

## Registering a Paper-Based and Already Approved study in the iRIS System

If you have a study that is paper-based and currently approved by the UH IRB, this manual is intended to guide you through the steps for registering this study in the iRIS system.

Once your registration has been submitted to and approved by the UHCMC IRB, you will then submit future forms (i.e. Amendments, AEs, Continuing Reviews) for that study electronically via iRIS. You may not make changes during the registration process. All studies are required to be registered by December 31, 2011.

- **Registrations will take a few weeks to process depending on the age of the study.**
- **If you have to make immediate changes to your study, or your study requires immediate continuing review, please do this via paper submission and then register your study once that approval is obtained.**

You do not need to register already approved determinations (NHR-XX-XX) or exemptions (EM-XX-XX) in iRIS. The registration process is intended for all other types of studies which have received regular IRB approval (i.e. clinical trials, chart reviews, discarded tissue studies, survey studies, etc.) and have IRB numbers (e.g. IRB# 01-01-01)

### There are three basic steps to the registration process:

**Step 1:** “Add a New Study” and fill out the protocol application. Select “No” to your research being cancer-related so that you are directed to the UH IRB’s application rather than the Case Comprehensive Cancer Center IRB application. When asked what type of study you are submitting, be sure to select the following from the drop down menu: **“Registration- paper-based study, already approved by IRB”**.

When filling out the protocol application, answer the questions to reflect what is contained in the currently approved study protocol, checklist, research plan, etc. Only minor updates to your currently approved IRB file (such as updating Key Study Personnel) will be allowed during the registration process.

**Step 2:** Attach your study documents that are approved for use at the time of registration

When it is time to put together your submission packet in iRIS, attach unstamped versions of all your currently approved documents including Word 2003 versions of any consent/assent documents (DO NOT ATTACH AS WORD 2007). As part of the registration process, the IRB office will verify that the versions you attach and the paper versions currently approved are the same. Once verified, you will be issued new stamped documents for use in iRIS.

Acceptable document formats are Word 2003, Excel 2003 or pdf only!.

Do not attach expired, outdated or previous versions of any of your study documents (protocols, consents, etc). Include the documents that are currently approved and in use. This includes Investigator Brochures, advertising materials, sponsor protocols, etc.

**Step 3:** Route for PI signoff – The PI is required to confirm the registration. Once the PI’s electronic signature is obtained, the submission will be routed to the UH IRB

## Completing the Application

The Study Assistant Module consists of two tabs, “Add a new Study” and “My Studies”. You can submit a protocol application by going to “Add a new study”. You can access your existing studies through the “My studies” link.

To begin registering a study, click on “Add a New Study”.

Account: **Test Study-Coordinator**  
Department: **Case - Department**

My Assistant  
Study Assistant  
**Add a new Study**  
My Studies

Your current Department is Case - Department

Worklist Filter: All

Incomplete Tasks Complete Tasks Not Opened Correspondence Previously Opened Correspondence

No tasks found

## Study Shell

The first three sections of the application are the study shell. These sections are common screens no matter which board you are submitting to (UH IRB, IACUC or Case Cancer IRB).

### 1.0 General Information

Study Title: This is where you enter the full study title

Keywords/Short Study Title: This is where you enter keywords or a short study title (e.g. Drug XYZ in cirrhotic adults). You can also capture a study number that you might have from the sponsor or department review board (e.g. Case 1234).

Short Study Title: 7/30  
PI: Kulaszewski, Meghan A CCRP

Study Application

Printer Friendly Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

1.0 General Information

1.1 \* Please enter the full title of your study:

Registration 7/30/10

1.2 \* Please enter 3 keywords or Short Study Title to describe the study:

7/30  
(e.g. "arthritis, pediatrics" and "CASE4Y02")

## Save and Continue

As you move through the application and complete each section, you will need to click “save and continue to next section” to continue moving through the application sections.

Short Study Title: UH IRB Test #2  
PI: Kulaszewski, Meghan

Study Application

Printer 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 study personnel (KSP) access to the study  
4.0 Board Selection  
5.0 UH IRB - Routing Questions

5.0

UNIVERSITY HOSPITALS CASE MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD FOR HUMAN INVESTIGATION

PROTOCOL APPLICATION

## 2.0 Add Departments

In question 2.1 you must designate which departments are associated with this study. If the study involves more than one department, list all applicable departments, marking one as the study’s primary department.

For example: If a study is being conducted by the Dept. of Medicine but the study also involves the Dept. of Pediatrics because children are being recruited as study subjects, both the Dept. of Medicine and the Dept. of Pediatrics should be listed as departments associated with this study with Dept. of Medicine being designated as the primary department.

The department of the person completing the application will populate by default. If this department is not needed, you can remove the department by clicking on the box next to department name and then clicking the “remove” button.

