

CHeRP IRB February 2011 Update

All Departments/ Divisions are now live on CHeRP! As of January 31, 2010 the Phase 2 departments listed below are live for new submissions. **All departments are expected to use CHeRP for all new submissions.** Any PI who is starting a new application (full protocols, medical record/ specimen, emergency requests,) will be required to use CHeRP. You will not longer find protocol applications on our website. Protocols that are submitted in paper WILL BE RETURNED.

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

All Departments and Divisions are currently 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.

Important Reminders Based on our Experience Thus Far

Legacy Conversions

- Please remember that for protocols started in paper, the approval process will continue in paper. However once the protocol is approved, the PI and research team

are still responsible for converting the protocol into CHeRP by the time of the next continuing review. This is not done automatically.

- As part of the legacy approval process the informed consent footers that (include expiration dates) are changed to a new format. The information remains the same. This is important for the new system to automatically insert dates when the protocols undergo continuing review. Once a protocol is converted to CHeRP please be sure to use the newly converted consent, when revising consent forms for an amendment. Do not use old versions. The converted version of the consent may be found in the consent library or as part of the approved CHeRP electronic protocol.
- If you are converting a legacy medical record or specimen review please be sure to use the correct form in CHeRP. The new form is titled. *“New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients”*. There is now one form for both medical record and discarded specimen reviews. The form will ask you to choose which activity you are conducting and then branch to the appropriate questions.
- Once you finish an electronic protocol application you need to use the “Submit”. When all forms and fields are complete you will get a message the protocol is finished, however you still need to “submit”.
- 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. 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

- Please use our How do I documents. 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>
Please consult these documents before you call our office .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 and it is hard for them to determine which email require immediate attention and their assistance.

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. There are only 4 more classroom dates for training. After these dates there will only be web based training available.**

2/3/2011 9:00 AM	Enders Auditorium
2/8/2011 3:00 PM	Enders Auditorium
2/17/2011 2:00 PM	Enders Auditorium
2/24/2011 2:30 PM	Enders Auditorium

Training is not 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. Detailed instructions to get to NetLearning may be found in the how do I documents:

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

Look for the section on “Research Team Member Training Materials and the sub section “Training Presentations”. There is a step by step guide with screen shots.

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.