Office of Human Research

Making IRB Submissions in The Portal

Office of Human Research
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Ver. 1.1

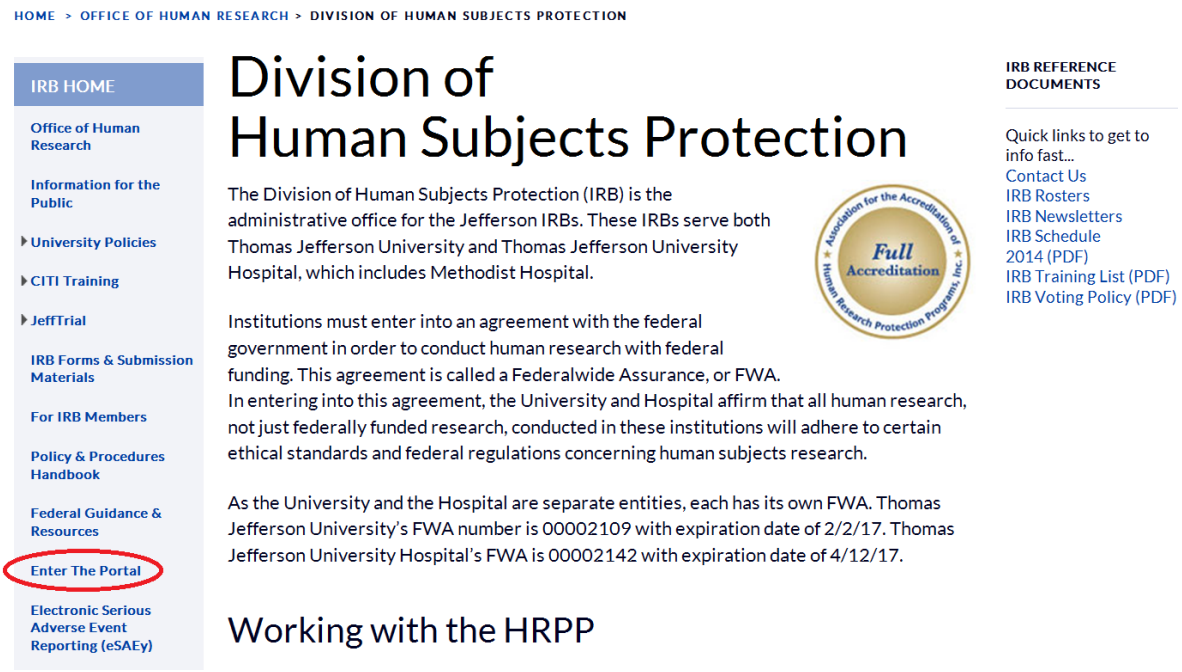
Contents

What Is The Portal?