Short Study Title: UH IRB Test #2  
PI: Kulaszewski, Meghan

Study Application

Printer 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 study personnel (KSP) access to the study  
4.0 Board Selection  
5.0 UH IRB - Routing Questions  
6.0 UH IRB Study Information and Personnel  
7.0 UH IRB COI Information  
8.0 UH IRB Study Population  
9.0 UH IRB Consent/Assent

2.0 Add Department(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name	Add	Remove
<input type="checkbox"/>	Case - Department		

Additional departments can be added by clicking the “Add” button. This will take you to a listing of departments to choose from.

The screenshot shows the 'Add Department(s)' screen in the iRIS by iMedRIS system. The user is logged in as 'Test Study-Coordinator' in the 'Case - Department'. The main content area is titled '2.0 Add Department(s)' and contains a section '2.1 List departments associated with this study:'. Below this is a table with columns for 'Primary Dept?' and 'Department Name'. The table lists 'Case - Department' with a checked box. To the right of the table are 'Add' and 'Remove' buttons. The 'Add' button is circled in red.

Find the department you wish to add from the list of departments in the system. You can search by department name. Once you have found the correct department, check the box next to the one you wish to add then click “Add”.

The screenshot shows the 'Adding Department - Search Window' dialog box. The dialog has a search bar with fields for 'Name', 'Dept Code', and 'School Code', and a 'Search' button. Below the search bar, it says '343 result(s) found...'. A table lists departments with columns for 'Select', 'Department Name', 'Institution', 'School Code', and 'Department Code'. The 'Case - Biomedical Engineering, Department of' row has a checked box. At the bottom of the dialog, there are 'Cancel' and 'Add' buttons. The 'Add' button is circled in red.

This process can be repeated to add as many associated departments as necessary.

### 3.0 Assign Key Study Personnel (KSP)

This is where you indicate the key study personnel from Case and/or UH that are involved with this

study. Adding someone to the KSP section gives them the ability to access the study files through their “My Studies” tab.

If you have additional personnel that are involved with the study but will not need to access the iRIS™ system, they can be listed just in the personnel table located later in the application.

Click on the “add” button and you will be taken to the user directory.

Short Study Title: 7/30  
PI: Kulaszewski, Meghan A CCRP

Study Application

Printer 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 study personnel (KSP) access to the study

3.0 Assign key study personnel(KSP) access to the study

3.1 \*Please add a Principal Investigator for the study:

Meghan A Kulaszewski CCRP

Select if applicable  
 Student  Resident  Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Protocol Staff personnel:

A) Additional Investigators Add  
B) Research Support Staff Add

You can search by first name and/or last name. Click “Find” and you will be given the results of your user search.

By default, the system will search the iRIS directory first. If the person you are looking for can't be located this way, change the “search from” button to now search the LDAP directory. This will search the UH and Case directories for the person.

iRIS: Search User Directory - Microsoft Internet Explorer

Account: Meghan A Kulaszewski CCRP  
Navigation: Home > my studies > study mgmt. > application

Short Study Title: demo 7/23  
PI: Kulaszewski, Meghan A CCRP

Search User Directory

Directory Browse/Find:

Last Name: princi (You may enter a partial name to search)  
First Name:  
Department: All Departments  
Search From:  iRIS Database  LDAP Directory

Select User(s)

Select	Select User	Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Principal-Investigator, IRB	OTHER (primary)	mxt64@case.edu
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Principal-Investigator, Test	OTHER (primary)	meghan.kulas@uhhospitals.org

Click the “select user checkmark” next to the person you wish to add. You will be taken back to the application question, with the person added.

Question 3.1: You will indicate the Principal Investigator for the study. If the Principal Investigator is a student, resident or fellow check the appropriate box. Their responsible investigator (RI) needs to be added in question 3.4.

Question 3.2A: Here is where you add any co-investigators.

Question 3.2B: Here is where you add any support staff; study coordinators, research assistants, etc. In this question, both the person's name and role must be specified.

Question 3.3: This is where study contacts are indicated. Anyone that needs to be copied on notifications regarding this study must be listed as a study contact person. The PI is automatically assigned as one of the study contacts by default.

The screenshot shows a web application interface for a 'Study Application'. The top navigation bar includes 'Short Study Title: UH IRB Test #2', 'PI: Kulaszewski, Meghan', and 'Study Application'. There are buttons for 'Printer Friendly', 'Save and Continue to Next Section', and 'Back'. A sidebar on the left lists sections 1.0 through 9.0, with 3.0 'Grant key study personnel (KSP) access to the study' selected. The main content area is titled '3.0 Assign key study personnel(KSP) access to the study' and contains several sub-sections:

- 3.1 \*Please add a Principal Investigator for the study:** A form with a text input containing 'Meghan Kulaszewski', checkboxes for 'Student', 'Resident', and 'Fellow', and a 'Department Chair' checkbox. An 'Add' button is present.
- 3.2 If applicable, please select the Protocol Staff personnel:** A table with two rows: 'A) Additional Investigators' and 'B) Research Support Staff'. Each row has an 'Add' button. The 'B' row also has a 'Remove' button. A dropdown menu for 'Study Coordinator' is visible.
- 3.3 \* Please add a Study Contact:** A list of checkboxes for 'Kulaszewski, Meghan' and 'Study-Coordinator, Test'. An 'Add' button and a 'Remove' button are present. A note below states: 'The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).'
- 3.4 If applicable, please add a Responsible Investigator:** An 'Add' button.

