² 는 는 A;• A * ∉ ∉ ≡ = =	
Biosketch, CV, Pubs	🔿 Format 🔹 Font 🔹 Size 🔹 🙈 🧟 🛅 🥅	
Medical Licenses		
Signature		
Disclosures		
Signoff Availability		
Vaccination History		
Notes		~

Announcements

When a System Administrator needs to contact every user in the system, they can post an announcement which appears in green text in the top portion of every user's home screen when they log into iRIS (see screenshot below). You can click on the message to view the new announcement. Once you have viewed the announcement, the notice will disappear from your home screen.

© iMedRIS Data Corporation

Ciris in the second sec	Account: Susan Investigator Department: Healthcare System - Sample Site	合 но	ne 🤇	Logout	•	Help
My Assistant	d Welcome Susan Investigator					
Conflict of Interest Forms						
Project Assistant	There are new system announcements since the last time you logged in! Click this link to view the announcements.					^
Study Assistant						

Clicking the link brings you to the System User Announcement screen where you can view the announcement.

	System User Announcement					
	1 result(s) found					
Date Posted Announcement(s)						
October 27, 2016 System Announcement: This is a system announcement.		System Announcement: This is a system announcement.				

You can view all of the current system announcements by clicking on the Announcements tab under My Assistant. System announcements can be viewed by clicking on the Announcements tab under My Assistant.

Clicking on the **View Post** button will bring up a new browser window (as shown in screenshot below). You can Close or Print this message by clicking on the appropriate buttons.

Exercises on a strength of the	
X close B print	
Welcome New User!	
We are pleased to have you as an iRIS user.	

Operating Procedures

This section is used for your site's Standard Operating Procedures (SOP's). Each site will have a different list of procedures. Different options are possible depending on the setup of this page.

Link to a Website – The SOP can be linked to a website within your network or to an outside web page (i.e. OHRP.com, FDA.com). The software will automatically open up a new browser window.

Link to Text – If the SOP is documentation not on a website, it might be captured as a text file. This will also load in a new browser window for your convenience.

Link to Attached Document – Typically this is a PDF upload of the SOP. This will also open in a new window.

Operating Procedures	Back
General Hospital Links	Submission Help & Policies
🗎 General Hospital SOP's	Initial Research Submission HELP
Research Education Links	Adverse Event HELP
User Training Certification	Continuing Reveiw HELP
🗎 Research News	
Resources	
NIH Website	
DHRP Website	
NIAID NIH Website	
NCI Website	

To view an SOP, click on the link. The SOP will open in a new browser window.

© iMedRIS Data Corporation

View Correspondence

When you receive correspondence from iRIS, generated from a notification or sent from the review board or study team, it is available for viewing under the View Correspondence link.

View Correspondence					Back
Search Co	Search Correspondence by Keyword : Search				
1143 result(s) found					1 - 20 🕨
Open	Study Number	Project Number	Task Details	Z Date Received	^
1	Application for Research		Are you attending the upcoming IACUC meeting?	2016-10-28 13:08:43.397	

From the View Correspondence screen, you can search for correspondence by keyword. Enter your search terms in the Search Correspondence by Keyword field, and click **Search**.

You can toggle between New Correspondence and Previously Read Correspondence by selecting the corresponding radio button.

To view the details of a message, click the icon in the Open column. This will open a screen similar to the one shown below.

View Correspondence			🔳 Back
Posted: 10/28/2016 01:08 PM PDT	*Content		
*Send Email 🗹	Sent From:	Susan Investigator	
*Subject	Send To:	Susan Investigator	
Correspondence	Project Number:	IRB-16-2869	
* Recipient(s):	Study Nickname:	Application for Research	
Susan Investigator	Title:	Copy of Application for Research	
Susan Investigator	Project Status:	Pending - Submitted for Initial Review	
Additional Recipients(s):	Principal Investigator :	Susan Investigator	
	Message Content:	Correspondence	
Attachments			
No Attachments have been added to this message			

All Department Reports

This section is for your site's All Department Reports. You will be able to run reports based off of numerous criteria, falling into categories including General, License, Studies by, Subject Tracking, Subject Tasks, Submission Tracking, and User's Schedule.

