Children's Hospital Boston

IRB

Institutional Review Board

CHeRP

Children's Hospital
eResearch Portal

Questions and Answers

Converting Existing Protocols into CHeRP IRB

Questions: (hold 'ctrl' and click on the question to jump directly to that answer)

1. Do I need to convert my existing protocol applications into the new CHeRP IRB?

Yes, over the period of the next year we will require that all approved paper based protocols be converted into the new electronic CHeRP IRB. This includes protocols that have been reviewed the full committee, expedited reviews, medical record and specimen requests. Protocols that have been determined to be exempt or represent non human subject research will transition directly into the new system and do not require any action by the investigator. We are using the term "legacy protocols" to describe those protocols that the investigator needs to convert.

2. Why can't the IRB office enter the protocols?

The IRB office cannot enter the existing protocols because they do not have electronic copies of the documents. In addition the CHeRP IRB forms have been revised to contain some additional information which only the PI can provide. There will be a "shell " for each existing protocol that will be pre-populated with limited data such as the protocol title, number, name of PI, most of the research staff and funding agency if applicable. These are the only electronic fields that we have and can enter for existing protocols. The shell for each protocol will all be placed in your CHeRP IRB workspace as of November 15, 2010 so that you have a full listing of what needs to be converted.

3. When should PIs complete their legacy conversions?

After November 15, the CHeRP IRB site is open to begin converting existing protocols. You may convert protocols at any time after November 15th however you WILL BE required to convert them before your next continuing review. You must convert your protocol before you may submit a continuing review. Investigators who need to submit their continuing review within the first three months of conversion (Nov 15-February) will have the option of completing the continuing review in paper, for this year only. We want to make sure everyone has enough advance notice to convert the protocols.

4. I expect that my protocol will be completed by the time of the next continuing review, do I need to convert the protocol from legacy and enter all the information that is required?

If you are going to complete your protocol before the next continuing review you may not need to convert to the protocol into CHeRP IRB. You may submit a paper completion report at anytime it is complete or at the time of continuing review. However, please be aware that if the research is not complete and you need to

request continuing review, you need to plan enough time to enter the protocol, get the protocol accepted so that you can submit a continuing review before it expires.

5. Once I convert a protocol, can I submit paper continuing reviews, amendments etc.

No, once a protocol is converted you must continue to use the CHeRP IRB for all future submissions on that protocol.

6. Will I get reminders to convert my existing protocols?

Yes. All Investigators will get an email shortly after November 15th to inform them it is now possible to convert existing protocols. After this first notification investigators will get a notification at 120 days before the protocol is expected to expire to remind them to convert the protocol. Investigators and those listed as contacts will also get the routine continuing review notices at 90, 60 and 30 days before expiration. These emails will also provide reminders about the conversion process.

7. How will I get these notices?

You will continue to get emails in your outlook accounts. Even after the conversion occurs, notifications will be sent to your outlook email account. This is no different than our current communication methods.

8. Who else will get these emails? Will other study team members?

Only those individuals previously listed as an additional contact will get the email notifications. This has not changed and is what we currently do.

9. What is the process to convert each protocol into CHeRP IRB?

You will need to go into the CHeRP IRB system and select the protocol you are converting. For each investigator there is a specific tab titled "legacy". When you click on this tab you will see a list of all protocols that require conversion. You will select the protocol you wish to convert and begin the process. You will be asked questions about whether you are still performing research activities or whether you are in a data analysis phase. If you are only performing data analysis there will be fewer items to enter. Please note once you submit that a protocol is in data analysis you cannot go back and reopen the protocol to allow other research activities so please be sure all research is complete before take this action. The

system will lead you through the forms you need to complete and attachments to up load. For example your consents, recruitment notices and body of the protocol are all attachments. It is likely you have these documents already in a word version and you will just need to upload them. You can also cut and paste from previous documents and enter it in the new forms. You must input only your most currently approved protocol and associated documents. You are not required to enter any history (amendments already approved, events reported).