#### 4.0 Board Selection

Based on your answers to the questions in this section, the system will direct you to the proper board (UH IRB, IACUC or Case Cancer IRB).

To be routed to the UH IRB’s application, select that your study involves Human Subjects Research and the project does not involve cancer (select “no” to cancer-related). This will take you down the path to complete the UH IRB application.

The screenshot shows the 'Study Application' interface. At the top, it displays 'Short Study Title: UH IRB Test #2' and 'PI: Kulaszewski, Meghan'. There are buttons for 'Printer Friendly' and 'Save and Continue to Next Section'. A sidebar on the left lists sections from 1.0 to 9.0, with '4.0 Board Selection' highlighted. The main content area is titled '4.0 Which Board?' and contains a question: '4.1 \* Is your project Human Subject Research requiring IRB approval or is the project Animal Research requiring IACUC review?'. Below the question are two radio button options: 'Human Subjects Research' (which is selected) and 'Animal Research'. A sub-question follows: 'If your project is Human Subject Research, does it involve cancer research or cancer-related issues?' with 'Yes' and 'No' radio buttons, where 'No' is selected.

## Application Tips

### Required Questions

If you click “save and continue to next section” and you have not answered a required question, an error box will appear and the field you missed will be indicated in red.

This screenshot shows a different section of the application, 'OPTION #1: Written and Signed Consent'. It contains a checkbox for 'Written, obtained in accordance with Federal Regulations (DHHS: 45 CFR 46 and FDA: 21 CFR 50 where applicable). \*Copies of all consent forms to be attached to the application packet prior to submission'. A red warning triangle icon is present with the text: 'You must select one option for the consent process'. Below this is a text area for 'If written, list all languages that will be used...'. A 'Microsoft Internet Explorer' error dialog box is overlaid on the screen, displaying a yellow warning icon and the message: 'An error occurred on the page. Please correct the mistake and resave the form'. Below the error box is an 'OK' button. Further down, there is another checkbox for 'OPTION #2: Waiver of Signed Consent' and a text area for 'How will consent be obtained:'.

### Draft

You do not need to finish the application all at one time. Finish the section you are currently working on and “Save and Continue”.

Incomplete applications will be saved as “Drafts”. You can log back into the system at any time and access your Draft study through the “My Studies” tab of the Study Assistant module.

## Revised Application

While you have an application in the draft stage, the system forms may be updated (meaning new questions have been added or old questions have been reworded). When you access your draft application, you will be prompted to convert the draft to the new form.

- The system will notify you that a new form version has been published.
- Click the OK and then the “Convert to the New Form Version” button.
- Click the “Save and Continue to Next Section” button through all of the sections of the application that you have already completed. If there are any additional questions that have been added to any sections of the form, you will have to answer these before you can save and continue to the next section.

The screenshot shows the 'Study Application' interface. At the top, there are buttons for 'Printer Friendly', 'Convert to the New Form Version' (circled in red), and 'Save and Continue to Next Section'. A 'Back' button is also visible. The main content area is titled 'Entire view of the Application' and shows section 1.0 'General Information'. A yellow notification dialog box from Microsoft Internet Explorer is overlaid on the screen, containing the following text: 'A new version of the application form has been published. Please click on the button Convert to the New Form Version. Then click through the wizard to verify that the application is complete.' Below the dialog, the form content is partially visible, including a field for '1.1 \* Please enter the full title' with the text 'iMedRIS testing UH IRB branch' and a field for '1.2 \* Please enter 3 keywords or Short Study Title to describe the study:'.

## Revising Previous Sections

As you move through the application (clicking “save and continue to next section”) the sections will build on the left side of the screen. If you would like to return to a section you already completed, you can click on the section’s link in the section view. You can then make the changes to the section. Click “save and continue” to save the revisions and proceed with the application.

The screenshot shows the 'Study Application' interface with the 'Section view of Application' on the left and the 'Entire view of the Application' on the right. The 'Section view of Application' lists sections 1.0 through 12.0, with section 6.0 'UH IRB Study Information and Personnel' circled in red. The 'Entire view of the Application' shows section 6.0 'Study Information and Personnel' and section 6.1 'Type of study:'. Below section 6.1, there is a list of study types with checkboxes: 'Chart Review Study', 'Discarded Tissue Study', 'Questionnaire/Survey Study', 'Data and/or Sample Repository', 'Blood Draw', 'Humanitarian Use Device', 'Clinical Trial' (checked), and 'Other (specify:)' with a text input field. Below this list, there is a dropdown menu for 'If Clinical Trial, select the Phase below:'.

## Printing the Application

When you have the application open, you can click on the “printer friendly” tab in the upper right hand corner. This will open a separate window that will allow you to print the application sections you have completed so far.

