

iRIS Researcher's Guide

iRIS information and FAQs available at:

<https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx> .

For additional support email iris-support@einsteinmed.org or call 718-430-2237.



Office of Human
Research Affairs

Montefiore

Logging in to the iRIS system

- <https://iris.einsteinmed.org/>
- Login using your MMCAD and password.
 - For more information about obtaining access to iRIS and obtaining a MMCAD go to <https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx> .

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*Throughout this document:
Red/italic text is used to denote
important/required steps.*

Black/normal text denotes
instructional information.

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Before beginning a new IRB application in iRIS

- All Key Personnel (KP) must obtain MMCADs
 - KP are individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process.
 - The iRIS FAQ has more information about obtaining a MMCAD (<https://www.einsteinmed.org/administration/institutional-review-board/irb.aspx?id=38577>)
- All KP **must** log on to iRIS and check their training history

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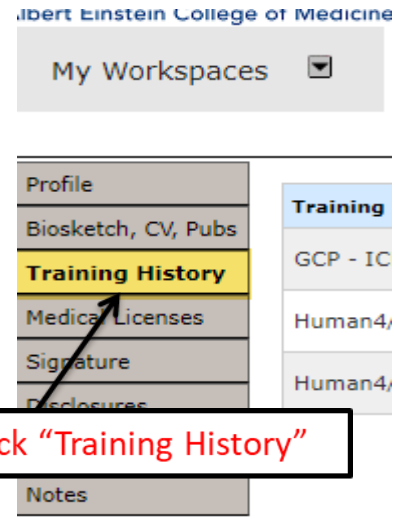
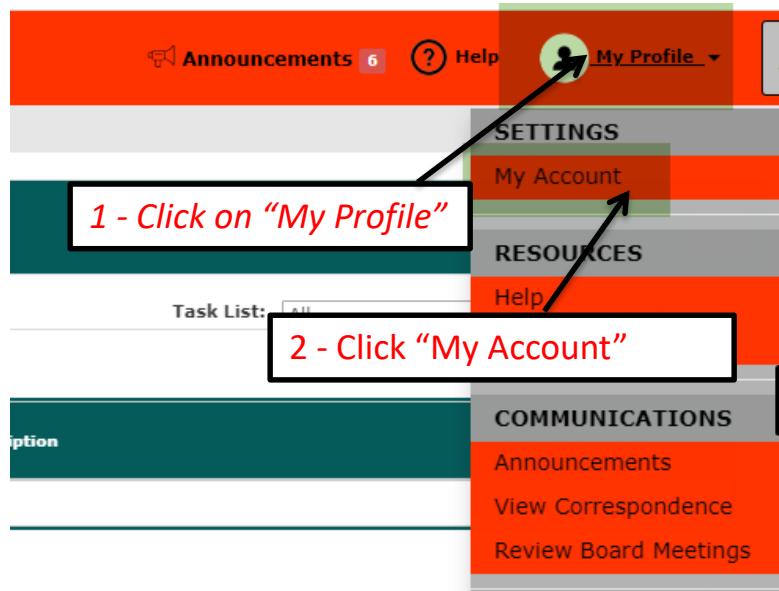
Check your iRIS e-mail address

The screenshot displays the Einstein iRIS user interface. At the top, there is a navigation bar with 'Announcements 6', 'Help', and a 'My Profile' dropdown menu. Below this, a sidebar contains 'SETTINGS' (with 'My Account' highlighted), 'RESOURCES', and 'COMMUNICATIONS'. The main content area shows a 'Profile' tab selected, with a 'My Account' button above it. Three numbered callouts with arrows indicate the steps: 1. Click on 'My Profile' (pointing to the dropdown), 2. Click 'My Account' (pointing to the button), and 3. Click on Profile (pointing to the 'Profile' tab). The profile form includes fields for personal information, contact details, and email addresses. The 'Additional Email Addresses' section is highlighted in yellow, and the 'Use for System Notifications' checkbox is checked.

All e-mail notifications from the iRIS system will be sent to the e-mail address listed in your profile and where “Use for System Notifications” has been selected. You are responsible for checking this e-mail account. The “preferred” e-mail address in your CITI member profile must also match any of the e-mail addresses listed in your iRIS profile. If your primary e-mail address in your iRIS profile is missing, add an e-mail address to the “Additional Email Addresses” section. Select which of the additional e-mail addresses you’d like for your iRIS notifications to be sent (notifications can only be sent to one of the selected e-mails).

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Check your current education status



Training Course	Course Date	Course Expiration	Score	
GCP - ICH	06/27/2018	06/26/2021		Add a New Document
Human4/SBR-R1	06/19/2012	06/18/2017		Add a New Document
Human4/SBR-R2	07/11/2017	07/10/2022		Add a New Document

At least one **Basic** or **Refresher** course must be listed here for any KP on an IRB application.

All investigators and personnel directly involved in new and ongoing clinical studies that involve the testing of drugs or devices must also have a **GCP** course.

If your CITI certificate is being requested by your PI, or study or regulatory coordinator, you can upload your certificates by clicking "Add a New Document". This option is only available after your training syncs to iRIS.

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What if my Training History is blank?

- There are several possibilities:
 - You have not yet taken the CITI exam. If this is true, follow the instructions for the CITI course here: <https://www.einsteinmed.org/administration/institutional-review-board/education/human-subjects.aspx>.
 - Your **“PREFERRED”** e-mail address in your CITI member profile does not match any of the e-mail addresses associated with your iRIS profile.
 - You are not affiliated with *“Albert Einstein College of Medicine”* in CITI.
 - You have not completed all the required coursework.
 - You have multiple CITI accounts.
 - You are missing an email address in your iRIS profile. Please go to your iRIS profile and add an e-mail address in the *“Additional E-mail Address”* field. Your preferred e-mail address in your CITI member profile must match the e-mail address you enter in iRIS.
 - It has been less than 24 hours since the last update to CITI training, CITI or iRIS profile information, or your initial login to iRIS. ***Note that it will take at least 24 hours for CITI training to synchronize to iRIS.***

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Updating Information on the CITI program website

Website: <http://www.citiprogram.org>



Page 1 of the CITI website

*Click "Log In" (if you already have a CITI account).
New CITI users should click "Register"*

Click "Register" if you have never used CITI.

Page 2 of the CITI website



Log in with your CITI Username and Password

Click "Forgot?" if you have forgotten your CITI username or password

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 - [E-mail address](#)
 - [Institutional affiliation](#)
 - [Coursework](#)
 - [Merging CITI accounts](#)

Checking and Updating E-mail Address in the CITI program

English

Iris Einstein ID: 3685164 | Log Out | Help

CITI PROGRAM Initiative at the University of Miami

Search Knowledge Base

Main Menu | **My Profiles** | CE Credit Status | My Reports | Support

Main Menu

▶ Albert Einstein College of Medicine of Yeshiva University Courses

▼ CITI Program Profile

First Name: Iris
Last Name: Einstein
Change my name

Preferred Email: iris-support@einstein.yu.edu
Secondary Email:
Change my email address

Username: iriseinstein

Show CE credit information when available: No
CE credit types:

Participate in research surveys: No
Change my research survey preference

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Updating Institutional Affiliation in the CITI program

Main Menu > My Profile > Affiliate with New Institution

* Select Institution

* indicates a required field.

Choose your institution from the appropriate dropdown menu. Choose only one institution. If you are affiliated with more than one institution, you will be able to select additional institutions after providing the information required..

Participating Institutions

Albert Einstein College of Medicine of Yeshiva University

Veterans Affairs

Department of Energy

HIV/AIDS Network Coordination (HANC)

Canadian Institutions

India Participating Institutions

Korea Participating Institutions

Next

*Once you have completed registering with Einstein, check the **Main Menu** to confirm that you have completed the required modules for Einstein CITI Certification.*

*Select **Albert Einstein College of Medicine, Inc.** from the first drop down menu. Leave the other sections blank. Then click **Next**.*

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Checking and Updating Coursework in the CITI program

Search Support Center

Main Menu | My Profiles | My CEUs | My Reports | Support | Admin

Main Menu

- ▶ Albert Einstein College of Medicine, Inc. Courses
- ▶ Click here to affiliate with another institution

Click here to check and update coursework.

Only courses labelled "Group" qualify for the "basic"/"initial review group training" for CITI check.

Completed modules. If you do not have training group courses listed in iRIS you may need to click on the "Add a course" link to *add a course*.

Course	Status	Completion Report	Survey
Albert Einstein	Passed 12/13/2012	Print Report	Take Survey
GCP	Passed 10/12/2009	Print Report	Take Survey
Group 2. BIOMEDICAL RESEARCH with DRUGS/DEVICES	Passed 02/28/2011		
IRB Reference Resource	Incomplete		

My Learner Tools for Albert Einstein College of Medicine of Yeshiva University

- ▶ Add a Course or Update Learner Groups


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 - [Coursework](#)
 - [Merging CITI accounts](#)




I have two CITI accounts. How do I merge them?