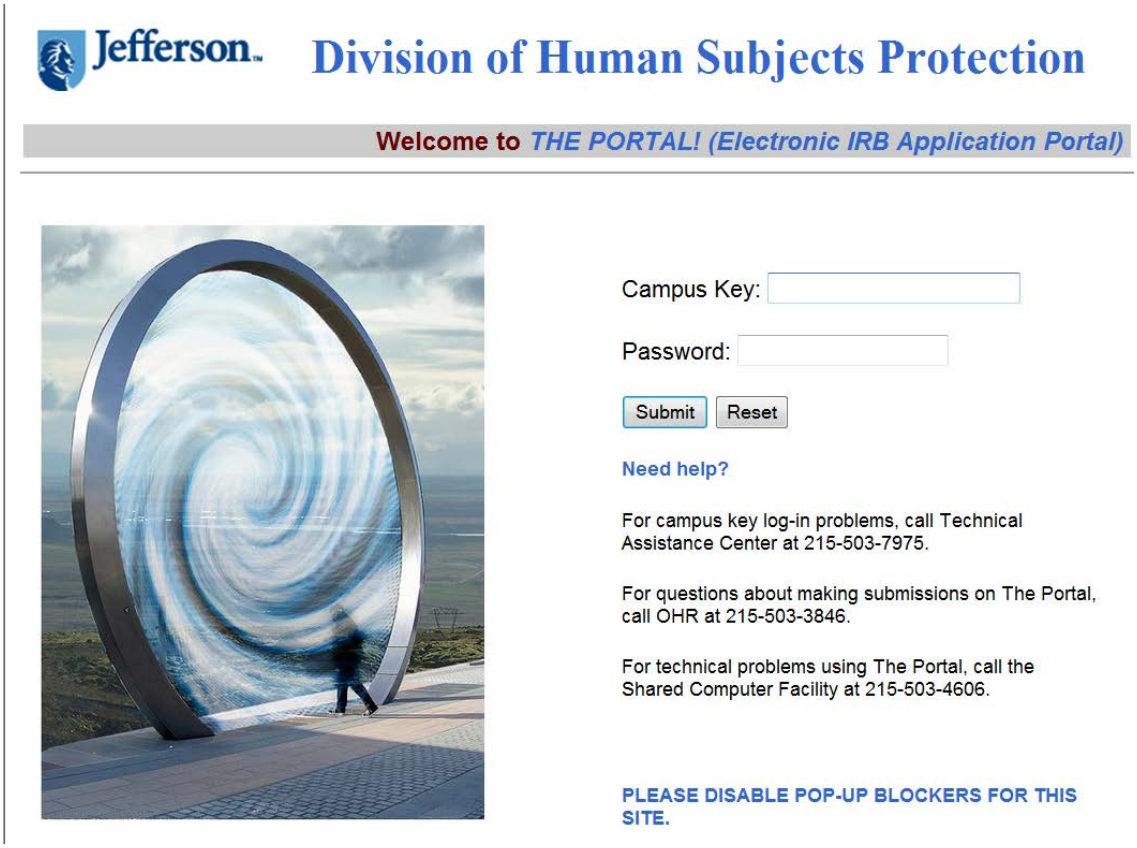
The Portal is the electronic interface between Thomas Jefferson University's IRB and its research community. It is where electronic documents comprising IRB transactions are uploaded. It also is where IRB members go to access these documents to review for IRB meetings.

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



This takes you to the Portal log-in screen:



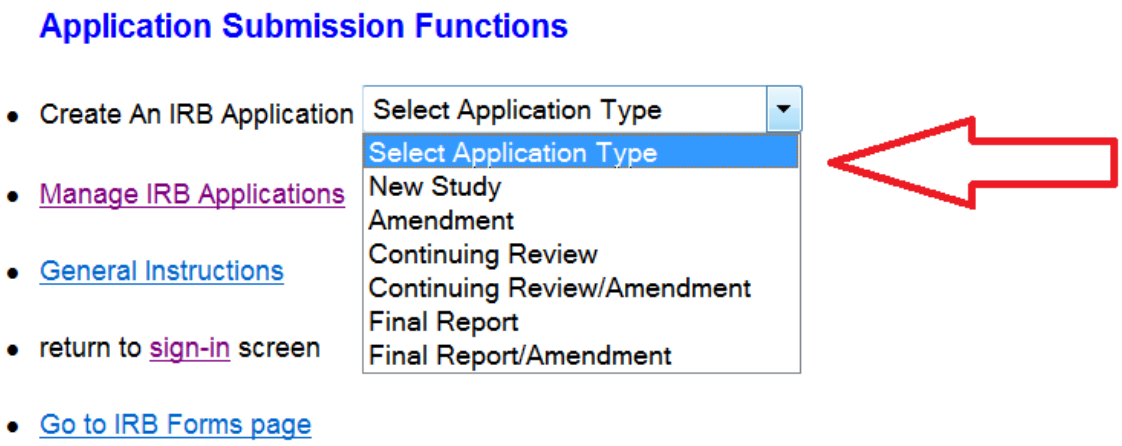
Enter your campus key and password to log-in. If you have not used the Portal before, please contact the Office of Human Research to be registered as a user.