## Help Bubbles

As you navigate through the application, you will periodically see help bubbles along the right side of the screen. When you click on a help link, a separate window will open containing helpful information related to that portion of the application.

The screenshot displays the MedRIS application interface. At the top, the header includes the IKIS by MedRIS logo, user information (Account: Test Study Coordinator, Department: Case - Department), and navigation links (Home, Logout, Help). Below the header, the page title is "Study Application" with a "Back" button. A secondary navigation bar contains "Printer Friendly" and "Save and Continue to Next Section" buttons. The main content area is divided into two tabs: "Section view of Application" and "Entire view of the Application". The "Section view of Application" tab is active, showing a list of sections: 1.0 General Information, 2.0 Setup Department(s) Access, 3.0 Grant key study personnel (KSP) access to the study, 4.0 Board Selection, and 5.0 UH IRB - Routing Questions. The "5.0 UH IRB - Routing Questions" section is expanded, showing three questions: 5.1, 5.2, and 5.3. Each question has radio buttons for "Yes" and "No". A red circle highlights a help bubble next to question 5.2, which contains the text "UH IRB Exemption Policy".

## Registration

When you get to Section 6.0, you will be asked what your submission is. To register an already approved and paper-based study, select the option “Registration – Paper-Based Study, Already Approved by IRB”.

In the next question, type in the IRB# for this study. The format for IRB numbers is XX-XX-XX.

IRIS: Study Application - Microsoft Internet Explorer

Account: Meghan A Kulaszewski CCRP  
Department: UH - Administration  
Navigation: Home > my studies > study mgmt.

Short Study Title: Lupus efficacy study  
PI: Principal-Investigator, Test

Section view of Application | Entire view of the Application

6.0 New Study or Registration of Paper-Based Study

6.1 This submission is... 1) a new study/project

2) a paper-based study that has been previously submitted and is currently approved by the UHCMC IRB that you are registering in iRIS or

3) a study currently approved that is already in the iRIS system

\*\*\*THE REGISTRATION PROCESS IS ONLY OPEN TO THOSE THAT HAVE BEEN SPECIFICALLY ASKED TO REGISTER A STUDY. ONCE BETA TESTING IS COMPLETE, THE RESEARCH COMMUNITY WILL BE NOTIFIED THAT REGISTRATION IS OPEN FOR ALL.

Registration - Paper-Based Study, Already Approved by IRB

--none--  
New Study  
Registration - Paper-Based Study, Already Approved by IRB  
Study Currently Approved and Already in iRIS

study, what is the study's IRB#? (IRB# format = xxx-xxx-xx)

**Note:**

- You do not need to register already approved determinations (NHR-XX-XX) or exemptions (EM-XX-XX) in iRIS. The registration process is intended for all other types of studies which have received regular IRB approval (i.e. clinical trials, chart reviews, discarded tissue studies, survey studies, etc.) and have IRB numbers (e.g., IRB# 01-01-01)
- If you have to make immediate changes to your study, or your study requires immediate continuing review, please do this via paper submission before registering your study. All registrations will take approximately 1-3 weeks to process depending on the age of the study.

Printer Friendly | Save and Continue to Next Section

“Save and Continue” will take you to the next application section and you can continue filling out the application.

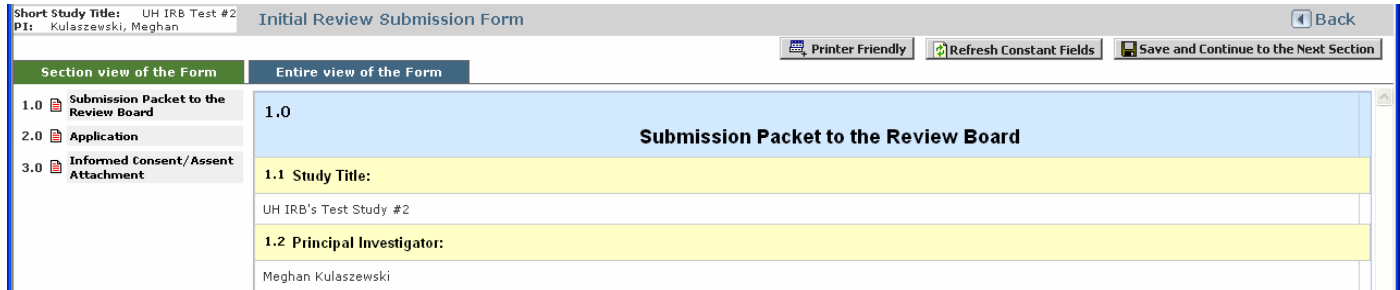
As you progress through the study application, how you answer the questions will determine the next section you need to complete. This is the branching functionality of the iRIS™ system.

For example: If you indicate in the consent section of the application that you are not obtaining written consent, when you finish the consent questions and click “save and continue”, the next section will be the waiver of consent documentation. If you had answered the question that you were going to obtain written consent, you would not be taken to the consent waiver section at all.

This type of branching has been configured throughout the iRIS™ system.