- Send an e-mail to support@citiprogram.org and include the following information:
 - Your first and last name.
 - The name of your institution.
 - The username or Member ID for the account to keep.
 - The username or Member ID for the account to merge.
- For further assistance please contact the CITI Program help desk at 888.529.5929 (U.S. toll free) or +1 305.907.3100 (Outside U.S.) and choose Option 1 or e-mail them at support@citiprogram.org.
 - Phone support is available 8:30 a.m. - 7:30 p.m., U.S. Eastern Time, Monday - Friday.

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General Orientation to the Home Screen


Hello Paula D Brown, B.A.
your last login was
02/24/2020 11:06 AM EST




Log out

Need help? Take a look at our handbooks and guides located in the iRIS help menu at any time during your iRIS session. Detailed instructions for all submissions, responses and frequently asked questions are available there 24/7.

Logout from anywhere in iRIS

Featured Study Operations


- Create a New Study
- Start a Study Submission Form
- View My Studies
- View My Studies Submissions
- Track Approvals
- Forms Pending Submission 10

Tasks

- View All Tasks 9
- View Study Tasks 9

A new option is available to you to open your studies, view/track your current approvals, submit new forms, and view tasks from your iRIS homepage. The vendor has included their own tutorial on how to navigate the homepage. To access their tutorial, click the "Tutorial" button located on the top of your screen.

Study Assistant



Find a Study

Study Tasks

Outstanding Completed

Search for RB Number, Title, Alias Search

Task List: All Board: All

9 result(s) found... 1 - 5

Click to open	Details	Task Type	Received	Study Status	Study Title	Principal Investigator	Review Board	RB Number	RB Expiration
		Reviewer status:	All reviewers are complete with their reviews		Open	Copy of A study to play with -SAMPLE			
		Analyst Assignment	09/24/2019 10:07 AM EST		A study to play with	Epstein, Melissa PhD, MBE	Einstein IRB	2014-3670 - SAMPLE	
		Submission Reviewer by System Role	09/12/2019 10:42 AM EST	Draft	umbrella admin	Testing, PI+GCP+CITI	Einstein IRB	2019-9002	

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The iRIS Help Menu



Conflict of Interest links

- Conflict of Interest Disclosure Information
- How to Access the COI form
- Can't access the COI Disclosure Form
- COI Disclosure Form
- List of Individuals with COI Disclosures on File

- Current Form Version Dates**
- IRB Application Version Date: July 2018
 - How do I begin a new application?

- IRB (Human Research)**
- Researcher Handbook v5
 - Migration Handbook v3
 - Instructions for PI to Sign Off v2
 - Instructions for Chair/Signatories to Sign Off v2
 - Response Review Submission Form Handbook v2
 - Amendment Handbook v3
 - Progress Report Guide v2
 - Policies and Procedures
 - IRIS Information
 - Administrative Approvals for IRB Applications
 - Signatories

- IRB (Templates)**
- Consent/HIPAA Template (for Full Board/Greater than Minimal Risk studies)
 - Consent/HIPAA Template (for Expedited/Minimal Risk studies)
 - Consent/HIPAA Template (for Biobanking studies)
 - Consent/HIPAA Template (for Exempt studies)
 - Assent Template (for enrollment of 7-12 year old participants)
 - Oral Consent Script (for survey studies ONLY)
 - Glossary of Terms for use in Preparing Informed Consent Documents
 - Consent Template (for non-research use of HUDs)

- iRIS Support**
- Frequently Asked Questions (iRIS FAQ)
 - Email iris-support@einsteinmed.org
 - Call 718-430-2237
 - Missing the Study Assistant Tab?

- Training**
- CITI Education Requirement Information
 - CITI Education Check Guide v2
 - List of Users with GCP Training (as of 12/17/18)

Consent templates. Templates are also available at:
<https://www.einsteinmed.org/administration/institutional-review-board/education/iris.aspx#forms>

CITI and GCP training links

The Help Menu has iRIS instructional manuals, links to IRB policies and guidance, and the Consent Document Templates.

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Panels on the Home Screen

- **Study Assistant** – Depending on the type of system access granted to the user. Users with global/departmental study access can find the “Find a Study” button here.
- **All Tasks** – Shows both outstanding and completed tasks. The user can opt to see a brief description of the task details via the “All Tasks” tab or view the study details via the “Study Tasks” tab. Requests for signoff, responses to stipulations, and to address denied submissions will be seen here.
- **Studies Submission Status** – Shows the status for both study submissions that are in progress and study submissions that have been completed. The “Actions” column allows the user to view the steps/history of the submission without the user having to open the study. The user is provided with the date each step was created, completed, and the duration of each step. If a submission was returned with stipulations, the duration is also calculated for each round.
- **All Studies** – This panel replaces the “My Studies” option. Users can search for studies via IRB number, Title, or Alias. When “Study Status” is selected, the user can choose to filter studies based on a specific study status. Under the “Actions” column, users can view the history of all submissions for the specified study (this includes pending and completed submissions, outcome letters, submission details). The following options are under the “Actions” column:
 - The “items” option allows the user to select the submitted items (documents) and create a PDF packet.
 - The “forms” option allows the user to view the versions of a form, begin a new form, or complete an existing form.
 - The “hide” option allows the user to hide the study from the panel. If you ever need to see the hidden study click the widget icon in the right corner of the panel section to select “Show Hidden”.
 - The “copy” option allows the user to copy the study.
 - The “delete” option allows the user who initially created the study to delete the study.
 - Lastly, the “Corr” option allows the user to view all study correspondence.

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Start a New Study

The screenshot shows the 'My Workspaces' dropdown menu. The menu items are: 'Research Workspace', 'Study Assistant', 'Study Workspace', 'Create a New Study', and 'View My Studies'. Three numbered instructions are provided:

- 1 – Use the mouse to hover over "My Workspaces"
- 2 – Hover mouse over "Study Assistant"
- 3 - Click "Create a New Study"

OR

The screenshot shows the 'Featured Study Operations' and 'Tasks' sections. The 'Featured Study Operations' section has a dark green header and a list of items: 'Create a New Study', 'Start a Study Submission Form', 'View My Studies', and 'View My Studies Submissions'. The 'Tasks' section has a dark green header and a list of items: 'View All Tasks' and 'View Study Tasks'. A callout box points to the 'Create a New Study' item in the 'Featured Study Operations' section.

Click on the "Create a New Study" Folder

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General Navigation within a Study Application

Navigation within iRIS.

Returns to last level in iRIS. DON'T use this to move between application sections.

The screenshot shows the iRIS application interface. At the top, there is a red header with the Einstein logo and user information: "Account: Paula D Brown, B.A., Department: E-MMC - Institutional Review Board, Path: Home". On the right, there are links for "Help", "My Profile", and "Log out". Below the header, a grey navigation bar contains "My Workspaces", "IRB Number: 2020-9003", "Study Assistant", and "Human Research Application (Version 1.0)". A "Back" button is located at the bottom right of this bar. Below the navigation bar, there are three buttons: "Print Friendly", "Save Section", and "Save and Continue to Next Section". On the left, a sidebar shows "Section view of Application" with two options: "Entire view of the Application" (circled in red) and "Section view of Application". Below the sidebar, there are two sections: "1.0 General Information" and "2.0 Setup Department(s) Access". The "1.0 General Information" section contains two text input fields. The first field is labeled "Please enter the full title of your study:" and contains the text "testing new version". The second field is labeled "Enter an ACRONYM, protocol nickname, or sponsor's protocol #. This field should contain the name colloquially used to refer to the study. It will assist in identifying the study easily. (Velos users: 20 character maximum.)" and contains the text "test new ver".

To move to the next section. Current page must be error free.

Navigate between sections on the application.

Your application will have unique section numbers depending on the content of your application. The section numbers in the Handbook may not correspond to the section numbers in your application.

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Set up Department Access

This department MUST match the PI's primary department. If it does NOT match change the department as follows:

2.0 Add Department(s)

2.1 List the PI's academic appointment department as the primary department here (for the Department of Medicine at Einstein/Montefiore, the Division must be identified). IN ADDITION: ** For studies conducted at NBHN, an NBHN department must be listed here. **For studies managed by the Office of Clinical Trials, OCT must be listed here. ** For studies conducted at the CRC, CRC must be listed here. **For Quality Improvement studies conducted at MMC, Network Performance Group must be listed here.** For drug studies: list either the Einstein-Montefiore Pharmacy or the NBHN Pharmacy here. :

Is Primary?	Department Name
<input type="checkbox"/>	E-MMC - Institutional Review Board

Add Department Remove Department

1 - ADD Department

Adding Department - Search Window

Select the Department(s) that you would like to filter by, then click Save. You may also filter these results by searching for Institution Name, Department name, Department Code or School Code on the inputs below. Any Departments already added will not appear here.

Institution Name Department Name

School Code Dept Code

3 result(s) found...

