



Office of Human Research

Making IRB Submissions in The Portal

Office of Human Research
9/17/2014
Ver. 1.1

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What Is The Portal?

The Portal is the electronic interface between Thomas Jefferson University's IRB and its research community. It is where electronic documents comprising IRB transactions are uploaded. It also is where IRB members go to access these documents to review for IRB meetings.

Accessing The Portal

To access the Portal, go to the IRB homepage and click on Enter the Portal in the navigation bar on the left side of the screen. The IRB homepage address is: http://www.jefferson.edu/university/human_research.html

HOME > OFFICE OF HUMAN RESEARCH > DIVISION OF HUMAN SUBJECTS PROTECTION

IRB HOME

- Office of Human Research
- Information for the Public
- ▶ University Policies
- ▶ CITI Training
- ▶ JeffTrial
- IRB Forms & Submission Materials
- For IRB Members
- Policy & Procedures Handbook
- Federal Guidance & Resources
- Enter The Portal**
- Electronic Serious Adverse Event Reporting (eSAEy)

Division of Human Subjects Protection

The Division of Human Subjects Protection (IRB) is the administrative office for the Jefferson IRBs. These IRBs serve both Thomas Jefferson University and Thomas Jefferson University Hospital, which includes Methodist Hospital.



Institutions must enter into an agreement with the federal government in order to conduct human research with federal funding. This agreement is called a Federalwide Assurance, or FWA. In entering into this agreement, the University and Hospital affirm that all human research, not just federally funded research, conducted in these institutions will adhere to certain ethical standards and federal regulations concerning human subjects research.

As the University and the Hospital are separate entities, each has its own FWA. Thomas Jefferson University's FWA number is 00002109 with expiration date of 2/2/17. Thomas Jefferson University Hospital's FWA is 00002142 with expiration date of 4/12/17.

Working with the HRPP

IRB REFERENCE DOCUMENTS

Quick links to get to info fast...

- Contact Us
- IRB Rosters
- IRB Newsletters
- IRB Schedule 2014 (PDF)
- IRB Training List (PDF)
- IRB Voting Policy (PDF)

This takes you to the Portal log-in screen:



Division of Human Subjects Protection

Welcome to **THE PORTAL!** (*Electronic IRB Application Portal*)



Campus Key:

Password:

Need help?

For campus key log-in problems, call Technical Assistance Center at 215-503-7975.

For questions about making submissions on The Portal, call OHR at 215-503-3846.

For technical problems using The Portal, call the Shared Computer Facility at 215-503-4606.

PLEASE DISABLE POP-UP BLOCKERS FOR THIS SITE.

Enter your campus key and password to log-in. If you have not used the Portal before, please contact the Office of Human Research to be registered as a user.

Once logged in, you will see the following screen:

Welcome to *THE PORTAL!* (Electronic IRB Application Portal)

Application Submission Functions



- Create An IRB Application
 - [Manage IRB Applications](#)
 - [General Instructions](#)
 - return to [sign-in](#) screen
 - [Go to IRB Forms page](#)
-
- **[IRB MEMBER ACCESS](#)**
-
- [Office of Human Research](#)

As a user submitting IRB transactions, you have access to all of the links on this page, except for the “IRB Member Access” link, which is for IRB members only.

Creating and Managing Submissions

To submit any type of IRB application in the Portal for formal IRB review, go to the first bullet on this screen, “Create an IRB Application.” Select the type of application you want to submit from the drop-down menu, “Select Application Type.”

Application Submission Functions

- Create An IRB Application
 - [Manage IRB Applications](#)
 - [General Instructions](#)
 - return to [sign-in](#) screen
 - [Go to IRB Forms page](#)
- Select Application Type ▼

 - Select Application Type
 - New Study
 - Amendment
 - Continuing Review
 - Continuing Review/Amendment
 - Final Report
 - Final Report/Amendment



The choices in the drop-down menu represent the different types of transactions that can be submitted in the Portal.

Note that two of the choices represent joint submissions: **Continuing Review/Amendment** and **Final Report/Amendment**. A joint submission is two separate transactions (for instance, a continuing review and an amendment) that, for the purposes of the Portal, can be submitted together as one transaction. When creating this kind of submission, be sure to upload all documents pertinent to both transactions included in the joint submission.

Outside of those types of transactions represented in the drop-down menu, any other documents you may need to provide to the IRB from time to time should not be submitted in the Portal, but can be emailed or hand-delivered, at the advisement of IRB staff.

Creating an IRB Submission

Select the appropriate application option from the drop-down menu. This takes you to the following screen:



Current IRB Control #/Jeff Trials Protocol # Search Parameter:

All Protocols Must Be Entered into JeffTrials First.