## Submission Packet to the Review Board

Once you have finished answering the questions in the last section of the application, you will see the “Submission Packet to the Review Board”. This is where you put together all the components of your submission. You are building your submission packet.



The screenshot shows the 'Initial Review Submission Form' for 'UH IRB Test #2' by 'Kulaszewski, Meghan'. The form is titled 'Submission Packet to the Review Board' and contains two sections: '1.1 Study Title:' with the value 'UH IRB's Test Study #2' and '1.2 Principal Investigator:' with the value 'Meghan Kulaszewski'. The left sidebar shows a navigation menu with '1.0 Submission Packet to the Review Board' selected. At the top right, there are buttons for 'Printer Friendly', 'Refresh Constant Fields', and 'Save and Continue to the Next Section'.

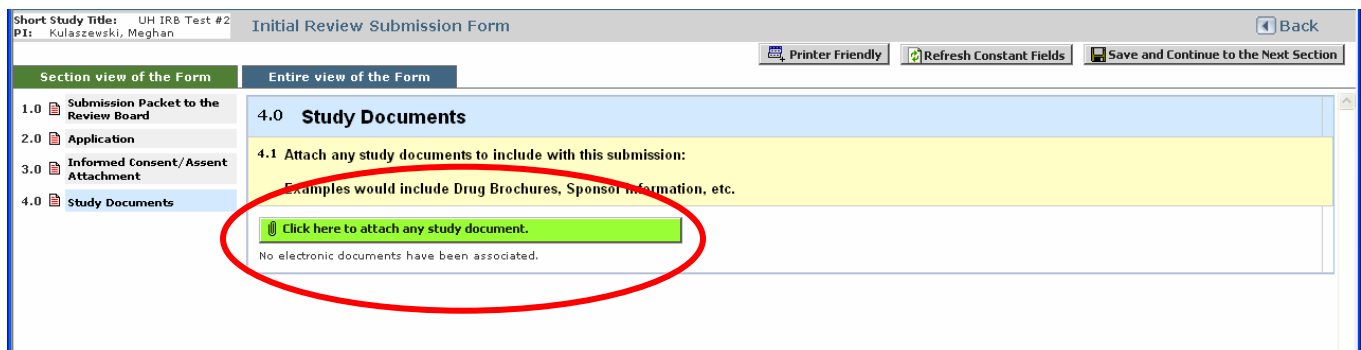
The submission packet functions similarly to the application in that you will move section by section, clicking “save and continue” to navigate through the screens.

Because of the branching built into the application questions, the items you are prompted to attach in the submission packet will depend on the answers in your application.

For example: If you indicated in the consent form questions of the application that you are going to consent study subjects over the phone, you will be prompted in the submission packet section to attach a copy of your script.

As you move through the sections of the submission packet, you will attach study documents.

Click on the green attachment bar in order to attach documents.



The screenshot shows the 'Study Documents' section of the 'Initial Review Submission Form'. The form is titled '4.0 Study Documents' and contains a section '4.1 Attach any study documents to include with this submission:' with the text 'Examples would include Drug Brochures, Sponsor information, etc.'. A green button labeled 'Click here to attach any study document.' is circled in red. Below the button, it says 'No electronic documents have been associated.' The left sidebar shows a navigation menu with '4.0 Study Documents' selected. At the top right, there are buttons for 'Printer Friendly', 'Refresh Constant Fields', and 'Save and Continue to the Next Section'.

You will be taken to the attachment screen. This will show you all the attachments you have loaded into the system so far and whether or not you want to attach another single document or multiple documents.

For each document you attach, you will enter the document title, version number and version date. You can select the document category (flyer, protocol, other, etc.) and you can enter a description.

By clicking on “upload” you can browse your computer to find the document(s) you want to save in

the system. Once uploaded, be sure to click “save document”.

Short Study Title: UH IRB Test #2  
PI: Kulaszewski, Meghan

Study Status: Draft Study Title: UH IRB's Test Study #2

Expiration Date:

\*Document Title:

\*Version Number: .0

Version Date:

Category: --none--

Description:

Load the document into IRI:

Once you have uploaded your document into the system, it will still need to be attached to the submission packet. This is done by checking the box in front of the document you wish to attach to the submission packet and then clicking on save attachment.

Short Study Title: UH IRB Test #2  
PI: Kulaszewski, Meghan

Click the checkbox to select/deselect the document(s).  
Click the Add New Document button to add a new document.  
Click the Add Revision button to create a revised document.  
Click the Delete Document button to delete the selected document.  
Click the Save Attachments to attach or unattach study documents.

IRB Rev.	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a New Document
<input checked="" type="checkbox"/>			1.2 04/09/2009		Test Protocol	Meghan Kulaszewski	04/09/2009	<input type="button" value="Add Revision"/>

Your attachment will now appear under the green attachment bar.

Short Study Title: UH IRB Test #2  
PI: Kulaszewski, Meghan

Section view of the Form | Entire view of the Form

1.0 Submission Packet to the Review Board  
2.0 Application  
3.0 Informed Consent/Assent Attachment  
4.0 Study Documents  
5.0 UH Grant Proposal

4.0 Study Documents

4.1 Attach any study documents to include with this submission:  
Examples would include Drug Brochures, Sponsor Information, etc.