Select	Institution	Department Name	School Code	Department Code
<input type="checkbox"/>	Einstein Montefiore	Microbiology & Immunology		
<input checked="" type="checkbox"/>	Einstein Montefiore	Obstetrics & Gynecology and Women's Health		
<input type="checkbox"/>	New York City Health and Hospitals Corporation	Obstetrics & Gynecology and Women's Health		

2- Search for the Department, then select the Department Name in the checkbox and click on "Save". You may need to scroll down to find the "save" button.

3 - Select Primary Department

4 - To REMOVE a department: select department and then click "Remove Department".

*** When you are finished adding/removing the departments, click "Save and Continue to next section".**

2.0 Add Department(s)

2.1 List the PI's academic appointment department as the primary department here (for the Department of Medicine at Einstein/Montefiore, the Division must be identified). IN ADDITION: ** For studies conducted at NBHN, an NBHN department must be listed here. **For studies managed by the Office of Clinical Trials, OCT must be listed here. ** For studies conducted at the CRC, CRC must be listed here. **For Quality Improvement studies conducted at MMC, Network Performance Group must be listed here.** For drug studies: list either the Einstein-Montefiore Pharmacy or the NBHN Pharmacy here. :

Is Primary?	Department Name
<input type="checkbox"/>	E-MMC - Institutional Review Board
<input checked="" type="checkbox"/>	E-MMC - Obstetrics & Gynecology and Women's Health

Add Department Remove Department

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Requirements for all KP

- Meet human subjects education requirements (<https://www.einsteinmed.org/administration/institutional-review-board/education/human-subjects.aspx>).
 - **Drug/Device studies:** Make sure all Key Personnel have satisfied the GCP requirement (<https://www.einsteinmed.org/administration/institutional-review-board/education/gcp.aspx>).
 - [Check your current education status](#) or [check the education status of all KP on the study](#) by clicking on these links or by going to the CITI Education Check Guide in the iRIS Help Menu.
- **PI, Additional Investigators and Key Personnel (KP)** (sections 3.1 and 3.2A): Must have a current (updated within the past 180 days) Conflict of Interest (COI) Disclosure Form with the Conflict of Interest Office (see <https://www.einsteinmed.org/administration/conflict-of-interest/disclosure-form/> for further guidance).
- *What happens if these requirements are not met?*
 - *The Migration Completion Form (MCF) may be submitted in iRIS, but the IRB will NOT receive the submission. [Check your study status](#) (page 62) on a regular basis to see if the submission is delayed due to COI check or CITI education check.*

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Assigning Key Personnel (KP)

A PI must be assigned to all studies. Only [faculty](#) may serve as PIs. All other internal KP (individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process) must also be added on this page. See the [“External Researchers & Sites”](#) page for guidance on external KP.

By default, only the PI receives system notifications and can access the study. Any other person who needs to receive notifications or access to the study must be listed as a Study Contact.

**** Study contacts do not need to be listed as key personnel.**

Click “Setup Study Personnel” to begin locating and adding personnel. Be sure to only search for personnel listed in the “iRIS Database”. The “LDAP Directory” option may consist of inactive accounts as this option gives you all users listed in Montefiore’s active directory.

Select the personnel’s role during this step also. You will be given the option to add the user as “Study Contact” without having to search for the same user multiple times. Click “Save” when you are done adding all your personnel. The personnel will then show in the key personnel section of the application.

Setup Study Personnel

User Search

Last Name: First Name:

Department:

Search From: iRIS Database LDAP Directory

Select	Training?	Name	Department	Email
<input checked="" type="checkbox"/>		Brown, Paula		
<input checked="" type="checkbox"/>		Brown, Paula D, B.A.	Institutional Review Board	paula.brown@einsteinmed.org

Selected Study Personnel:

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

3.0 Assign Key Personnel access to the project

3.1 * Please add a Principal Investigator for the study:

3.2 Identify all other Key Personnel (individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process) here. Individuals listed here.

A) Additional Investigators

B) Research Support Staff

3.3 * Please add a Study Contact:

In this section, list the PI and all individuals who should receive communications (e.g. notification of approval, issues requiring revisions, etc.). Note that this section is not considered "Key Personnel" - any conduct of the project must be named in one of the sections above.

3.4 If the PI is an Einstein faculty member, Montefiore physician or if the study will consent participants at any Montefiore facility, please identify the Regulatory Coordinator for this study to their study in the Velox Clinical Research Management System and will be RESPONSIBLE for: (1) Entering/verifying all of the study information in Velox; Assigning access roles; IRB approval. This person must be trained in the Velox system. Note that this section is not considered "Key Personnel" - anyone listed here who is involved in the conduct of the study about Velox, please view the Velox Information Portal (https://epublic.montefiore.org/Velox_CTRIS) or contact veloxhelp@montefiore.org.

Add Personnel Role

Select the Role for **Paula D Brown, B.A.** :

- Principal Investigator
- Additional Investigators
- Research Support Staff
- Study Contact

Would you like to include as a Study Contact? Yes No

Cancel Save

Close Setup of Study Personnel

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Adding a User

3.0 Assign Key Personnel access to the project

3.1 * Please add a Principal Investigator for the study:

3.2 Identify all other Key Personnel (individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process) here. Individuals from external institutions covered by their own IRB approval listed here.

A) Additional Investigators

B) Research Support Staff

3.3 * Please add a Study Contact:

In this section, list the PI and all individuals who should receive communications (e.g. notification of approval, issues requiring revisions, etc.). Note that this section is not considered "Key Personnel" - anyone listed here who is involved in the conduct of the project must be named in one of the sections above.

3.4 If the PI is an Einstein faculty member, Montefiore physician or if the study will consent participants at any Montefiore facility, please identify the Regulatory Coordinator for this protocol. (PIs must designate here the individual that will to their study in the Velos Clinical Research Management System and will be RESPONSIBLE for: (1) Entering/verifying all of the study information in Velos; assigning access roles/rights in Velos and Epic for all study personnel; (2) Acting on IRB approval. This person must be trained in the Velos system. Note that this section is not considered "Key Personnel" - anyone listed here who is involved in the conduct of the project must be named in one of the sections above. If you are about Velos, please view the Velos Information Portal (https://ephpublic.montefiore.org/Velos_CTMS) or contact veloshelp@montefiore.org.)

Setup Study Personnel

Add Personnel Role

Select the Role for **Paula D Brown, B.A.** :

Principal Investigator

Additional Investigators

Research Support Staff

Study Contact

Would you like to include as a Study Contact? Yes No

1 – Click "Setup Study Personnel". In the next window, type (partial or full) first or last name, then click "Find User/ Search Directory"

Setup Study Personnel

User Search

Last Name: First Name:

Department:

Search From: iRIS Database LDAP Directory

Find User/Search Directory

Select	Training?	Name	Department	Email
<input type="checkbox"/>	<input type="checkbox"/>	Brown, Paula		
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Brown, Paula D, B.A.	Institutional Review Board	paula.brown@einsteinmed.org

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel | Close Setup of Study Personnel

2 – select iRIS Database

4 – Select user

3 – check training. See next slide for details

5 - Select the role for the personnel. Indicate whether you also want this person to be added as "Study Contact". Click "Save".

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Check education training status of users

Setup Study Personnel

Last Name:

First Name:

by Department:

Search From: iRIS Database LDAP Directory

Select	Training?	Name	Department	Email
		Brown, Paula		
		Brown, Paula D, B.A.	Institutional Review Board	paula.brown@einsteinmed.org

Click on the icon.

At least one course must have a green light.

Training Details for Testing, PI

Training Group	Courses (Course Date - Expiration) All Courses must be green within one rule for the group to be valid	Status
Group 2.BIOMEDICAL RESEARCH with DRUGS/DEVICES	Rule 1 Basic Course (01/05/2013 - 01/05/2016) Rule 2 Refresher 2 Course Rule 3 Refresher 3 Course Rule 4 Stage 1 Rule 5 Refresher Course	Active
Group 1.BIOMEDICAL RESEARCH (includes EPI)	Rule 1 Basic Course (01/05/2013 - 01/05/2016)	Active

- [Return to Table of Contents](#)
- [Return to Adding a User](#)

External Researchers & Sites

- **Generally**, collaborators from external institutions do not need to be listed in iRIS.
- **Exception**: the external institution does NOT have its own IRB but is "engaged" in the research.
 - Contact the Einstein IRB at 718-430-2237 for guidance.
 - If the Einstein IRB serves as the IRB of record for the collaborators, they will need to satisfy Einstein IRB educational and COI requirements. In addition, a legal agreement (IIA or IAA depending on the circumstances) is required.

• [Return to Table of Contents](#)

Conflict of Interest Disclosure Requirements

- *The IRB will NOT begin its review until the Conflict of Interest Committee completes its review.*
- In order to ensure prompt review by the COI committee, you must complete the following steps:
 - Verify that any additional PIs or Additional Investigators have current (filed within the past 180 days) COI disclosures on file. Please contact the COI department at coi@einsteinmed.org for a list of individuals with COI disclosures on file.
 - The IRB recommends that you send the following information by e-mail to all investigators who do not have a current COI disclosure on file:

PI Name:

Protocol Title:

Please complete or update your Conflict of Interest disclosure form. COI disclosure forms must be filed or updated electronically.