Please Enter A Protocol Number or IRB Control Num From JeffTrials:

Enter the 4-digit JeffTrial protocol number that appears in the upper left field of the Main>Details tab of the JeffTrial study record, or enter the IRB control number. (For a **new study** submission, you will not yet have an assigned IRB control number, in which case you must use the JeffTrial protocol number.)

Once either number is entered, click "Search." The Portal will now retrieve information about your study:



Current IRB Control #/Jeff Trials Protocol # Search Parameter: **2717**

IRB Control #	
JeffTrials PROTOCOL #	2717
JeffTrials PROTOCOL ID #	2717
Study Title	This Is a Test Protocol
PI Name	Bruce Smith
IRB Review Type	
Department	Medicine
Sponsor	Thomas Jefferson University

Use The Above Trial, Continue With Submission

All Protocols Must Be Entered into JeffTrials First.

Please Enter A Protocol Number or IRB Control Num From JeffTrials:

If the correct study information appears, click "Continue." (If it isn't correct you can try entering the JeffTrial protocol number again. If that doesn't work, you should contact OHR.)

On the next page, you will create your IRB submission.

(*Note that all types of IRB transactions follow the same submission process on this page. Also note that previous submissions in the Portal cannot be accessed or modified once the meeting to which they were assigned has passed. Thus resubmissions of NOT APPROVED transactions must be submitted again under the original transaction type. For example, to resubmit a NOT APPROVED amendment, select "Amendment" from the drop-down menu.)

 **Jefferson. Division of Human Subjects Protection**

[menu](#) [studylist](#) [sign-in](#) **THE PORTAL (Electronic IRB Application Portal)**

IRB Control #:
JeffTrial ID #: 2717
PI Name: Bruce Smith
Study Title: This Is a Test Protocol
Sponsor: Thomas Jefferson University
Review Type:
Submission Type: NEW SUBMISSION

1

Additional E-Mail Addresses

Click on filename to download, click on red X to DELETE a file from the submission

Filename **File Type** **Date Uploaded** **File Size**

2

Select A File To Add To Submission

Type Of File:

OHR-1 (Proposal Transmittal and Approval)

Other Description

Personnel Access To This Application

Campuskey **Name** **E-Mail** **Access Type**

3

Please Note: Only Add personnel other than the PI and the Submitter -- they will already have access not have to be added in this areas

To Provide Access to this record for Additional Personnel,
Search By Name. Select an Access Privilege: ReadOnly or Modify. Type and Click on Add This Person.
Click On Red X To REMOVE This Person's Access Privilege For This Record.

Lookup Person By Last Name:

Name	CampusKey	E-Mail	Role
<input type="text"/>	<input type="text"/>	<input type="text"/>	ReadOnly

Please ensure that all Co-Investigators and Key Personnel have a completed and up-to-date IRB training status before submitting your application.

4

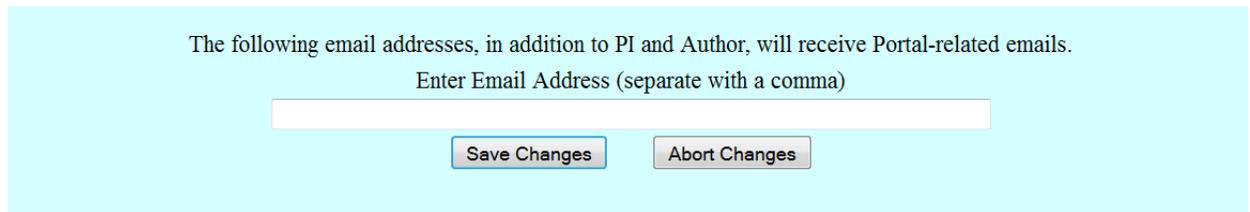
A file with the IRB Training Status of Individuals is posted [here](#)

5

Your study information appears at the top of the screen.

To create the transaction, following these 5 steps as you work your way down the screen:

1. If you want other personnel copied on Portal notification emails regarding this application, click on “Additional Email Addresses Update.”



The following email addresses, in addition to PI and Author, will receive Portal-related emails.

Enter Email Address (separate with a comma)

In the pop-up screen, enter the email addresses and click “Save Changes” or “Abort Changes.”

2. In the next section, you will assemble your transaction by uploading all relevant documents. For each document you are uploading, click “Type of File” to choose the appropriate file type from the drop-down menu:

Note: Please ensure that no patient identifiers (name, DOB, MR#, etc.) appear on the documents you upload (e.g. SAE reports, monitoring reports, etc.). If the document must be uploaded as part of the submission, please redact all patient identifiers before uploading.