Show Rev.	Edit/View	Version	Category	Title
		1.2 04/09/2009		Test Protocol

If you have navigated through all the submission packet screens and there are still documents you need to include in your packet, go back to the “Study Documents” section and attach them there then click “save a continue”. “Study Documents” is a catch-all for miscellaneous documents.

When you have gone through all the sections of the submission packet you will see a screen letting

you know that you have completed the submission packet.

The screenshot shows the 'Initial Review Submission Form' interface. At the top, it displays 'Short Study Title: UH IRB Test #2' and 'PI: Kulaszewski, Meghan'. The main content area features a large blue banner with the text 'Form has been Completed!'. Below this banner, there are two buttons: 'Exit Form' and 'Signoff and Submit'. On the left side, there is a navigation menu with sections: 'Section view of the Form' and 'Entire view of the Form'. Under 'Section view of the Form', there are five items: '1.0 Submission Packet to the Review Board', '2.0 Application', '3.0 Informed Consent/ Assent Attachment', '4.0 Study Documents', and '5.0 UH Grant Proposal'. At the top right, there are buttons for 'Printer Friendly' and 'Signoff and Submit', along with a 'Back' button.

## Designating Sign-offs

When you have completed the protocol application and gone through all sections of the submission packet and uploaded your study documents, you will see a screen letting you know that you have completed the submission packet.

If you are ready to assign the personnel that needs to sign off on the submission, click “signoff and submit” (2 locations – clicking on either is fine).

This screenshot is identical to the one above, but with two red circles highlighting the 'Signoff and Submit' buttons. One circle is around the 'Signoff and Submit' button in the top right corner of the page, and the other is around the 'Signoff and Submit' button located in the center of the page below the 'Form has been Completed!' banner.

You will be asked if you require additional routing for approval.

Selecting “No” will bypass your opportunity to view the personnel designated to sign off on the submission. The submission will be sent to just the Principal Investigator and routing for signatures is done. **For registrations, the IRB is only requiring that you get PI signoff.**

Selecting “Yes” will allow you to view the sign-offs that can be designated for this submission and add additional sign-offs if you choose.

Research Information System

Short Study Title: UH IRB Test #2  
 PI: Kulaszewski, Meghan

Setup Signoff Submission Routing

Back

Save and Continue

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

After clicking “Yes”, you will be shown a list containing the Principal Investigator, any Co-investigators and any Research Support staff that were selected as part of the KSP in the study shell (questions 3.1, 3.2A and 3.2B).

The box next to the Principal Investigator will be selected by default. If any of the additional Key Study Personnel need to sign off on the submission, check the box next to their name and click on “save and continue”.

Short Study Title: UH IRB Test #2  
 PI: Kulaszewski, Meghan

Setup Signoff Submission Routing

Back

Return to Previous Screen

Save and Continue

Select the Key Study Personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in Signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Meghan Kulaszewski	Principal Investigator
<input type="checkbox"/>		Test Study-Coordinator	Study Coordinator
<input type="checkbox"/>		Phil Cola	Biostatistician

**Screen Instructions:**  
 This screen enables the selection of key study personnel required to review this form.  
 Check the boxes next to the names of the personnel required for routing and signoff.

If you need to add any additional people for sign off, you can do so by clicking “add signoff”. You can then “find” and select the person you wish to add, just as you did when selecting personnel for the study shell.

If you add multiple people for sign off, you can select the order in which they will receive the submission for electronic signature.

Short Study Title: UH IRB Test #2  
 PI: Kulaszewski, Meghan

Setup Signoff Submission Routing

Return to Previous Screen Add signoff Save and Continue

Select the additional personnel required for routing and signoff  
 Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Order	Approved	Name/Role
<input type="checkbox"/>	1		Test Department-Review Department Chair

**Screen Instructions:**  
 This screen enables the selection of personnel required to review this form and the routing order before submission.  
 - Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions.  
**Adding Reviewers:**

1. Click on the [Add signoff](#) link on the iRIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.
4. When all reviewers are selected click the [Save and Continue](#) button to go signoff complete screen.

Once you click on “Save and Continue”, you will see a screen summarizing the sign-offs that have been selected for the submission. If you are satisfied with the designated sign-offs, select “Yes – you have completed your selection” and then “Save and Continue”.

Short Study Title: UH IRB Test #2  
 PI: Kulaszewski, Meghan

Setup Signoff Submission Routing

Save and Continue

**Routing Confirmation**

Click here to Add/ Remove Key Study Personnel from the Routing List	Approved	Name	Role
		Meghan Kulaszewski	Principal Investigator

Have you completed your selection of required signatories?  
 Yes  
 No

**Screen Instructions:**  
 This screen enables the verification of personnel required to review and signoff.  
 Click on Yes to indicate selection of reviewers is complete.  
 Click and [Save and Continue](#) button to start the routing process.