You will find very specific instructions with screen shots in the "How Do I" documents under research team member training materials, see the specific section on legacy protocols

http://chbshare.chboston.org/elibrary/isd/educate/cherp/default.aspx

10. Is there something similar to a "part B" so I can just upload and attach that?

CHeRP IRB consists of a serious of questions (smart forms) and uploads for an individual research protocol. One section of the form asks you to upload your "protocol". The form also contains an informational outline of what needs to be included in this upload. You will note that some topics previously required in Part B have now transitioned to separate questions in the forms. We specifically pulled out some topics such as (recruitment, data and safety monitoring) to ask separate questions in hopes of getting more complete information. We hope this will result in fewer IRB questions during the review process.   When you convert your existing protocol, if there are individual questions in the new forms that are included in your old "Part B" and you upload the old Part B as your "protocol" upload you may just refer to the page and location where it is addressed. Please note some of the questions are mandatory so you will need to enter something. We are allowing this for converting legacy protocols only. New submissions will require that each question be individually addressed. Also the new CHeRP IRB no longer refers to "part B" it just refers to uploading your protocol.

11. Can I amend my protocol at the time of legacy conversion?

NO, Amendments at this time are prohibited.   You must enter what is already approved. If it is noted you have included changes in the protocol, it will be returned so that changes can be removed. This will add time to the conversion process and could be problematic especially if you need to complete the conversion in order to submit a continuing review. We recognize that during this process you may realize that you want to revise or amend your protocol. If so, you must wait until after the legacy protocol is verified and accepted by the IRB office. After you receive a confirmation that the legacy document has been accepted you may then submit an electronic amendment.

12. What if I have not maintained electronic copies of all my protocol information, for example I do not have the recruitment postings?

We certainly hope that PIs have all their protocol materials but we understand that occasionally documents may be missing or misplaced. We expect this to be the exception. The IRB office does maintain complete files of all materials submitted to the IRB. Only if absolutely necessary, you are welcome to come to the IRB to obtain a copy of a document. The IRB staff will not be able to make copies for you or to send them to you in paper or electronic format. IRB staff are very busy assisting researchers and support staff with their questions about the new electronic system in addition to doing their daily work and will not have time. If you need documents from the IRB files you will need to come to the IRB office (2 Avenue Louis Pasteur, Le Favour Building at Simmons College 4th floor) and retrieve and copy any materials. You may use our copier machine. Under no circumstance can an IRB protocol leave our office. A PI may come and copy their protocol and associated documents or they may send someone who is currently listed on the protocol. If you are not listed as part of the research team, you will not be given access to the protocol. In addition please contact the office and set up a time to view and copy what you need. Staff are not always in the office to assist you so you must coordinate a time with them.

13. Who can enter the information in the new electronic system to convert an existing legacy protocol into CHeRP IRB?

The investigator will automatically have the protocol available to them in their IRB workspace as of November 15, 2010. In addition anyone previously listed as a contact on a protocol will have the protocol in their IRB workspace and can work on the protocol. The only exception would be if the contact information did not transition over. (Please see question 20 to see why a name may not transition over)

We realize that investigators may need additional help so we have established a mechanism for investigators to add "legacy editors" to assist with conversion on an individual protocol basis. When the investigator enters the workspace for an individual protocol he/she has the ability to add any individual currently listed in Children's Hospital peoplesoft as a legacy editor for that individual protocol. Once added that person may go into the protocol workspace and help complete the forms and attach associated documents. There is no training required to serve as a "legacy editor" therefore it is the responsibility of the PI to chose qualified individuals for this role. "Legacy editors" have rights to enter protocol information only on the protocol for which they are listed. If they need to work on two different protocols, the need to be entered on both protocols as a legacy editor.

14. If I have a staff member and I want them to be a legacy editor for multiple protocols how do I do that?

The PI needs to enter the workspace for each protocol and enter the name of the legacy editor.

15. Will a legacy editor remain on the protocol and be able to continue to work on the protocol once the conversion is accepted?

No, once the protocol is submitted and accepted, legacy editors will lose all rights to access the protocol. If the PI wants to add them to the protocol on a permanent basis, the PI will need to submit an amendment after legacy acceptance. The individual will need to meet all training requirements at that time which may include CHeRP training (if they are going to continue to interact with the electronic system) as well as any necessary CITI training for their role as a research team member.

16. Once I complete the required forms and upload my approved documents what do I do, what happens?

Once all information is entered and uploaded, the PI, primary contact or a legacy editor may submit the legacy protocol for acceptance. IRB analysts will perform a review to make sure you have accurately entered the information and included all of the materials on file as approved for your protocol. If the IRB office notes documents or items that are not included or addressed you will receive feedback through CHeRP IRB and will need to modify your submission. Once the IRB office is satisfied that the electronic protocol is accurate and complete we will accept it and you now have an electronic protocol on CHeRP IRB.