- OHR-1 (Proposal Transmittal and Approval)
- OHR-2 (Protocol Application)
- OHR-2A (Protocol Addendum)
- OHR-3 (PHI Waiver)
- OHR-4 (Record/Chart Review/Electronic Database Study)
- OHR-5 (De-Identified Certification Form)
- OHR-8 (Universal Consent Form)
- OHR-8A (Blood Draw Consent Form)
- OHR-8B (Surrogate Consent Form)
- OHR-8C (Child Assent Form)
- OHR-8D (Consent Addendum - Relying on Another Institution)
- OHR-8E (Phone Contact Script)
- OHR-8F (Subject Recruitment Letter)
- OHR-8H (Verbal Consent For Use/Disclosure PHI)
- OHR-8S (Short Consent Form)
- OHR-9 (Continuing Review)
- OHR-12 (Amendment to Research Protocol)
- OHR-15 (Biological Specimen Use)
- OHR-15A (Biological Specimens Chart)
- OHR-16 (Genetic Research)
- OHR-16A (Genetic Consent Guide)
- OHR-17 (Descendants PHI User Certification)
- OHR-18 (Exemption Request)
- OHR-19 (Research Involving Coded Or Anonymous Data/Specimens)
- OHR-22 (Collection of Discarded Tissue)
- OHR-25 (Investigational Devices Worksheet)
- OHR-26 (Research Involving Children)
- OHR-27 (Research Involving Pregnant Women, Fetuses, & Neonates)
- OHR-28 (In Vitro Diagnostic Device Research)
- IIT Protocol (No Sponsor, Departmentally Funded)

Once you have chosen a file type, click “Browse” and select the file you want to upload from your computer. Once selected, click “Add File To Submission.” The uploaded file now appears in the green box.

Follow this process until you have uploaded all required documents for the submission. You can delete files by clicking on the red X next to each one.

Filename	File Type	Date Uploaded	File Size
 OHR-1.doc	OHR-1 (Proposal Transmittal and Approval)	April 30 2014 11:20:57.	62.00 KB
 OHR-2.doc	OHR-2 (Protocol Application)	April 30 2014 11:24:11.	130.00 KB
 OHR-8A Blood Draw.doc	OHR-8A (Blood Draw Consent Form)	April 30 2014 11:24:37.	56.00 KB
 sponsor protocol.doc	Sponsor Protocol	April 30 2014 11:26:56.	21.50 KB

If the document type in the drop-down menu does not adequately describe your document, you can add an additional description in the “Other Description” field. This additional description will appear on the electronic agenda that is viewed by the IRB.

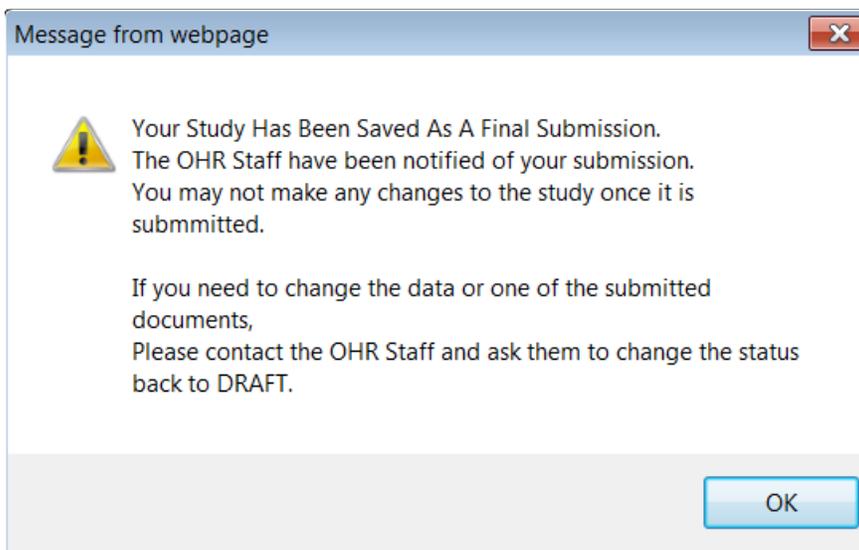
3. If you would like to allow other personnel (other than yourself and the study PI) to access your Portal submission, you can add them here. You do this by typing in their name and clicking “Search TJU Directory for Key Person.” In the pop-up menu, click on the appropriate person and their information will populate the next section.

Then Click on “Add This Person.” You can remove them by clicking on the red X next to their name.