Click here to select Additional Personnel for Signoff	Order	Approved	Name	Role
	1		Test Department-Review	Department Chair

To view where your submission is in the signoff and submission process, go the “My Studies” and open up this study.

On the right under “Outstanding Submissions” you can track the location and workflow of this submission by click on the magnifying glass symbol under “Track Location”.



Short Study Title: UH IRB Test #2 Submissions Back  
 PI: Kulaszewski, Meghan  
 Study Status: Draft Study Title: UH IRB's Test Study #2  
 Expiration Date:

Submissions Study Management

Protocol Items	Submission Forms	Outstanding Submission(s)									
<ul style="list-style-type: none"> <li>Application</li> <li>Informed Consent</li> <li>Other Study Documents</li> <li>Contract Documents</li> <li>Miscellaneous</li> <li>Study Correspondence</li> <li>Submissions History</li> <li>Forms</li> <li>Building Room Test</li> <li>IACUC SubForm A: Fluid Collection</li> <li>IACUC SubForm B: Immunizations</li> </ul>	<ul style="list-style-type: none"> <li>Initial Review Submission Form</li> <li>Case Cancer Adverse Event Form</li> <li>Case Cancer IRB Protocol Deviation</li> <li>Case Cancer Note to File Form</li> <li>Case Cancer Performance Site and Personnel Registration Form</li> <li>Case Cancer Protocol Closure Form</li> <li>Case Cancer Request for Continuing Review Form</li> <li>IACUC Addenda to an Approved Protocol</li> <li>IACUC Animal Incident Report</li> <li>IACUC Annual Review of Animal Use</li> <li>IACUC Clinical Score Sheet</li> <li>IACUC Elective Surgical Repair Form</li> <li>IACUC Harvested Tissue Use Form</li> </ul>	<table border="1"> <thead> <tr> <th>Track Location</th> <th>Req Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td></td> <td>000168</td> <td>Click on the hyperlink to edit/view the submission. Initial Review Submission Form</td> <td><b>Retract Submission</b></td> </tr> </tbody> </table>	Track Location	Req Number	Request Type	Process Submission		000168	Click on the hyperlink to edit/view the submission. Initial Review Submission Form	<b>Retract Submission</b>	
Track Location	Req Number	Request Type	Process Submission								
	000168	Click on the hyperlink to edit/view the submission. Initial Review Submission Form	<b>Retract Submission</b>								

You can see the date and time each step of the sign off process has occurred

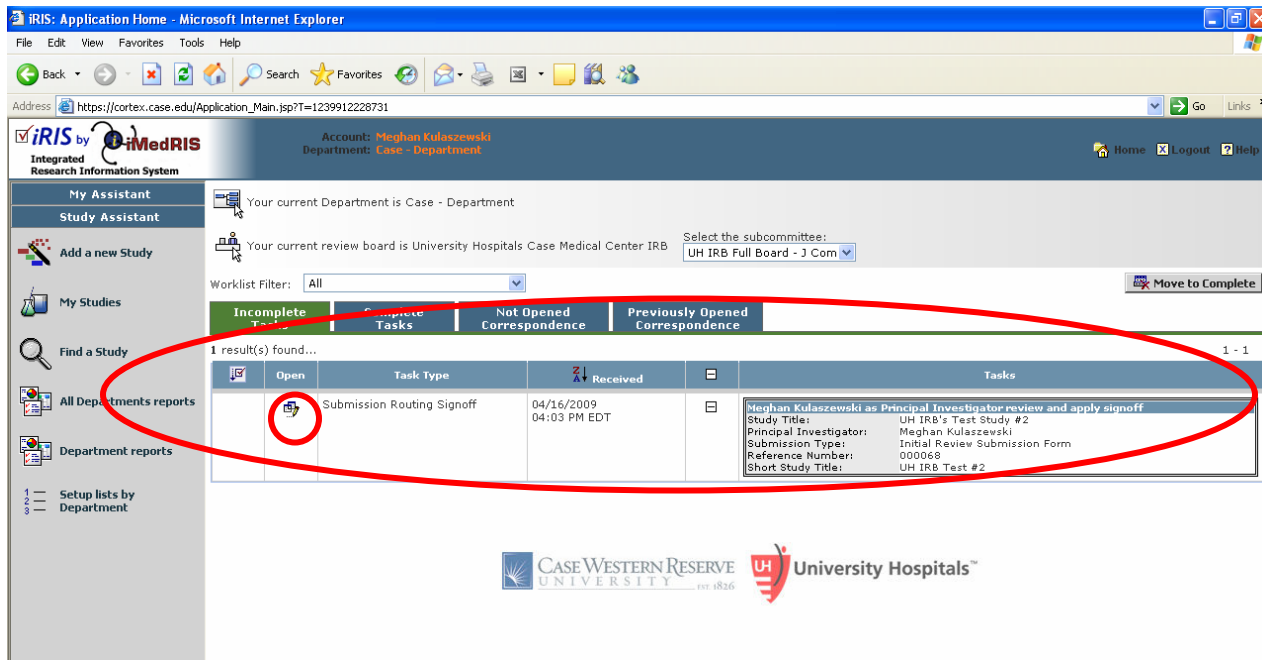
Short Study Title: UH IRB Test #2 Workflow - Submission Tracking Back  
 PI: Kulaszewski, Meghan Printer Friendly

