Children's Hospital Boston

IRB
Institutional Review Board

CHeRP
Children's Hospital
eResearch Portal

Electronic CHeRP IRB is going Live in December!

We are pleased to announce that the CHeRP IRB application (Children's Hospital Electronic Research Portal) will go live in December. All Departments and Divisions will begin to use the electronic system for continuing reviews starting in December. There will be a Phase 1 and Phase 2 for new protocol submissions. More information about the phases is included in the newsletter.

There will be many changes and mandatory training requirements for all individuals who will interact with the system. The CHeRP IRB application allows an investigator to input a protocol and the protocol will move through all reviews electronically. This includes Scientific Review, Department/Division sign off, IRB pre-review, IRB review and Ancillary Reviews (for example: CTO, Pharmacy, Radiation Safety). At this time, we would like to provide you with a brief overview of the major events and requirements that you need to begin to plan for. More detailed information and instructions will be provided as necessary.

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Important Dates and Events

October 11, 2010: CHeRP IRB Sandbox Available

An IRB CHeRP "Sandbox" is available for the clinical research community to practice viewing and preparing electronic submissions. **DO NOT USE** the sandbox to prepare actual IRB protocols that you intend to submit. The protocols created in the sandbox **CANNOT** be converted into the actual system when it goes live. The electronic protocol forms have been revised in content and format. The forms now include "smart form" logic, which allows specific questions and forms to appear only if pertinent to the research. We recommend that you familiarize yourself with the new forms and format before the system goes live. This is the place to practice!

The Sandbox may be found at http://rc-cherpirb/sandbox.

November 15, 2010: IRB Electronic Forms Become Available

The CHeRP IRB application will be open for investigators and their research team members to begin to input **NEW** protocol applications for IRB submission on November 15th. These will be the "real" forms. You may complete and store the forms; however, you will not be able to submit **NEW PROTOCOLS** until the go live date of December 13th for Departments/Divisions in Phase 1 or January 31st for Departments/ Divisions in Phase 2. The chart below lists the Departments and Divisions scheduled for Phase 1 and Phase 2. All departments have access to the forms on November 15th; however, you will only be able to submit New Protocols when your department is scheduled to go live for new submissions. We are opening the forms before going live so that investigators can get a head start and have ample time to input protocols if desired. **All Departments and Divisions will begin to**

use the CHeRP IRB application for continuing review submissions as of December.

November 15, 2010: Legacy (Existing Protocol Information) Transferred

To completely convert to an electronic submission and review process, existing protocols must be entered into the new system. This will be accomplished over the upcoming year by requiring each protocol to be converted to CHeRP IRB at the time of the protocol's continuing review. Our current protocol tracking database has limited amounts of electronic data, which is geared towards operational issues (i.e. sending continuing review notices). The body and text of the forms and protocols are not in an electronic format.

In order to convert protocols to the CHeRP IRB application we will require that all investigators input their protocols and associated documents (consents, recruitment postings, investigational brochures) into the CHeRP IRB application at the time of your next continuing review. Investigators who have continuing reviews due within the first 3 months of go live will have the choice of submitting continuing reviews in paper if they need more time to convert the protocols. You may choose to convert protocols to the CHeRP IRB application sooner than the next continuing review, however **once the protocol is converted, the electronic system MUST be used for all additional protocol review activities including the submission of amendments**.

To assist investigators in the conversion process we will import basic information on all existing active protocols. These protocols will be referred to as 'Legacy' protocols. For each protocol that is active and requires continuing approval, PIs and their research team members will need to go into the Legacy tab of the CHeRP IRB application, select the protocol, populate all forms and attach the protocol and other associated documents (consents, recruitment postings, drug brochures etc). The completed legacy protocol will then need to be submitted to the IRB office for review and acceptance. This is done electronically. The IRB staff will determine that all the associated forms and documents are complete and accept the legacy protocol. **This will initiate the use of the CHeRP IRB application for that particular protocol. From this point forward, all submissions for that protocol must be electronic**. Investigators, who have continuing reviews due during the first three months, may need some additional time to convert the protocols so they will be allowed to submit a paper continuing review for this year only. They will need to complete the legacy process the following year.

We realize the initial effort to input existing protocols is a great deal of work especially if investigators have more than one protocol. We have consulted with many institutions that have transitioned to an electronic system and determined this is the best and only method to accomplish a complete electronic conversion.

Legacy Protocol Conversion Chart

	Go Live	Paper Not Accepted After
Continuing Reviews All Dept/Div	**December 13**	**April 1,2011**
New Protocols		
Phase 1	**December 13**	**March 1,2011**
Phase 2	**January 31**	**April 1,2011**

PHASE 1

December 13, 2010: Go Live

The following Departments/Divisions begin submitting **new** protocols during Phase 1.

Anesthesia (all divisions)
Cardiac Surgery
Cardiology
Developmental Medicine
Emergency Medicine
Endocrinology
Gastroenterology/Nutrition
Hematology /Oncology
Immunology
Medical Critical Care Program
Nephrology
Neurology
Neurosurgery
Orthopedic surgery
Plastic and oral Surgery
Psychiatry
Respiratory Diseases

PHASE 2

January 31, 2011: Go Live

The following Department/ Divisions begin submitting **new** protocols during Phase 2 .

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

At the time of " go live" if a NEW protocol has already been prepared in paper and/or is undergoing scientific review, the IRB will accept the protocol in paper only for a period of two months after "go live". After two months all submissions must be electronic and no paper will be accepted. Please reference the chart above.

Required Training for PIs and Research Team Members

In order to familiarize PIs and research team members with the CHeRP IRB application there **will be 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: CHeRP training is available now through NetLearning. Login to NetLearning and search for the 'CHERP IRB Research Training' class.

Classroom Training: You do not need to register, just show up.

The schedule for classes is:

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

How Do I Documents

We will maintain and publish "How Do I" documents that include specific instructions on how to complete common activities within the system.

How do I documents may be found at:
http://chbshare.chboston.org/elibrary/isd/educate/cherp/default.aspx

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.