Contact COI at coi@einsteinmed.org for the link to the COI disclosure form.

If you can't access the disclosure form or can't login to the COI website, e-mail coi@einsteinmed.org.

NOTE: THE IRB WILL NOT RECEIVE THIS SUBMISSION UNTIL ALL INVESTIGATORS HAVE A CURRENT CONFLICT OF INTEREST DISCLOSURE ON FILE.

• [Return to Table of Contents](#)

Protocol Sites: Adding external sites

Application

Print Friendly Save and Continue to Next Section Back

Section view of Application Entire view of the Application

1.0 General Information 2.0 Setup Department(s) Access 3.0 Grant Key Personnel access to the project 4.0 Preliminary Questions 5.0 Protocol Sites 6.0 General Information for the Standard Application 7.0 Confidentiality 8.0 Informed Consent 9.0 Exclusion/Inclusion Criteria 10.0 Informed Consent Process 11.0 Recruitment 12.0 Costs and Remuneration 13.0 Application Customization 14.0 Expedited Categories 15.0 Additional Questions About Minors

8.0 Informed Consent 9.0 Exclusion/Inclusion Criteria 10.0 Informed Consent Process 11.0 Recruitment 12.0 Costs and Remuneration 13.0 Application Customization 14.0 Expedited Categories 15.0 Additional Questions About Minors

5.3 External sites

Enter the name of each external site in the dynamic table below and select the responsible IRB and appropriate site characteristics. If this is a multi-center trial, enter each participating site only if the YU/MMC/JMC/NCB PI is the national/international coordinator for this study.

In question #3, click on "Add a new row."

+ Add a new row Copy existing row(s) X Delete selected row(s)

Name of Site	Responsible IRB	Site Characteristics
No record has been added		

*Before selecting IIA (Individual Investigator Agreement) or IAA (IRB Authorization Agreement), please consult with the Einstein IRB Office.

5.3 External sites

Enter the name of each external site in the dynamic table below and select the responsible IRB and appropriate site characteristics. If this is a multi-center trial, enter each participating site only if the YU/MMC/JMC/NCB PI is the national/international coordinator for this study.

+ Add a new row Copy existing row(s) X Delete selected row(s)

Name of Site	Responsible IRB	Site Characteristics
<input type="checkbox"/>	<input type="radio"/> Institution's own IRB <input type="radio"/> Not Applicable (site not engaged in research) <input type="radio"/> Einstein IRB (IIA)* <input type="radio"/> Einstein IRB (IAA)*	<input type="checkbox"/> International <input type="checkbox"/> School (nursery - 12th grade) <input type="checkbox"/> None of the above

*Before selecting IIA (Individual Investigator Agreement) or IAA (IRB Authorization Agreement), please consult with the Einstein IRB Office.

5.4 What is the anticipated total number of participants to be enrolled by the local...

Complete all the columns in the row. Additional sites may be added by clicking on "Add a new row". Rows do not need to be saved individually. Instead, save the entire Protocol Sites section by clicking "Save and Continue to Next Section" on the upper right of the page.

Return to Table of Contents

Sources of Support

If you answered "Yes" to question #5 of the Preliminary Questions page (Are there any sources of support (e.g. funds, supplies, drugs, devices or equipment)?) you will be directed here.

Only current sources of support must be added.

6.0 Sources of Support

1.

+ Add a New Sponsor to the Study

Delete Edit View Details Sponsor Name External Award
No Sponsor has been added to this Study

Find a Sponsor: Search Options

Sponsor Name: ab Find Sponsor
Familiar Name:
Legal Name:

2. Type a few letters in the **Sponsor Name** field and then click **Find Sponsor**.

Find a Sponsor: Search Options

Sponsor Name: ab Find Sponsor
Familiar Name:
Legal Name:
+ Add a New Sponsor to the Master List

3. Click on the green plus sign to select a sponsor.

If the sponsor is not in the list, click on **Add a New Sponsor**.

• [Return to Table of Contents](#)

Frequently Asked Questions about the Application

- [28. Where am I? How can I tell which study I'm working on? How can I tell which section of the application I'm working on?](#)
- [29. How do I move between sections of the application? Can I go back to a section I already completed?](#)
- [30. How do I stop working on the application?](#)
- [31. How can I return to a draft application that I already started?](#)
- [34. I have a message that there is a **new version of the application**. What do I do?](#)
- [52. How do I check-out an uploaded document and check-in the edited document?](#)

- [Return to Table of Contents](#)
- [Go to Initial Review Submission Packet](#)

Where am I? How can I tell which study I'm working on? How can I tell which section of the application I'm working on?

IRB Number and PI name

Account: Paula D Brown, B.A.
Department: E-MMC - Institutional Review Board
Path: Home

Help My Profile Log out

My Workspaces Study Assistant Human Research Application (Version 1.0) Back

IRB Number: 2020-9003
PI: Brown, Paula D, B.A.

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Key Personnel and Project Contacts
4.0 IRIS Resources
5.0 Type of Application
6.0 Clinical Trials
7.0 Umbrella Studies & Delayed Human Subject Involvement
8.0 Protocol Sites
9.0 Internal and External Sources of Support
10.0 CITI Education Check Information
11.0 Conflict of Interest Disclosure Requirements
12.0 General Application Introduction
13.0 Preliminary Questions

13.0 Preliminary Questions

13.1 Does this research involve Einstein medical students as collaborators? These protocols must be approved by the Dean of Students, Christina Chin, via the signature routing pages. See the Researcher Handbook (located in the help menu) for additional information.

Yes No

13.2 This IRB application is being sent for exemption determination prior to January 1, 2019. This option may not be selected after January 1, 2019.

Yes No

13.3 We are applying for an exempt determination on or after January 1, 2019. This option must be selected for new exempt submissions submitted to the IRB after January 1, 2019.

The following categories of research may be eligible for exempt determination and/or limited IRB review:

- Determinations that the institution is not engaged in research
- Research on deidentified specimens or data
- Research conducted in established or commonly accepted educational settings
- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) of adults
- Research involving benign behavioral interventions with adult subject if the subjects prospectively agrees to the intervention and information collection.
 - Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
 - The research may not involve deception (unless subjects are prospectively informed that they will be misled).
- Secondary research uses of identifiable private information or identifiable biospecimens

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)
- [Go to Initial Review Submission Packet](#)

How do I move between sections of the application? Can I go back to a section I already completed?

The screenshot displays the Einstein IRB application interface. At the top, the Einstein logo and account information for Paula D. Brown, B.A., are visible. The main navigation bar includes 'My Workspaces', 'Study Assistant', and 'Human Research Application (Version 1.0)'. A sidebar on the left lists application sections from 1.0 to 13.0, with '13.0 Preliminary Questions' selected. A callout box with a black border and white background points to the '13.0 Preliminary Questions' section in the sidebar, containing the text: 'Click on application section name. You can return to any previous section. *Must be in "Section view of Application".' Below the sidebar, the main content area shows the '13.0 Preliminary Questions' section, including question 13.1 and 13.2. At the bottom right, a grey box contains three blue links: 'Return to Table of Contents', 'Return to Frequently Asked Questions', and 'Go to Initial Review Submission Packet'.

Account: Paula D Brown, B.A.
Department: E-MMC - Institutional Review Board
Path: Home

IRB Number: 2020-9003
PI: Brown, Paula D, B.A.

Study Assistant Human Research Application (Version 1.0)

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Key Personnel and Project Contacts
4.0 IRIS Resources
5.0 Type of Application
6.0 Clinical Trials
7.0 Umbrella Studies & Delayed Human Subject Involvement
8.0 Protocol Sites
9.0 Internal and External Sources of Support
10.0 CITI Education Check Information
11.0 Conflict of Interest Disclosure Requirements
12.0 General Application Introduction
13.0 Preliminary Questions

13.0 Preliminary Questions

13.1 Does this research involve Einstein medical students as collaborators? These protocols must be approved by the Dean of Students, Christina Chin, via the signature routing pages. See the Researcher Handbook (located in the help menu) for additional information.

Yes No

13.2 The following categories of research may be eligible for exempt determination and/or limited IRB review:

13.3 W

This opt

The following categories of research may be eligible for exempt determination and/or limited IRB review:

- Determinations that the institution is not engaged in research
- Research on deidentified specimens or data
- Research conducted in established or commonly accepted educational settings
- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) of adults
- Research involving benign behavioral interventions with adult subject if the subjects prospectively agrees to the intervention and information collection.
 - Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
 - The research may not involve deception (unless subjects are prospectively informed that they will be misled).
- Secondary research uses of identifiable private information or identifiable biospecimens

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)
- [Go to Initial Review Submission Packet](#)

How do I stop working on the application?