Status	View Details	Date Received / Date Completed	Event Description
In Process		04/16/2009 04:03 PM EDT	Meghan Kulaszewski as Principal Investigator review and apply signoff
In Process		04/16/2009 04:02 PM EDT 04/16/2009 04:03 PM EDT	Assign Department Personnel for Signoff
Completed		04/07/2009 03:36 PM EDT 04/16/2009 04:02 PM EDT	Initial Review Submission Form is waiting to be submitted

## Signing Off on a Submission

If the study's Principal Investigator has their email address entered into iRIS under "My Assistant" and then "My Account Information", they will receive an email notification that a submission has been sent to them to review and signoff on.

When the PI logs into the iRIS system, they will see an incomplete task on their iRIS homepage that says "Submission Routing Signoff".



The screenshot shows the iRIS system interface in a Microsoft Internet Explorer browser window. The browser address bar shows the URL: [https://cortex.case.edu/Application\\_Main.jsp?T=1239912228731](https://cortex.case.edu/Application_Main.jsp?T=1239912228731). The page header includes the iRIS logo and the user's account information: Account: Meghan Kulaszewski, Department: Case - Department. The main content area displays a task list with columns for Task Type, Received, and Tasks. A task titled "Submission Routing Signoff" is highlighted with a red circle. The task details show it was received on 04/16/2009 at 04:03 PM EDT. The task description includes: "Meghan Kulaszewski as Principal Investigator review and apply signoff", "Study Title: UH IRB's Test Study #2", "Principal Investigator: Meghan Kulaszewski", "Submission Type: Initial Review Submission Form", "Reference Number: 000068", and "Short Study Title: UH IRB Test #2".

After clicking on the "Open" symbol, the PI can see their signoff sheet (it is all on one page).

They can open the study documents and/or select and print portions of the submission packet.

The Principal Investigator must check the boxes for each investigator certification statement.

There is a section for the PI to add optional comments regarding the submission.

The Principal Investigator can then approve or deny the submission and then apply their electronic signature. Their electronic signature is the user name and password they used to log in to the iRIS system.

Submission Signoff Sheet Back

Save Signoff

Print selected item(s)

Print	Open	Type	Document Name	Version	Date Submitted into Workflow
<input type="checkbox"/>		Submission Form	Initial Review Submission Form	Version 1.0	03/02/2010 11:04 AM EST

**Submission Form(s):**

**Submission Attachments below:**

<input type="checkbox"/>		Application	Study Add Interview Process	Version 1.0	03/02/2010 11:04 AM EST
<input type="checkbox"/>		Consent (English)	⊞ Patient Volunteer Consent	Version 1.0	03/02/2010 11:04 AM EST
<input type="checkbox"/>		Document - Protocol	⊞ Patient Volunteer Protocol	Version 1.0	03/02/2010 11:04 AM EST
<input type="checkbox"/>		Document - Other	⊞ Patient Volunteer Telephone Script_Appendix B	Version 1.0	03/02/2010 11:04 AM EST
<input type="checkbox"/>		Document - Other	⊞ Patient Volunteer Invite Letter_Appendix A	Version 1.0	03/02/2010 11:04 AM EST

**Investigator Certifications**

**The Principal Investigator must certify all of the following points:**

- I have reviewed this protocol and acknowledge my responsibilities as Principal Investigator.
- The information in this submission accurately reflects the proposed research.
- I will not initiate this study until I receive written approval from the IRB.
- I will promptly report to the IRB any unanticipated problems and adverse events, as well as any findings during the course of the study that may affect the risks and benefits to the subjects.
- I will obtain prior written approval for modifications to this protocol including, but not limited to, changes in procedures.
- I am currently certified under the Research Compliance Education Program administered by Case or will achieve certification before subjects are enrolled in this protocol.
- I accept responsibility for assuring adherence to applicable Federal and State research regulations and hospital policies relative to the protection of the rights and welfare of the subjects enrolled in this study.
- I am in full compliance with the UHCMC/Case policies on Conflict of Interest.
- I understand that the UHCMC IRB operates under a Federal Wide Assurance (FWA) from the Department of Health and Human Services.
- I understand that this study is subject to continuing review and approval by the IRB.
- I have not submitted this protocol to any other IRB unless it is disclosed in the submitted protocol.
- I understand that as the Principal Investigator of this study it is my responsibility to assure proper registration of this trial on clinicaltrials.gov.

**Comments:**

**Test Principal-Investigator as Principal Investigator**  
do you Approve or Deny this submission?

Approve  Deny

User ID:

Password:

Once the Principal Investigator has signed off on the submission, it will be routed to the next person designated in the sign-off order (if any).

Once all signoffs have been completed, the submission packet will be routed to the IRB office.