

CHeRP IRB January 2011 Update

We are pleased to report that the CHeRP IRB application (Children's Hospital Electronic Research Portal) has been live since December 10. We have received our first completely electronic submission that is ready to go before the full IRB on January 10th. This will allow our IRB members to begin their work on the system. Many other new protocols are in process and we continue to convert the old protocols into the system. All uses of CHeRP are proceeding smoothly. As expected there have been a few unanticipated minor issues but there have been no major problems. We want to thank the investigators and research team members who are "going first" and using the system as they are helping us work through many of the small implementation issues.

Starting on January 31, 2010 the Phase 2 departments listed below will go live for new submissions. **As of January 31, all departments will be expected to use CHeRP for any new submission.** All Departments and Divisions are now using the system for continuing reviews. We will only accept a paper continuing reviews if your protocol expires before March 1, 2010. You must submit your continuing review within CHeRP if your protocol expires after March 1, 2010. In order to submit a continuing review you must first convert your protocol into CHeRP so please plan ahead, this takes time

Phase 2

Adolescent Medicine
Dentistry
General Pediatrics
Genetics
Infectious diseases
Laboratory Medicine
Molecular Medicine
Newborn medicine
Nursing
Ophthalmology
Otolaryngology
Pathology
Physical Therapy
Radiology
Surgery
Urology

Important Reminders Based on our Experience Thus Far

Legacy Conversions

- While we have advised you not to change protocols when entering your legacy protocols, we also realize there are some new questions that we ask. This is because we changed our forms to try and obtain more detailed information for the IRB on topics that they consistently needed to ask for more information. We also realize the new questions may ask for more detailed information than previously specified. As you complete new questions, please base your answer on the information from the approved protocol. Please do not change the approved protocol, recruitment methods, informed consent issues etc. If you have any questions please call our office
- As part of the legacy conversion process you are asked to upload your protocol (which was previously Part B) Only upload the most recent version. DO NOT UPLOAD old versions. We only want the most recent version.
- Be sure to include the most recently approved informed consent document(s) . If you are not sure you have the most recently approved version please visit the informed consent library and obtain a copy from there. The link to the library is <http://chbcfapps/research/consents>
- Do not submit your consents in pdf format. We require a word version
- A good reference question and answer guide for legacy protocol conversions can be found at http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/QA.pdf

Training

- CHeRP IRB will check that all individual listed on protocols, continuing reviews and amendments have the appropriate human subject trainings. This includes medical record and specimen requests . CHeRP will also track when training has expired. This means that for all legacy conversions, new protocols ,continuing reviews and amendments, the system will check that all listed research team members have up - to-date training . CHeRP is programmed to prohibit the release of approval unless all listed are trained. In the past we have not had the manpower to continually check the training , however CHeRP IRB will. This means it is essential for all those listed on the protocols to obtain and maintain human subject training in order to avoid any delays. We are already delaying approvals because of lapses in training.
- Please DO NOT notify CHeRP support once you complete CHeRP training. If you complete net learning your information will automatically be loaded in CHeRP overnight. You need to wait until the next day in order use CHeRP. If you complete classroom training, the information will also be entered overnight.

Your Questions

- In preparation for introducing CheRP , we developed extensive “How do I documents” . We realize that any new system will require extensive training and these documents are an important component of our training effort. We want to remind everyone that these documents contain step by step instructions with screen shots of CheRP IRB to guide you through submission and response activities. The documents may be found at

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

We ask that you consult these documents before you call our office . While the IRB staff is always willing to assist, these documents actually contain more detailed information that we can ever provide on the phone. If after consulting the documents you still need help, feel free to call our office (57052) or CheRP support at 43267 (617 919-3267 externally)

- CHeRP support is there to answer your questions and assist you, however please do not automatically continue to include CHeRP support in emails and subsequent correspondence when they are not needed. They are receiving numerous emails when they are not required. This makes it difficult to sort through the emails and respond to the ones the issues that need their immediate attention.

Other General Information

Required Training for PIs and Research Team Members

In order to familiarize PIs and research team members with the CHeRP IRB application there **is required training. You will not be able to submit new applications, continuing reviews, amendments or unanticipated events unless you complete the training.** This requirement will apply to the PI and staff designated as able to prepare and submit IRB documents. There will be ongoing classroom and web-based training. You may choose whichever is more convenient but **you must complete one.**

Training will not be required to input a legacy protocol. However, once the legacy protocol is accepted, you will require training to submit a continuing review, amendment, unanticipated event or a new protocol and this will require training

Web Based training is available through NetLearning. Instructions to get to Net learning are

Step 1: From CHB's Intranet site, click on "Net learning" under the "Quick Links" menu in the lower left side of the page. You can also visit it directly at <http://cbl.childrens.harvard.edu>

Step 2: Enter your CHB ID# without the CH prefix (i.e. 123456) and click Login.

Step 3: GO to section "Enroll in CBL".

Step 4: Please find the course 'CHeRP IRB Research Training', click on the green plus sign and enroll for the course (You should disable the popup blocker on browser).

Step 5: Click "Enroll" next to the "CHeRP IRB Research Training" course

Step 6: Now you can launch the course by clicking the link in your My Courses/Classes.

Next Class Room Trainings are

1/12/2011 3:00 PM Enders Auditorium

1/19/2011 10:00 AM Enders Auditorium

Visit our Website for all your CheRP links.

http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/mainpageS2206P68.html

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.