The screenshot shows the iRIS application interface. At the top, the Einstein logo and user information are visible: Account: Paula D Brown, B.A., Department: E-MMC - Institutional Review Board, Path: Home. The main header displays the IRB Number: 2020-9003 and the role: Study Assistant. The application title is "Human Research Application (Version 1.0)". A sidebar on the left lists sections from 1.0 to 13.0, with "Preliminary Questions" selected. A callout box with a black border and white background contains the following text: "Click on the 'Home' link next to 'Path'. Any page where you have clicked 'Save and Continue to Next Section' will be saved. If you do not click on 'Save and Continue to Next Section' or 'Save Section' on the last page, the information will not be saved. Clicking the banner will also bring you to your iRIS 'Home' screen." Two arrows point from the callout box to the "Home" link in the top navigation bar and the "Preliminary Questions" section in the sidebar. The main content area shows a table with columns for "Enrollment" and "Status", and a yellow banner with text: "This option must be selected for new exempt submissions submitted to the IRB after January 1, 2019." Below the banner, there is a list of research categories eligible for exempt determination or limited IRB review.

Account: Paula D Brown, B.A.
Department: E-MMC - Institutional Review Board
Path: Home

IRB Number: 2020-9003
PI: Brown, Paula D, B.A.

Study Assistant

Human Research Application (Version 1.0)

Section view of Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Key Personnel and Project Contacts
4.0 iRIS Resources
5.0 Type of Application
6.0 Clinical Trials
7.0 Umbrella Studies & Delayed Human Subject Involvement
8.0 Protocol Sites
9.0 Internal and External Sources of Support
10.0 CITI Education Check Information
11.0 Conflict of Interest Disclosure Requirements
12.0 General Application Introduction
13.0 Preliminary Questions

Click on the "Home" link next to "Path". Any page where you have clicked "Save and Continue to Next Section" will be saved. If you do not click on "Save and Continue to Next Section" or "Save Section" on the last page, the information will not be saved. Clicking the banner will also bring you to your iRIS "Home" screen.

This option must be selected for new exempt submissions submitted to the IRB after January 1, 2019.

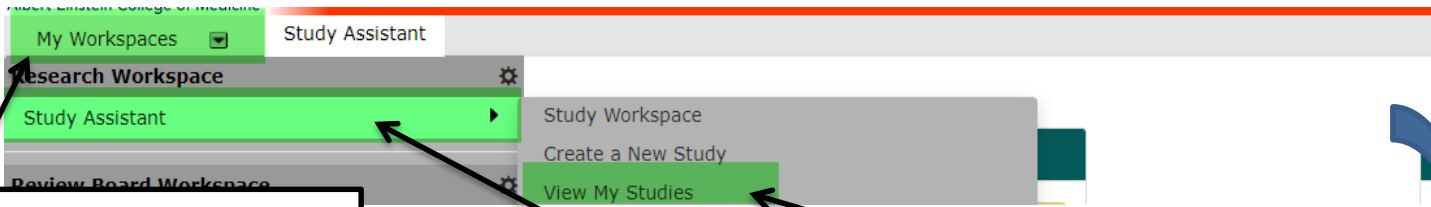
The following categories of research may be eligible for exempt determination and/or limited IRB review:

- Determinations that the institution is not engaged in research
- Research on deidentified specimens or data
- Research conducted in established or commonly accepted educational settings
- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) of adults
- Research involving benign behavioral interventions with adult subject if the subjects prospectively agrees to the intervention and information collection.
 - Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
 - The research may not involve deception (unless subjects are prospectively informed that they will be misled).
- Secondary research uses of identifiable private information or identifiable biospecimens

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)
- [Go to Initial Review Submission Packet](#)

Opening a draft of a study that has NOT been submitted to the IRB

Page 1

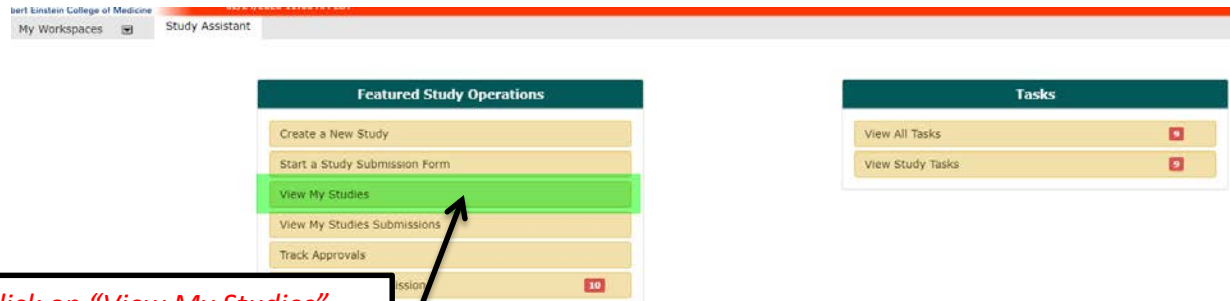


1 – Use the mouse to hover over “My Workspaces”

2 – Hover mouse over “Study Assistant”

3 – Click “View My Studies”

OR



Click on “View My Studies”, the system will bring you down to the “All Studies” Panel. Or you can scroll down the page to go to “All Studies”.

3 – Click the notepad icon to open the study.

All Studies Recently Used Study Status

All Draft Einstein IRB

11 result(s) found...

Click to open Study Dashboard	Study Status	Review Board	RB Number	RB Expiration
	Draft	Einstein IRB	2020-9003	
	Open	Einstein IRB	2013-2006-SAMPLE	03/04/2020

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)

If you have **NOT** completed the application, the Study Application screen will open.

Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Account: Coordinator Testing (You are working under someone else's account. Click here to return to your account)
Department: Einstein-Montefiore - General Internal Medicine
Navigation: Home > my studies > project mgmt.

Home Logout Help

Short Title/Sponsor Protocol Number: Melissa's case study #1
PI: Testing, PI

Study Application Back

Print Friendly Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the project

4.0 Preliminary Questions

5.0 Protocol Sites

6.0 General Information for the Standard Application

7.0 Confidentiality

8.0 Informed Consent

9.0 Exclusion/Inclusion Criteria

10.0 Informed Consent Process

11.0 Recruitment

12.0 Costs and Remuneration

13.0 Application Customization

14.0 Expedited Categories

15.0 Additional Questions About Minors

1.0 General Information

Please enter the full title of your study:

Copy of Copy of Copy of Melissa's case study #1

Enter a short title for the study (this may be the Sponsor Protocol Number):

Melissa's case study #1

This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Click on "Save and Continue" until the form is complete.

Navigate between sections on the application.

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)

If you've **completed** the application, the Project Management Screen will open.

EINSTEIN
Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Account: Coordinator Testing
Department: Einstein-Montefiore - General Internal Medicine
Navigation: Home > my studies

Home Logout Help

Short Title/Sponsor Protocol Number: A draft that has not been submi ...
PI: Testing, Chair

Submissions Back

Study Status: **Draft** Study Title: A draft that has not been submitted to the IRB

Protocol Items

- Study Application
- Informed Consent
- Other Study Documents
- Contract Documents

Regulatory Forms

Forms

- Initial Review Submission form

Attachment Forms

Please do not complete from this screen

- Advertisement Form

Submissions History

Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

Click on Study Application to re-open the application.

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)

I have a message that there is a ***new version of the application***. What do I do?

The screenshot displays the 'Human Research Application (Version 1.2)' interface. At the top, there are buttons for 'Print Friendly', 'Convert to the New Form Version', and 'Save Section'. A notification box in the center reads: 'New Form Version has been published. A new version of the Study Application Form (Human Research Application) has been published. Please click on the Convert to the New Form Version button. New Sections and Questions may be present on this form so please click through each section to verify that the application is complete.' Below the notification are two buttons: 'Cancel conversion - Retain Current Version' and 'Convert to New Form Version'. A callout box labeled '1' points to the 'Convert to the New Form Version' button at the top and the 'Convert to New Form Version' button below the notification, with the text: 'Click on "Convert to New Form Version". If you happen to accidentally click "Cancel conversion - Retain Current Version" in the window that pops up, click "Convert to the New Form Version" at the top of your application page.'

On the left, a sidebar shows a 'Section view of Application' with sections 1.0 through 14.0. Section 1.0 'General Information' is highlighted. A callout box labeled '2' points to sections 1.0, 2.0, and 3.0, with the text: 'All but the first three sections of the application will disappear.'

Below the notification, a table with columns 'Einstein', 'Montefiore', 'NBHN', and 'Yeshiva Univers' is partially visible. A callout box labeled '3' points to the 'Save and Continue to Next Section' button, with the text: 'Click on "Save and Continue to Next Section" as many times as needed to restore the completed sections. If new questions or branching have been added, you may need to answer new questions.'

At the bottom right, there are two links: 'Return to Table of Contents' and 'Return to Frequently Asked Questions'.

Initial Review Submission Packet – Section 1

The submission packet contains the new protocol application, the protocol and any other documents you wish to include in the submission. Below is the first page of the submission packet.

