



## **CHeRP June IRB Update: What You Need to Know.**

CHeRP has now been live for 6 months and the roll out has gone extremely well. Investigators and research team members are successfully converting existing protocols and submitting new protocols. The IRB has transitioned to paperless meetings and the IRB staff are now working extensively on CHeRP. We realize this has been a big transition but we can already begin to see the results for a more efficient review process. Thank you for your continued support and patience as we move forward.

During the past six months we have also received important feedback from the research community and we continue to "tweak" the system to make it more user-friendly. Your comments are appreciated. We cannot change everything, but when it makes sense and where we can, we will try to implement a change.

CHeRP support and IRB staff continue to answer many of your questions. This has given us knowledge as to where there are common questions, issues and problems. As a result we are providing you with the following information to assist you in utilizing CHeRP.

## "Submit Response" vs. "Contact IRB Staff"

There has been some confusion as to when to use these two different activities. Both are activities listed on the left side of the screen, however they have different functions

- Submit Response: When you are asked to respond to questions following pre-review, IRB review or expedited review you need to prepare a response, possibly modify the protocol and your smart forms and then you must also click the "submit response" activity. This is the activity used to formally respond to any inquiry. Some researchers are attaching a response, modifying the smart-forms etc and then forgetting to hit "submit response." If you do not click the "submit response" activity the protocol and response will not move forward and will not come back to our office.
- Contact IRB Staff: There is also an activity on the left side "Contact IRB Staff". This is NOT the activity to submit responses, protocol documents or attachments. This activity should only be used for communications with the IRB staff for general questions on a protocol and for advice. We ask that you use this activity instead of email if you have a question about a specific protocol.

1

## **Completions:**

If any of your <u>existing paper protocols</u> are completed at the time of continuing review notification or at any other time, you do not need to submit a legacy protocol for conversion into CHeRP before submitting a

completion report. You may just submit a paper completion report. Some investigators are doing more work than necessary to close out a protocol.

#### **Password Protected Documents.**

If you need to attach a document that is password-protected (i.e. protocol from drug company sponsor) there needs to be a mechanism so that IRB members can read these documents. There are two options possible, the first one being more favorable:

<u>Option 1:</u> Attach the password-protected document as one attachment and immediately below, attach another document that includes the password that can be used to open the document. The second document should be titled "Password Information."

<u>Option 2:</u> Print out the entire document and then scan it in as a pdf. This is more time consuming is not a ideal solution as the scanned version is now a PDF and you will not be able to revise the document with track changes if necessary. For documents that will never require revision this may be an option

### **Help Documents**

Please remember there are help documents that provide text and graphics to help you complete many of the CHeRP processes. You may find them wherever you are in CHeRP by going to the top of the page where the blue tool bar exists. It is labeled as "How Do I." While the IRB staff are always willing to help, we ask that you check these documents first before calling our office. Staff may direct you to these documents when you call the office. They can also be accessed via our website.

# **Consents and the Consent Library**

- O CHeRP has its own consent form library. As paper protocols are converted to CHeRP, the approved consent forms will be removed from the current library and moved into the CHeRP library. They will not longer show up in the old consent library. Consents for new protocols submitted in CHeRP will be finalized and placed into the CHeRP library only. Please remember that you will find your consents in only one of the libraries. The links to both libraries are located together. You may access both libraries wherever you are in CHeRP by going to the top of the page where the blue tool bar exists. It is labeled as "IC Library" Once all paper protocols are converted we will only maintain the CHeRP consent Library.
- O If you need to obtain a copy of your approved consent for in order to amend it, you must go into the protocol workspace to obtain a Word version for adaption. The CHeRP library only contains pdf versions of the consents. Please do not store approved consents in other locations (your personal hard drive, etc). When the IRB office finalizes a consent document there are specific settings and headers we add. If you use other versions and revise them and submit them as part of amendment, it will contain wrong settings and create a problematic situation for the staff that need to finalize your amended consent documents.

#### **Mange Ad Hoc Access**

Investigators and those listed as editors on a protocol may now give "read access" to anyone who has an account in CHeRP. On the left side you will see an activity called "Manage Ad Hoc Access. This access will allow a PI to add a person to view and read the protocol only. They will not be able to conduct any activities or receive notifications. An example as to when this might be helpful is as follows. You are asking the CH data warehouse staff to provide you with data for an approved protocol. The data warehouse will ask to see an approved protocol. You can certainly print a copy of the CHeRP protocol and give it to them or you may add data warehouse staff with read access.

# **Working in the Correct Workspace**

CHeRP is established so that there are separate work spaces for new protocols, continuing reviews amendments and reportable events. Please be sure you are in the correct workspace when trying to submit or revise any submission or when you are trying to use the "Contact IRB Staff" activity. For example if you are working on a continuing review, make sure you are in the continuing review workspace if you want to use "Contact IRB Staff" with a question about the continuing review. Otherwise your question will go to the wrong IRB staff person.

#### **Amendments**

CHeRP will only allow one amendment to be open at a time. Once an amendment is created by the research team (even if it just stays in the draft state), you cannot create a second amendment. We realize this potentially creates an issue for investigators especially when you want to modify research staff while you are waiting for an amendment to be reviewed and processed. If you find yourself in a situation that you need to add or remove a research staff member while an amendment is open, you may contact our office and we will be able to make the adjustment in the approved protocol, however you must also remember to add them to the amendment (if still in the draft state) before it is submitted or process a second amendment if the initial amendment was already submitted. Otherwise they will be removed when the original amendment is approved.

# **Exceptions**

If you submit an exception that is time sensitive please be sure to call or mail your IRB administrator. Although we are on the system frequently, we may not know that that the exception is time sensitive.

We hope this information is helpful and we will periodically put out newsletters to keep you updated.

## **Support and Questions**

For technical assistance, please contact CHeRP Support at 4-3267 or <a href="mailto:CHeRP.Support@childrens.harvard.edu">CHeRP.Support@childrens.harvard.edu</a>.

For other questions, you may contact your IPB administrator at 5, 705

For other questions, you may contact your IRB administrator at 5-7052