Reports				
Run Reports				
Accessible Depts - General	Subject Tracking			
Subject Visit Schedule General Subject Count and Screenings by Institution Subject Visit by Assessment Date License License License Expiration Studies By	 Subject Count by Studies Subject List for All Studies Subject On Study Race/Gender Percentages Subject Visit Schedule Subjects Counts for All Departments Subjects Enrollments Subjects for All Studies - All Sites Subjects for All Studies - Summary Subjects Generation Subjects Summary 			
Studies By Department	Subjects Tasks			
Studies By Enrollments Studies By Institution Studies By Parent Department	Subjects Randomization and Screening Subjects Visits and Procedures Details			
	Submission Tracking			
	 Submissions In Process Studies due Expiration Submission Package Tracking 			
	Users Schedule			
	 Appointment for Patient Schedule Per Day(s) Appointment for Patient Schedule Per Day(s) Appointment Schedule Per Day(s) Appointment Schedule Per Month(s) 			

Above is a screen shot of what the all department reports may look like. To run a report, you should select the report you. We will run a Subject Visit Schedule report under the Accessible Depts header.

Subject Visit Schedule	🖪 Back
Helpful Information	Run Report 🕨
Display Report as: PDF HTML CExcel	^
Please Enter Start Target Date 01/01/2008	
Please Enter End Target Date 01/01/2012	
Select User : All	

In the above screenshot, the user will be given the option to display the report as a PDF, HTML, or Excel file. The user will also be able to select date parameters. Lastly, in order to run a report in this section you must have at least one user selected. Click the search icon next to the Select User field to select specific iRIS users or all users. Next, click the **Run Report** button.

Department Reports

This section is to run department-specific reports. This section is very similar to All Department Reports. When a user is associated with more than one department, they will need to toggle between departments to run reports for each. This can be done on the home screen by selecting **Change your Department**.



Selecting a default department is required for running department reports. Click on the department you wish to have set as your default.

Change your default Department x
Instructions
Select the Department that you wish to work with. Department selection is required for adding studies, adding subjects, running Department reports, and managing Department list selections.
Department Name
Healthcare System - Sample Site
ADMIN Redlands

Below is a screen shot of what the department reports may look like. Select the report you wish to run. As an example, we will run a Review Boards History report under the Accessible Depts - General header. Click the Review Boards History

Link.

Accessible Depts - General	License
Review Boards History	License Expiration
Subject Count by Studies	Patient Trials
Subject Count by Studies - Following CRC Subject Count by Studies - Sponsor	Subject Clinical Trials
Subject List for All Studies	Recuiting Filtered Trait
Subject Visit Schedule	Patient Trait Accural
CRC - Subject Tracking	Screening
CRCs Subject Subject Schedule	All Screenings All Screenings
CRC - Tasks	Screenings by Reason
CRCs Completed Tasks	Screenings by Study
CRCs Incompleted Tasks	Studies By
Credits	Studies by Enrollments
Credit by CRC	Studies by Status
Current Dept - General	Study Procedures and Visitis Count
Subject Count	Study Arm Procedures , Visits Count
Enrollment Reports	Subject Tracking
Enrollments by All Studies	Study Visit Weekly
Enrollments by CRC	Subject Count Summary
Enrollments by Race	

In the below screenshot, the user will be given the option to display the report as a PDF, HTML, or Excel file. The user will also be able to select date parameters to run reports on only necessary data. Run the report by clicking the **Run Report** button.

Review Boards History	Back
Description: This report shows RB info. of protocols to be expired by the input date	Helpful Information Run Report
Display Report as: PDF O HTML O Excel Please Enter Expiration Date	^