Once logged in, you will see the following screen:

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."



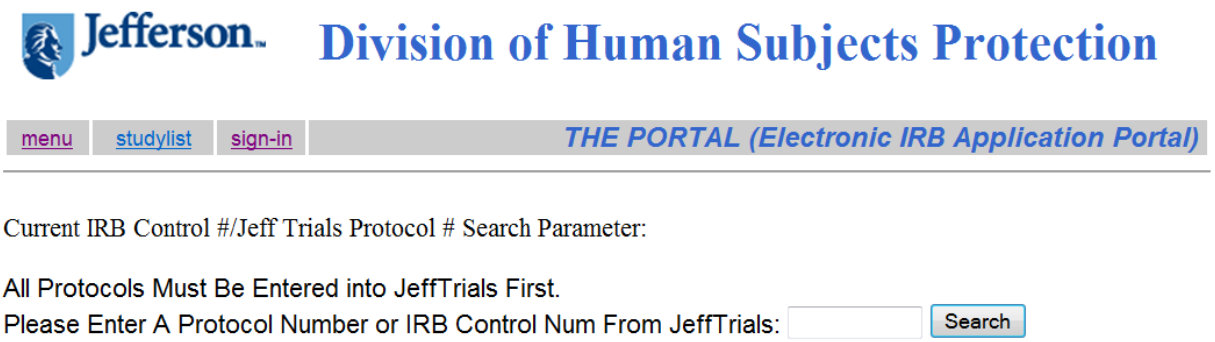
The choices in the drop-down menu represent the different types of transactions that can be submitted in the Portal.

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.

