



Human Subjects Protection Update Special Communication

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**Office of Clinical Investigation
Children's Hospital, Boston**



New CHeRP and Pharmacy Requirement for Dispensing Investigational Drug

The Children's Hospital Pharmacy is required to verify that informed consent is obtained prior to dispensing drugs for research purpose. Investigators have been asked to fax, email or hand carry a copy of the signed consent to the pharmacy. We are pleased to announce that as part of a CHeRP IRB enhancement, a separate module has been developed in CHeRP IRB to assist investigators in documenting consent for enrolled research subjects. Investigators will be required to enter the names of research subjects and include the date the consent was signed. The pharmacy now has the ability to view this information.

This new consent module is attached to the CHeRP individual protocol, however it is protected so that only the pharmacy and staff listed on the protocol will have access to patient information. This will assure confidentiality of the research subjects. Investigators are also able to enter and store scanned signed consent documents in this module, however this is not a requirement. The IRB office is not able to view any part of this module.

As of February 1, 2012 for any new subject enrolled on a drug associated protocol, the pharmacy will verify in CHeRP that consent was obtained prior to dispensing the drug. Subjects enrolled prior to February 1 will be "grandfathered" so you do not need to enter their consent information, however it is strongly recommended.

The following questions and answers will provide information about this new requirement.

1. Why is this change being made?

The pharmacy may only dispense investigational drugs if informed consent is obtained. The current process of sending the pharmacy a copy of the consent is time consuming. It is also difficult for the pharmacy to store copies of the signed

consent documents. With an electronic protocol system it is easy to utilize the CHeRP technology to simplify the process.

2. When is this change effective?

The change is effective February 1, 2012.

3. What information will I need to add and how is this accomplished?

There is a detailed “How Do I “ document with text and screen shots. It can be found in CHeRP under “How Do I - IRB Research Team Training Materials – Other” or by clicking the following link:

<http://chbshare.chboston.org/elibrary/isd/educate/cherp/cherp/How%20Do%20I%20Enroll%20a%20Patient%20into%20a%20Study%20in%20CHeRP.doc>

In summary, when you select a CHeRP protocol, you will see a new activity titled “Enroll a Patient” on the left column. Once you select that activity you will be asked to enter subject information which includes, name, medical record number and date of birth (or any combination) . A list of matching patients from the hospital’s medical records database will appear. You will select the correct patient and enter the date the consent was signed. There is also a section where you can upload a scanned signed informed consent but this is not required.

4. Although this is not required until February 1st, can I begin to input subject information now?

Yes, you may begin to input subject information into CHeRP however the pharmacy will not begin to use the system until February 1, 2012.

5 .Do I need to enter the names of subjects who already received research drugs prior to February 1, 2012?

No, you are not required to enter subjects who already received drug prior to February 1, 2012 . However if you have consented a patient but the drug has not been initially dispensed before February 1, you will be required to enter the subject and consent information.. **The criteria to enter a patient depends on whether drug has been dispensed for the first time before or after February 1, 2012**

6. What date should be entered?

Enter the date the subject/parent/guardian signed the consent.

7. Who can enter subject and consent information in CHeRP?

Anyone who is listed as an editor on the protocol can enter this information. If you need to change roles of exiting staff to add additional individuals to the editor's role you may submit an amendment.

8. Will the pharmacy view CHeRP each time to be certain consent information is listed before dispensing drug?

Yes, as of February 1, 2012 the pharmacy will either check their existing records or verify in CHeRP that an informed consent was obtained, however they will not ask for or view a copy of the actual signed consent document.

9. Should investigators enter information for subjects who were enrolled in the trial and were provided with drug prior to February 1, 2012?

Yes, it is recommended but not required, especially if subjects will continue to receive drug after February 1, 2012. Entering this information retrospectively will make it much easier for the pharmacy to verify from one source that consent was obtained. It can also serve as centralized record that you have obtained and documented consent for all subjects.

10. Is there a way to view all subjects you have entered in CHeRP?

Yes, you can view a list of all subjects you have entered by going to the "Patient Data" tab in the CHeRP protocol. The "How Do I" document provides a screen picture of the location for that tab.

11. If the subject does not have a medical record number is there a way to enter them in CHeRP?

Yes, while it is expected that most subjects will be patients of Children's Hospital it is possible that there may be a situation where drug is dispensed but provided to individuals who are not Children's patients. There are separate fields to add these subjects.

12. Will the use of this this module be monitored?

Yes, the EQuIP staff will monitor use of this system for any protocol review that includes dispensation of investigational drugs. EQuIP may also perform general monitoring outside a specific protocol as well.

13. If I have questions who do I call?

Please call CHERP Support at 43267 or from outside the hospital please call (617) 919-3267. To protect the confidentiality of the subjects, the IRB analysts will not have access to any section of CHERP with subject identifying information. CHERP Support will be your best option for help.