4. Check training status of your study personnel by clicking on the link provided.
5. If you want to return to the submission page later to continue working, click “Save As A Draft.” This will return you to a list of all submissions created under your name that have not yet been reviewed by the IRB. (See p. 11 for image.) The status of each submission is indicated. You can access those submissions that you have not yet saved as a finalized submission by clicking on the study title.

If you are ready to submit the application to the IRB, click “Save As A Finalized Submission.”

You will see the following message:



Managing an IRB Submission

To return to an application that you are still working on, go to the second bullet on the Portal menu page and click on “Manage IRB Applications.”

The page that follows will show you all of the applications created by you. You can view any of these by clicking on the study title.



Currently Displaying Records 1 To 10 of 16

Search By Keyword in the Title: Search Clear Search

Click on Study Title to Modify An Existing Study or



Create A New IRB Application Select Application Type



App ID	Study Title	PI	Creator	Created On	Status	# Files	Review Type	Submission Type	E-Mail Msgs.
2842	This Is a Test Protocol	Bruce Smith	Kyle Conner	2014-04-30 13:52:50	DRAFT	0		AMENDMENT	0
2839	This Is a Test Protocol	Bruce Smith	Kyle Conner	2014-04-30 13:45:06	SUBMITTED	4		NEW SUBMISSION	3
920	New study	Smalley, Karl J.	Kyle Conner	2013-09-12 11:12:40	DRAFT	0	FULL	NEW SUBMISSION	0
886	Test protocol	Smalley, Karl J.	Kyle Conner	2013-09-05 11:50:55	DRAFT	0	FULL	NEW SUBMISSION	0
774	Test case	Smalley, Karl J.	Kyle Conner	2013-08-13 14:26:41	DRAFT	0	FULL	NEW SUBMISSION	0
473	Test 321000	Smalley, Karl J.	Kyle Conner	2013-06-13 10:56:19	DRAFT	1	FULL	NEW SUBMISSION	0
203	New study with a quote in the title ' skskks	Smalley, Karl J.	Kyle Conner	2013-04-30 13:05:31	DRAFT	0	FULL	NEW SUBMISSION	6
187	(IGNORE) A Test Protocol Designed to Test the Clinical Trials Repository	Smalley, Karl J.	Kyle Conner	2013-03-28 13:46:54	DRAFT	0	FULL	CONTINUING REVIEW	0

If the application has DRAFT status, you may continue working on it.

If the application has SUBMITTED status, you must request that it be changed back to DRAFT status in order to modify it by clicking on the button at the bottom of the screen:

Please Change Status Back To DRAFT

Notification Emails

You and those you have designated will receive a notification email for each signal event in the submission process of your transaction.

These events are:

- DRAFT – Submission has not been finalized and can be modified.
- SUBMITTED – Confirmation that you have recently submitted a finalized transaction that has been received by the IRB.
- ACCEPTED – The submission has been accepted for review by the IRB.
- REJECTED – The submission has not been accepted. You must modify your submission to address additional requirements, as stated in the email.
- SCHEDULED FOR IRB – The transaction has been scheduled for review at an IRB meeting.
- IRB APPROVED – Submission has been approved by the IRB and can no longer be accessed or modified by user.
- IRB APPROVED WITH MODIFICATIONS - Submission has been approved by the IRB with modifications and can no longer be accessed or modified by user.
- IRB NOT APPROVED - Submission has not been approved by the IRB and can no longer be accessed or modified by user.

(*Note that notification emails for the final three status events listed above are provided as a courtesy and do not constitute official IRB correspondence or approval.)

Tips for Using the Portal

- When uploading documents in the Portal, use only Word and PDF formats.
- The Portal can be used only for submitting IRB applications. It is not a data repository. Once transactions have been reviewed by the IRB, they no longer are accessible to the user.
- The process of receiving and replying to IRB review comments from IRB secretaries following review of transactions remains the same and is not conducted through the Portal.
- Currently, the IRB still requires a nominal amount of paper copies to accompany the Portal submission. For exempt and expedited transactions, the number of copies is 1. For full transactions, the number of copies is 6. Please deliver copies to The Office of Human Research, 1015 Chestnut, #1100. (*The exception to this rule is that OHR-12Bs & OHR-12Cs are submitted only in 1 paper copy.)

Remember that your submission is not complete until the IRB has received both your Portal and paper submissions!

Whom To Contact About Problems With the Portal

For general questions about the Portal, contact Tracey Smith in the Office of Human Research at 215-503-3646.

For technical problems (such as error messages), contact Karl Smalley in the Shared Computer Facility at 215-503-4606.

For log-in issues, contact the Technical Assistance Center at 215-503-7975.