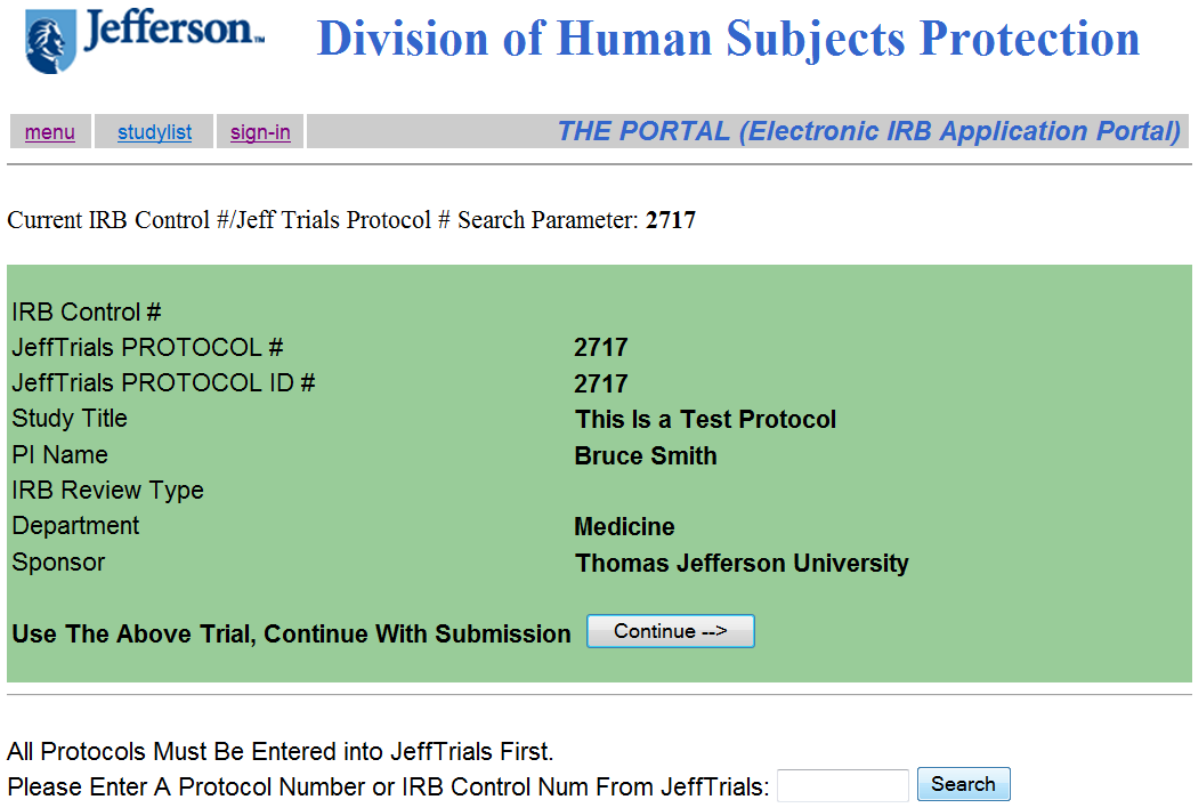
Creating an IRB Submission

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



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.)