EINSTEIN
Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Account: **Coordinator Testing** (You are working under someone else's account. Click here to return to your account)
Department: **Einstein-Montefiore - General Internal Medicine**
Navigation: **Home > study mgmt.**

Home Logout Help

IRB Number: **2013-2078**
PI: Testing, PI

Initial Review Submission form

Back

Print Friendly Refresh Constant Fields Save and Continue

Section view of the Form Entire view of the Form

1.0 Initial Review Submission Packet

1.1 Today's Date:
01/04/2013

1.2 Study Title:
January 4th - another study.

1.3 IRB #:
2013-2078

1.4 Principal Investigator:
PI Testing

1.5 * Lay summary (1 to 3 brief sentences):

Click here to access the text editor.

Save

1
Create lay summary.

2
Save lay summary.

• [Return to Table of Contents](#)

Initial Review Submission Packet – Sections 2-4

The next five sections allow you to edit the application form and attach the consent document, protocol and any other supporting materials. On the first section you add the lay summary. The final page provides instructions for signature routing.

The screenshot shows the Einstein Initial Review Submission form interface. At the top, the user is logged in as 'Coordinator Testing' under the 'Einstein-Montefiore - General Internal Medicine' department. The page title is 'Initial Review Submission form'. A sidebar on the left shows a navigation menu with 'Section 2' highlighted. The main content area is titled '2.0 Application Form' and contains a yellow instruction box: '2.1 Click Save and Continue.' Below this is a link to attach the application and a table of existing attachments.

Remove	Edit/View	Version	Title
		1.0	Study Application (Version 1.0) - Attached

Click on "Save and Continue" if you do not need to edit the application. Click on the notebook icon below Edit/View if you need to edit the application before submission.

The screenshot shows the '3.0 Consent Documents' section of the Einstein Initial Review Submission form. It includes a yellow instruction box: '3.1 Attach the informed consent documents (consent/assent forms, consent scripts, and/or information sheets) for this protocol:'. Below the instruction is a table with columns for Detach, Version, Title, Category, Language, Last Modified, Last Modified By, Checked Out, and View Unapproved Consent. A message at the bottom states: 'No Consent(s) have been attached to this form.'

The screenshot shows the '4.0 Other Study Documents' section of the Einstein Initial Review Submission form. It includes a yellow instruction box: '4.1 Attach the study documents here (e.g. investigators brochure, instruments, case report forms, study handouts or other miscellaneous documents). THE STUDY PROTOCOL MUST BE ATTACHED IN THE NEXT SECTION. Recruitment material must be attached through the Application Form in the appropriate section.' Below the instruction are buttons to 'Add a New Document' and 'Add Multiple Documents', followed by a table with columns for Detach, Version, Title, Category, Expiration Date, Review Outcome, Checked Out, and View Document. A message at the bottom states: 'No Document(s) have been attached to this form.'

Add Consent Documents here. If the study does not involve written/oral consent, just press "Save and Continue".

Add Other Study Documents here. Note: Recruitment Materials must be added within the application form. The protocol must be attached in the next section.

[Return to Table of Contents](#)

Initial Review Submission Packet – Sections 5-6

Section 5

Form Entire view of the Form

1.0 Initial Review Submission Packet

2.0 Application Form

3.0 Consent Documents

4.0 Other Study Documents

5.0 Study Protocol

5.0 Study Protocol

5.1 Attach the Study Protocol here. THIS IS REQUIRED INFORMATION on creating a protocol is available.

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Review Outcome	Checked Out	View Document
	1.0	Protocol dated August 27, 2013	Protocol				23.55 KB

Save and Continue

You must add a protocol in order to submit the application to the IRB.

Section 6

Form Entire view of the Form

1.0 Initial Review Submission Packet

2.0 Application Form

3.0 Consent Documents

4.0 Other Study Documents

5.0 Study Protocol

6.0 Signature Instructions

6.0 Signature Instructions

6.1 To go to the signature routing pages:
Coordinators: Click "Save and Continue" and then "notification routing pages."
PIs: Click "Save and Continue" and then "Signoff and Submit."

6.2 Signature Requirements
Only the signature of the PI is required on the first signature of the routing list.
You must add departmental or other signatories on the routing list. For example, Dr. Baum as Dean of Students. The application will be automatically approved if you do not add any other signatories.

6.3 Please check the box below to proceed.

I understand that omitting signatures will result in a delay of IRB review and approval.

Print Friendly Refresh Constant Fields Save and Continue

Signature

Signoff from

to add Dr.

Read the signature instructions carefully. Failure to obtain the appropriate signatures will delay the approval of your submission.

- [Return to Table of Contents](#)
- [Instructions for signature routing](#)

Additional guidance on adding consents and other study documents

For consent documents, choose the 2nd option. For guidance on the new Einstein Consent and HIPAA Templates go to the iRIS Frequently Asked Questions ([FAQ](#)) section of the Einstein IRB website (<https://www.einsteinmed.org/administration/institutional-review-board/>).

For both consents and study documents, carefully consider the *Document Title*. It will be used for your reference, the IRB's reference, and in any documentation you give to the Sponsor

The image shows two overlapping web forms. The top form, titled 'Study Consent Add Selection Method', has two radio button options. The second option, 'Add an informed consent from an existing electronic document you already have', is selected. An arrow points from this option to the 'Study Document Add' form below. The 'Study Document Add' form contains several fields: a text input for '*Document Title:', a file selection field for '*Select the document to upload:' with a 'Browse...' button, a text input for '*Version Number:' followed by a '.0' suffix, a date picker for 'Version Date:', a dropdown menu for 'Category:' currently set to '--none--', a text area for 'Description:', and another text area for 'Comments:'. A 'Save Document' button is in the top right corner. A callout box points to the 'Document Title' field. A 'Return to Table of Contents' link is in the bottom right corner.

Form Completed!

Account: Melissa Epstein PhD, MBE
Department: E-MMC - Institutional Review Board
Path: Home > study mgmt.

My Workspaces IRB Number: **2020-9003-SAMPLE** Study Assistant Initial Review Submission form - (Version 1.0) Back

Print Friendly Notify PI to Signoff

Section view of the Form Entire view of the Form

1.0 Initial Review Submission Packet
2.0 Application Form
3.0 Consent Documents
4.0 Other Study Documents
5.0 Study Protocol
6.0 Signature Instructions

Form has been Completed!
Instruction of Form has Been Completed Screen

Click here to exit the form and save a draft copy.

Exit Form
Notify PI to Signoff
Create PDF Packet

Click here to route for signatures.

- [Instructions for signature routing.](#)
- [Return to Table of Contents](#)

Routing Submission for Signoff

The next three pages allow you to assign the required approvals for the application.

1

- Among the KSP, only the PI is required to approve the submission.
- By default, the PI will appear under "Finalize List of Personnel for Submission Routing and Signoff:".
- Additional signatories are required for initial submissions and may be required for other types of submissions i.e., amendments to change PI.

Setup for Submission Routing and Signoff

This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		Paula D Brown, B.A.	Principal Investigator

Please verify the list above represents the finalize Personnel for review and signoff? Yes No

Buttons: Cancel - Finalize later, Go back to Make changes, Save - Start Signoff Routing

2

- Add the PI's department chair and other required signatories by using the "Go back to Make changes" button.
- Click the "Add Additional Personnel to the Routing List" button.

Setup for Submission Routing and Signoff

When enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" is the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. If of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Key Personnel for Submission Routing and Signoff:

Approved	Name	Role
	Paula D Brown, B.A.	Principal Investigator

Buttons: Cancel - Finalize later, Add Additional Personnel to the Routing List, Save - Signoff Routing List

3

- Enter the Signatory's last/first name. You can do a full or partial entry. Make sure you are searching from the "iRIS Database".
- Click "Find User/Search Directory".
- Click the Folder under "Select" to select the signatory.
- A role must be selected for each signatory.

Add Additional Key personnel to the Routing Signoff List

Last Name: hippo First Name: step Find User/Search Directory

by Department: All Departments

Search From: iRIS Database LDAP Directory

Select	Name	Department	Email
<input checked="" type="checkbox"/>	Hippolyte, Stephanie	Institutional Review Board	stephanie.gonzalez-vitale@einstein.yu.edu

The Additional Personnel will to be added to the signoff routing list upon clicking the "Save - Add to Routing List" button

Remove	Name	Role
<input checked="" type="checkbox"/>	Melissa Epstein PhD, MBE	Department Chair
<input checked="" type="checkbox"/>	Stephanie Hippolyte	--none--

Routing List

• [Return to Table of Contents](#)

Routing Submission for Signoff - Continued

Add Additional Key personnel to the Routing Signoff List

Last Name: First Name:

by Department:

Search From: IRIS Database LDAP Directory

Select	Name	Department	Email
<input checked="" type="checkbox"/>	Hippolyte, Stephanie	Institutional Review Board	stephanie.gonzalez-vitale@einstein.yu.edu

The Additional Personnel will be added to the signoff routing list upon clicking the "Save - Add to Routing List" button

Remove	Name	Role
<input checked="" type="checkbox"/>	Melissa Epstein PhD, MBE	Department Chair
<input checked="" type="checkbox"/>	Stephanie Hippolyte	Division Chief

4

- Once all signatories have been added, click "Save - Add to Routing List".