17. How will I know if my protocol requires continuing review after the legacy protocol is accepted into CHeRP?

The IRB office will continue to send reminders via email 90, 60 and 30 days before a continuing review is due. This will not change. The email you will receive will look different because it is generated from CHeRP IRB but the notifications will be sent at the same time sequences. The emails will also contain a direct link into the protocol workspace to make it easier to begin the process.

18. How do I submit my continuing review?

Once the protocol is accepted you will then need to go into the protocol workspace and complete a continuing review form. No paper submission will be accepted once

your protocol is converted. Please see "How do I documents" that may be found at
http://chbshare.chboston.org/elibrary/isd/educate/cherp/default.aspx
for further information about submitting through CHeRP and the continuing review
process"

19. Does submission and acceptance of the legacy protocol mean continuing review is complete?

No, continuing review needs to occur as a separate activity within CHeRP IRB. You
will need to go back into the electronic workspace for the protocol and begin the
continuing review activity which includes completing additional forms and attaching
specific documents (i.e., recent DSMB reports). This is an entirely separate
process.

20. I noted that in my "shell" for a legacy protocol, some research staff who were previously listed did not show up. Why has this happened and what do I do?

While most of the individual who are listed as staff on a protocol will automatically
transition over, we already know there will be some exceptions that could not be
avoided. They are as follows:

1)   If we do not have a CH ID number for a research team member, their name
will not be listed in the legacy protocol.
2)   Individuals listed as research team members who do not have a CH ID
number will not be transitioned over into CHeRP IRB. This means individuals who
are listed as part of the research staff from other institutions will not appear in the
legacy "shell".

For both of these categories , when your protocol is submitted to the IRB office for
acceptance into CHeRP IRB, the IRB analysts will add these individuals back to
your protocol. When you get the notification that the legacy protocol is accepted
you can then go into the protocol and verify that they are added back.

21. I noted that the legacy protocol "shell" contains incorrect information about the sponsor and or the individuals listed as research staff. How do I change that?

The purpose of the legacy conversion is to convert into CHeRP IRB what the IRB
has on record as approved for your protocol. This is not the time to submit
amendments; however we do want to make sure that you change the information
at a later date. To make a correction, convert your legacy protocol and once
accepted submit an amendment via CHeRP IRB to change the sponsor or research
team members.

22. If I already submitted a new protocol via paper and it is currently under review do I need to convert the protocol to CHeRP IRB at this time? If not when do I need to convert it

New protocols that have been submitted via paper to the IRB before December 13th for phase I departments and January 31 for phase 2 departments will continue to be reviewed through the paper process. Do not convert a protocol that is currently undergoing initial IRB review until after it has received final approval from the IRB. You will need to wait until you go into your IRB workspace and see the protocol listed as a legacy protocol before you may convert it. Once a paper based protocol is approved and shows up as a legacy protocol, we do ask that you convert the protocol into CheRP as soon as possible. All protocols need to be in CheRP IRB within the next year.

23. Will my approved consent document still be included in the consent library once the protocol is converted into the new CHeRP IRB?

We will continue to maintain a consent library for all approved consents, however because the consents will now be submitted and stored electronically with a protocol, we need to make changes to the consent library software. As new protocols are submitted and approved in CHeRP IRB or converted from a legacy protocol into the CHeRP IRB we need to store them differently. The result is we will need to maintain two consent libraries until all existing protocols and their associated consents are converted into CHeRP IRB. After November 15th any newly approved consent document or consent documents that are part of a legacy conversion will be included in the new consent library. Existing approved consent documents will remain in the old library until they are converted into CHeRP IRB.

Within a year the old library will be phased out. What this means is that there will be two libraries that will store approved consent documents. There will be links between the two libraries on each library site. If a consent document is not found in one location you can automatically go to the other site. We realize this is not an ideal situation but there was no way to avoid this situation unless we required all PIs to convert all their protocols into the new system immediately. Instead we took the approach of requiring conversions at the time of continuing review as a way to reduce the burden on the PIs.

24. I have not converted my legacy protocol into CHeRP IRB but I need to submit an amendment or a reportable event, can I use CHeRP IRB?

No ,if you have not converted your protocol from a legacy protocol into CHeRP IRB you must continue to submit by paper.

Support and Questions

For technical assistance, please contact CHeRP Support at 4-3267 or CHeRP.Support@childrens.harvard.edu.

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