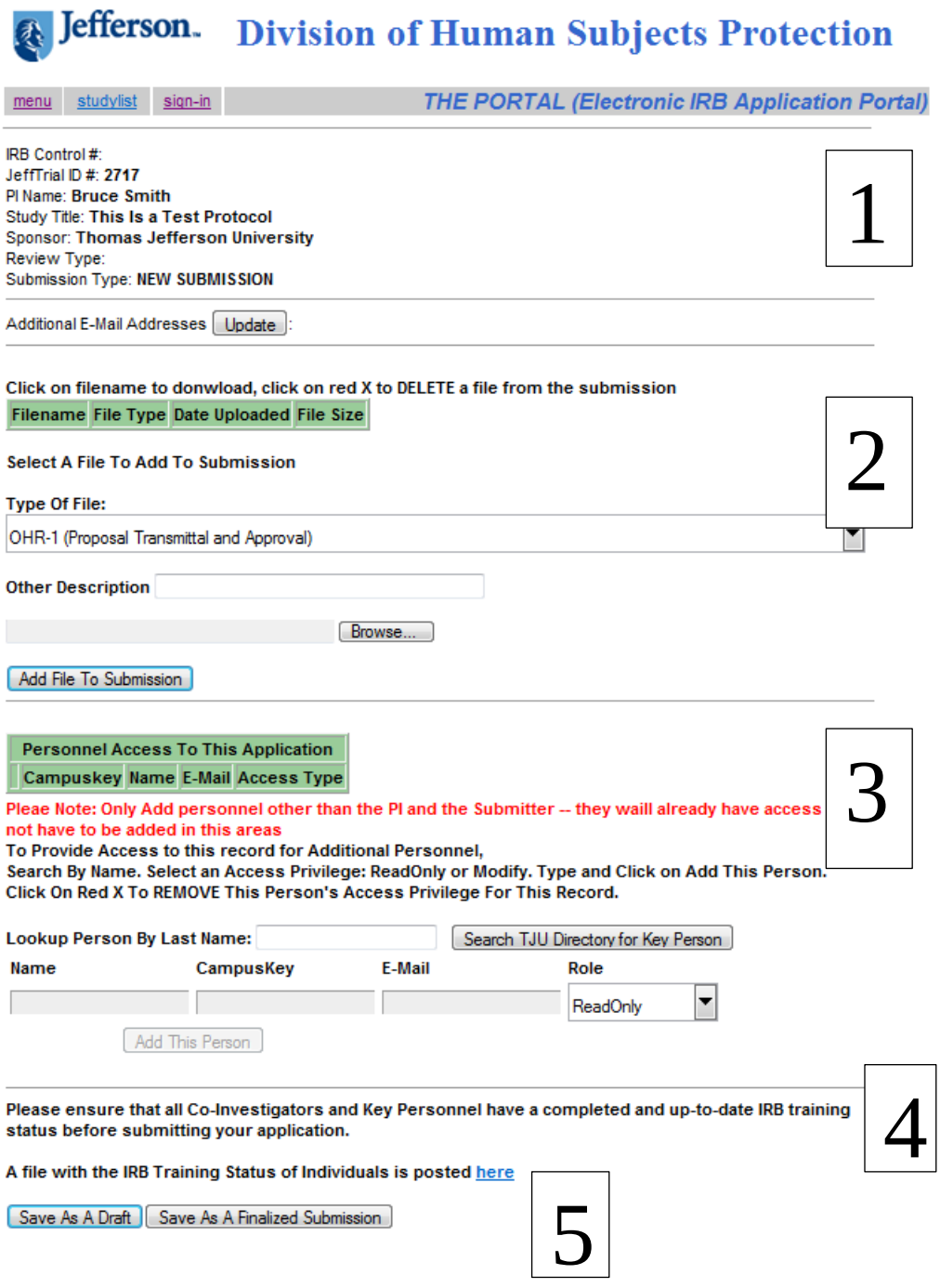
Once either number is entered, click "Search." The Portal will now retrieve information about your study:



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.

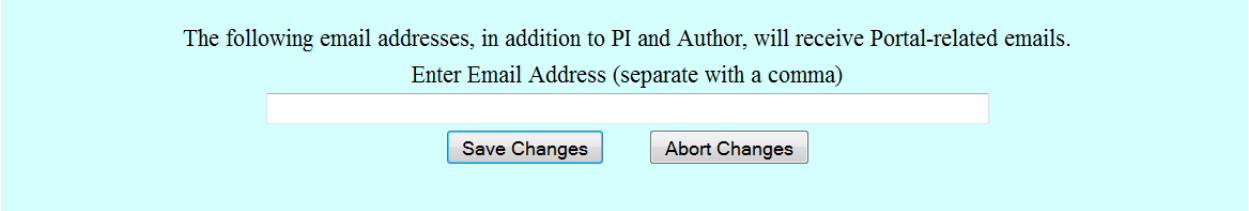
(*Note that all types of IRB transactions follow the same submission process on this page. Also note that previous submissions in the Portal cannot be accessed or modified once the meeting to which they were assigned has passed. Thus resubmissions of NOT APPROVED transactions must be submitted again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



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:

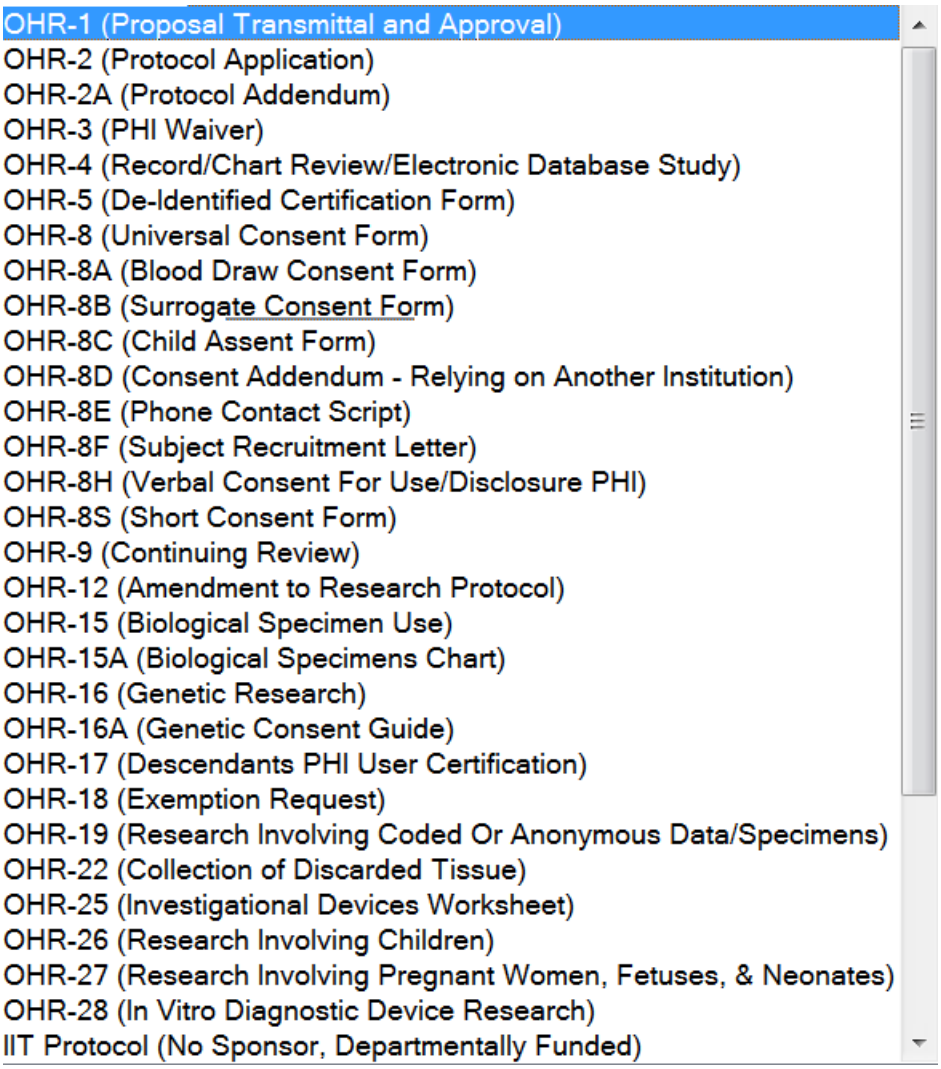
1. If you want other personnel copied on Portal notification emails regarding this application, click on "Additional Email Addresses Update."



   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.



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.

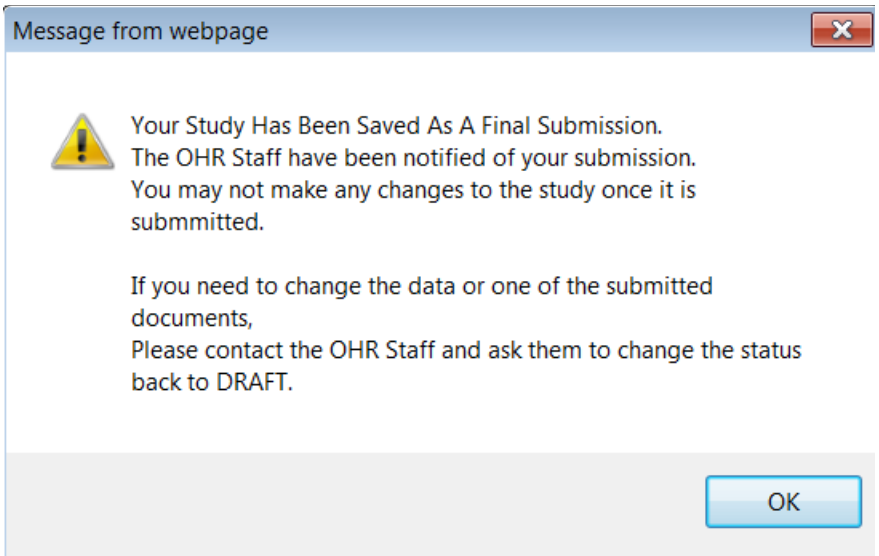
   Then Click on "Add This Person." You can remove them by clicking on the red X next to their name.

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

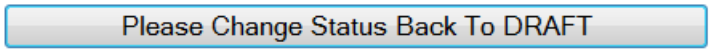
To return to an application that you are still working on, go to the second bullet on the Portal menu page and click on "Manage IRB Applications."

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.

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:



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 <u>both</u> 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.