Setup for Submission Routing and Signoff

This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Paula D Brown, B.A.	Principal Investigator

Additions or changes to signoffs may be done by clicking "Add Additional Personnel to the Routing List"

Select Additional Personnel for Submission Routing and Signoff:

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>	<input type="checkbox"/>	Melissa Epstein PhD, MBE	Department Chair
<input checked="" type="checkbox"/>	<input type="text" value="1"/>	<input type="checkbox"/>	Stephanie Hippolyte	Division Chief

5

- If you would like all signatories to be notified simultaneously (recommended), set each order to 1.
- When you are done, with specifying the routing order, click "Save - Signoff Routing List".

List of required approvals: <https://www.einsteinmed.org/administration/institutional-review-board/approvals.aspx>
 List of authorized signatories: <https://www.einsteinmed.org/administration/institutional-review-board/authorized-list.aspx>

Finalizing Routing for Submission Signoff

Setup for Submission Routing and Signoff

i This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		Paula D Brown, B.A.	Principal Investigator
1		Melissa Epstein PhD, MBE	Department Chair
1		Stephanie Hippolyte	Division Chief

Please verify the list above represents the finalize Personnel for review and signoff? Yes No

Select "Yes" then click "Save - Start Signoff Routing".

Cancel - Finalize later Go back to Make changes Save - Start Signoff Routing

Additions or changes to signoffs for approval may be added by clicking "Go back to Make changes" and then following instructions in the previous slide(s).

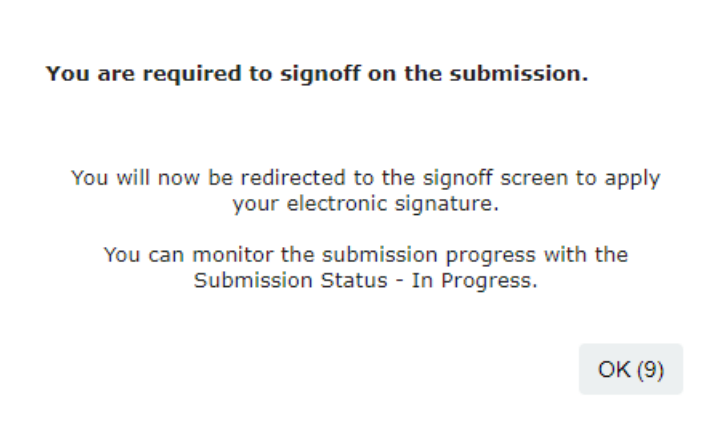
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The submission has now been sent for signatures!
Now you must wait for the submission to be signed and for the IRB to review.

Upon finalizing the routing and sending the submission for signoff, you will receive a pop-up message which displays the following:



If you are the PI and have routed the submission for signoff, you will receive a pop-up message which displays the following:



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How to View Submission Status

- Once you've submitted for signoff you are automatically re-directed to your iRIS homepage.
- To view the status, go to the "Studies Submission Status – In Progress" Panel:
 - Option 1: Click the notepad icon to open the entire study
 - Under track location click the magnifying glass icon.
 - Click the "+" symbol under "Task Status" next to "Pre-Submission".
 - The "Task Status" column tells you whether the task has been received or completed and the "Task Action/Details" tells you the type of task that is pending or has taken place.
 - Option 2: Click "Steps +" under the "Actions" column in the "Studies Submission Status – In Progress" Panel (on your iRIS homepage):
 - Click the "+" symbol under "Task Status" next to "Pre-Submission".
 - To collapse the history, click "Steps -". You can then choose another submission to view without having to enter a new IRB number.
 - The IRB number, submission reference number, and form name are all available via this view.

** iRIS now calculates how long a submission has been at each step. This could be useful to determine why a submission has not yet gotten to the IRB for review, and who the submission is with and for how long (if signoffs are still required). The duration is listed under the "Total Time" column.

Click to open Study Dashboard	Reference Number	Review Board	IRB Number	Form Name	Study Title Short Title/Sponsor Protocol Number	Form Author	Date Submitted	Actions
	039494	Einstein IRB	2020-9003-SAMPLE	Initial Review Submission form	testing new version test new ver	Brown, Paula D, B.A.	02/25/2020 02:00 PM EST	Incomplete Tasks Open Steps to Complete
	003667	Einstein IRB	2013-2006-SAMPLE	Amendment Form	kap -SAMPLE kap	Epstein, Melissa, PhD, CIP	02/07/2020 02:20 PM EST	Incomplete Tasks Open Steps to Complete
	039471	Einstein IRB	2017-7482 - SAMPLE	Amendment Form	testing that this study begins with '2017' none	Brown, Paula D, B.A.		Incomplete Tasks Open Steps to Complete
	035549	Einstein IRB	2018-8914 - SAMPLE	Initial Review Submission form	testing Q2 status changes testing Q2 status changes	Brown, Paula D, B.A.		Incomplete Tasks Open Steps to Complete
	034469	Einstein IRB	2017-8379 SAMPLE for iMedRIS	Initial Review Submission form	Copy of Reactivation and Elimination of Latent HIV-1-infected Cells HIV Latency Elimination	Brown, Paula D, B.A.	09/15/2017 11:14 AM EST	Incomplete Tasks Open Steps to Complete
	026657	Einstein IRB	2017-7482 - SAMPLE	Progress Report	testing that this study begins with '2017' Testing Issues	Brown, Paula D, B.A.	05/24/2017 04:01 PM EST	
	030086	Einstein IRB	2016-7063-SAMPLE	Progress Report	TI	Brown, Paula D, B.A.	05/24/2017 04:00 PM EST	Incomplete Tasks Open Steps to Complete

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How to View Submission Status – Continued (Option 1 details on slide 44)

1

EINSTEIN
Albert Einstein College of Medicine

Hello Paula D Brown, B.A.
your last login was
02/25/2020 09:08 AM EST

My Workspaces Study Assistant

All Tasks

Studies Submission Status - In Progress

In Progress Completed

7 result(s) found...

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form
	039494	Einstein IRB	2020-9003-SAMPLE	Initial
	003667	Einstein IRB	2013-2006-SAMPLE	Amenc

B.A.
Institutional Review Board

Study Assistant **Submissions**

RB Number : 2020-9003-SAMPLE Study Title : testing new version

2

Submissions History
Study Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type
Waiting for PT signoff	039494	Click on the hyperlink to edit/view the submission. Initial Review Submission form

3

Albert Einstein College of Medicine

My Workspaces IRB Number: 2020-9003-SAMPLE Study Assistant Workflow - Submission Tracking
PI: Brown, Paula D, B.A.

Pre-Submission

Task Status	Task Action/Details	Task Name
Pre-Submission		

Retract Submission

4

Pre-Submission

Task Status	Task Action/Details	Task Name
Pre-Submission		
Completed	Initial Review Submission form is waiting to be submitted	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Melissa Epstein PhD, MBE	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.	
Received	Modify Signoff Routing List	Assign Department Personnel for Signoff

Retract Submission

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How to View Submission Status – Continued (Option 2 details on slide 44)

1 Study Assistant [User Name]

Studies Submission Status - In Progress Search for RB Number, Title, Alias Search

In Progress Completed

7 result(s) found... 1 - 7

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form Name	Study Title		Form Author	Date Submitted	Actions
					Short Title/Sponsor Protocol Number				
	039494	Einstein IRB	2020-9003-SAMPLE	Initial Review Submission form	testing new version	test new ver	Brown, Paula D, B.A.	02/25/2020 02:00 PM EST	Incomplete Tasks Open Steps to Complete

2 Studies Submission Status - In Progress Search for RB Number, Title, Alias Search

In Progress Completed

7 result(s) found... 1 - 7

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form Name	Study Title		Form Author	Date Submitted	Actions
					Short Title/Sponsor Protocol Number				
	039494	Einstein IRB	2020-9003-SAMPLE	Initial Review Submission form	testing new version	test new ver	Brown, Paula D, B.A.	02/25/2020 02:00 PM EST	Incomplete Tasks Open Steps to Complete
Pre-Submission									
Task Status	Task Action/Details			Task Name	Date Created	Date Completed	Total Time		
	Pre-Submission			Retract Submission	02/25/2020 10:01 AM EST		0 Day(s) 4 Hour(s) 34 Minute(s)		

3 Studies Submission Status - In Progress Search for RB Number, Title, Alias Search

In Progress Completed

7 result(s) found... 1 - 7

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form Name	Study Title		Form Author	Date Submitted	Actions
					Short Title/Sponsor Protocol Number				
	039494	Einstein IRB	2020-9003-SAMPLE	Initial Review Submission form	testing new version	test new ver	Brown, Paula D, B.A.	02/25/2020 02:00 PM EST	Incomplete Tasks Open Steps to Complete
Pre-Submission									
Task Status	Task Action/Details			Task Name	Date Created	Date Completed	Total Time		
	Pre-Submission			Retract Submission	02/25/2020 10:01 AM EST		0 Day(s) 4 Hour(s) 34 Minute(s)		
Completed	Initial Review Submission form is waiting to be submitted				02/25/2020 10:01 AM EST	02/25/2020 02:00 PM EST	Day Hours Minutes 0 3 59		
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.				02/25/2020 10:07 AM EST	02/25/2020 10:07 AM EST	Day Hour Minute 0 0 0		
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.				03/26/2020 10:06 AM EST	03/26/2020 10:06 AM EST	Day Hour Minute 0 0 0		
Completed	Initial Review Submission form has been retracted by Paula D Brown, B.A.				02/25/2020 10:10 AM EST	02/25/2020 10:10 AM EST	Day Hour Minute 0 0 0		
Completed	Initial Review Submission form has been retracted by Melissa Epstein PhD, MDC				02/25/2020 10:13 AM EST	02/25/2020 10:13 AM EST	Day Hour Minute 0 0 0		

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Training Validation Failed - Identifying KSP with missing education requirements


IRB Number: 2013-2148 **Submissions** ◀ Back
PI: Testing, PI


Study Status: Pending - Submitted for **IRB Number:** 2013-2148 **Study Title:** Retract submission

Submissions Study Management



- Protocol Items**
- Protocol Items
 - Study Application
 - Informed Consent
 - Other Study Documents
 - Contract Documents
 - Initial Review Submission form

Submissions History
 Study Correspondence

 **Outstanding Submission(s)**

Track Location	Ref Number	Request Type	Process Submission
	000173	Click on the hyperlink to edit/view the submission. Initial Review Submission form	Retract Submission

1 - click the magnifying glass icon

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Completed			02/25/2020 10:01 AM EST		0 Day(s) 5 Hour(s) 4 Minute(s)
Completed			02/25/2020 10:01 AM EST	02/25/2020 03:04 PM EST	Day Hour Minute 0 5 3
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.	02/25/2020 10:07 AM EST	02/25/2020 10:07 AM EST	Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Melissa Epstein PhD, MBE			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed		Initial Review Submission form has been retracted by Paula D Brown, B.S.			Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff			Day Hour Minute 0 0 0
Completed	View Signoff	Paula D Brown, B.S. as Principal Investigator review and apply signoff			Day Hour Minute 0 0 0
Warning Error Occurred	View Details	The following Study Personnel are not registered with up to date training records:			Day Hour Minute 0 0 0

2 - click the "+" sign to expand the "Task Details". Click "View Details" a new window opens displaying details.

Training Records

Training Failure	Personnel
Personnel without valid Initial Review Group training:	Weston, Gabriella

Lists the personnel that are missing education requirements.

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Checking the education status for all KP

1 – Click on the “Study Management” Tab

Albert Einstein College of Yeshiva
 IRB Number: DEMO-2013-7047
 PI: Testing, PI
 Study Status: Draft
 IRB Number: DEMO-2013-7047
 Study Title: Retra

Submissions Study Management

Protocol Items

- Study Application
- Informed Consent
- Other Study Documents
- Contract Documents
- Initial Review Submission form

Post-Approval Forms

- General

2 – Click on “Study Summary/Profile”

IRB Number: DEMO-2013-7047
 PI: Testing, PI
 Study Status: Draft
 IRB Number: DEMO-2013-7047

Submissions Study Management

Study Details

- Study Summary/Profile
- Screen Access
- Key Personnel

3

Click on the “person” icon of the personnel whose Education History you would like to track.

Current Enrollments: 0
 Accrual Ceiling:
 Accrual Target:
 Enrollment D

Study Department(s)

Name
 Einstein-Montefiore - General

Study Personnel

Principal Investigator: PI Testing

Study Contact: Coordinator Testing PI Testing

4

Review the Education History. They must have one of these courses: Human, Basic Course, a Refresher Course. The course must be completed and not expired for the KP to pass the education check.

5

Click on “Back” to return to the study summary page.

Education - PI Testing

Contact Information

Last Name: Testing First Name: PI Middle Name:
 Contact Information:

En Address Prim Number: Number: Page Number: Fax Number: Location: Mailing Address

Education History

Training Group	Course	Course Date	Course Expiration	Score
	Basic Course	01/05/2013	01/05/2016	
	CRTP Ethics Course	01/30/2013	01/30/2016	

Back

- [Return to Table of Contents](#)
- [Retract & Resubmit](#)

Retracting & Resubmitting the Study to Clear Education Validation

Once ALL KP have completed their required training and checked their status on iRIS, the submission must be retracted and resubmitted. Note that CITI information is automatically updated in iRIS overnight, so it may take up to 24 hours for the update to occur.

Studies Submission Status - In Progress

In Progress **Completed**

7 result(s) found...

1 - 7

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form Name	Study Title	Short Title/Sponsor Protocol Number	Date Created
	039494	Einstein IRB	2020-9003-SAMPLE	Initial Review Submission form	testing new version	test new ver	02/25/2020

1 - On your iRIS homepage, go to the "Studies Submission Status – In Progress" Panel. Click "Steps +" then click "Retract Submission"

2 Confirm Retracting the Submission
Are you sure you want to retract this submission from review?

Studies Submission Status - In Progress

In Progress **Completed**

1 result(s) found...

Study Title	Form Author	Date Submitted	Actions
testing new version	Brown, Paula D, B.A.	02/25/2020	Incomplete Tasks Open Steps to Complete

4 - On your iRIS homepage, go to the "Studies Submission Status – In Progress" Panel. Click "Steps +" then click "Retract Submission"

5 Confirm Submission is Ready for Review.
Are you sure you want to submit this submission for review?

3 The submission has been retracted.
Please modify your submission, and the supporting documents, and then resubmit.

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Retracting the study when you have opted to open the entire study either via the “All Studies” panel or the Studies Submission Status – In Progress” panel .

The screenshot shows a web application interface for managing submissions. The top navigation bar includes the IRB Number (2013-2148), PI (Testing, PI), and a Back button. Below this, there are tabs for Submissions and Study Management. The main content area is divided into Protocol Items and Post-Approval Forms. The Protocol Items section includes Study Application, Informed Consent, Other Study Documents, Contract Documents, and Initial Review Submission form. The Post-Approval Forms section includes General. The Outstanding Submission(s) table shows a submission with Ref Number 000173 and Request Type Initial Review Submission form. A red banner indicates Education validation failed. A 'Retract Submission' button is visible next to the submission. A callout box with the number 1 and the text 'Click the "Retract Submission" button' points to this button. A blue arrow points from this callout to a second screenshot below. The second screenshot shows a confirmation dialog box with the number 2 and the text 'Confirm withdrawal of submission. Are you sure you want to withdraw this submission for review?'. The dialog has OK and Cancel buttons. A blue arrow points from this dialog to a third screenshot below. The third screenshot shows a success message dialog box with the number 3 and the text 'Your Submission has been successfully withdrawn!'. The dialog has an OK button. A blue arrow points from this dialog to a final callout box with the text 'Return to Table of Contents'.

1 – Click the “Retract Submission” button

2

3

Return to Table of Contents

Resubmitting the study

Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY
Department: Einstein-Montefiore - General Internal Medicine
Navigation: Home > my studies

IRB Number: 2013-2148
PI: Testing, PI
Study Status: Draft
IRB Number: 2013-2148
Study Title: Retract submission

Submissions History
Study Correspondence

Track Location	Ref Number	Request Type	Process Submission
	000173	Click on the hyperlink to edit/view the submission. Initial Review Submission form	Send Submission

1 – Click the “Send Submission” button.

Message from webpage

2 Confirm Request for Review.
Are you sure you want to submit this submission for review?

OK Cancel

3 - Signatures must be re-assigned (follow instructions in slides 40-42).

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How to check out a document for editing

For both consents and study documents, carefully consider the *Document Title*. It will be used for your reference, the IRB's reference, and in any documentation you give to the Sponsor.

Update document information here if needed.

Are you sure you want to check-out the document?
If yes, document will be downloaded to your local computer to save as part of your local files. Modify and check in later.

CONFIRM

CANCEL

Check-out Document...

Check out the document for editing.
Confirm check-out

Save Consent

- [Return to Table of Contents](#)
- [Return to Frequently Asked Questions](#)

How to “check-in” a document after editing OR Undo the “check-out”

Study Consent Revision:

Version Number: 1 .0

*Version Date: 02/25/2020

* Category: Consent

* Language: English

Description:

This document is currently checked out by: Paula D. Brown at 02/25/2020 04:29:32 PM

Check-in when you are done editing upload the document back into iRIS.

Revert to the document stored in iRIS.

Check-in Document...

Undo Check-out Document...

Save Consent

For both consents and study documents, carefully consider the *Document Title*. It will be used for your reference, the IRB's reference, and in any documentation you give to the Sponsor.

Update document information here if needed.

Check in the saved document. Remember where you saved it on your computer.

When you are done click "Save Consent" or "Save Document".

If you checked -out the document in error, or no longer wish to make changes to the document, click "Undo Check-out Document" and the initial document will remain attached.

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- [Return to Frequently Asked Questions](#)