Monitoring Visits, Audits & Inspections
obtaining **Access** to **Research Documents** & **Data** for **non-BCH Personnel**

Purpose

Provide guidance to the BCH research community that need to obtain compliant access to clinical research documents for monitoring, audit and inspection visits conducted by **non-BCH personnel**.

Things to think about:

- Identify all required documents that may be reviewed at the time of an external monitoring visit, audit or regulatory inspection: consent forms, IRB documents, research data, training documents, source data, etc.
- Know what external entities (sponsor, DCC, CRO, monitor, FDA, NIH and other regulatory agencies) have rights to access research files, what files need to be available to them and how. Review the study contract, Investigator agreement, Manual of Operations, approved protocol and consent, as they apply to the study.
- Just ask! As soon as you can (ideally before study begins), just ask your sponsor or monitor what the monitoring plan is: frequency and timing of monitoring visits, what files they will need access to during the visits and any expectation of how they documentation should be presented. As much as possible, know your monitors and expectations.
- The standards and expectation of safe and secure storage for paper documents are the same for electronic records.
- If monitors will need direct access to Power Chart/Eclipses (electronic medical records), CHeRP (IRB files) and other electronic files (e.g. shared network drives), please review the processes for obtaining access for non-BCH personnel and put in the request as soon as possible to avoid delays right before a visit.
- Once the monitor obtains access rights and is on site, ensure they will know ***how to access*** the pertinent electronic files. Will you need to provide a computer/laptop or will they bring their own device. How will you be able to easily provide links and map access to the appropriate files? Think about what kind of instructions a monitor may need on how to navigate the electronic systems.
- Note: Please ensure all links/access permissions are terminated at the conclusion of the external monitoring period.

Access to Medical Records

If research data and documents pertinent to the study are originally documented in medical records, as soon as possible, ask your monitor, auditor, inspector if they will want direct access to the medical records, or if they prefer certified print-outs. If the monitor expects copies to be certified, ask what constitutes 'certified.'

If an external monitor needs direct access to medical records, you will need to obtain access/rights for the monitor before they come (process takes up to 2 weeks). Follow steps in *Addendum A: Access to Electronic Medical Records.*

Access to CHERP: IRB Documents

If you rely on CHeRP for you IRB documents (i.e. do not print them out and file), you need to obtain temporary access for the monitor. This request should be placed to the IRB/CCI office (usually takes about 3-5 days).

If you do rely on CHeRP, make sure you know where to find documents (will you know where the approved consent versions are, protocols, etc). You should be able to provide basic instructions to the monitor. See *Addendum B: CHeRP How Do I? View a Submission: Auditor Role*

Access to Database or Electronic Data Capture (EDC) systems (e.g. InForm, RedCAP)

If a study is being conducted in InForm by a Children's investigator and a monitor is being contracted, that monitor can have their own account created and will be granted Clinical Research Associate (CRA) rights to review case histories, conduct source document verification, generate queries and generate monitoring reports. For account creation and training please contact the Clinical Research Center at crc@childrens.harvard.edu.

REDCap databases should not be audited by an external auditor as an EDC system (electronic case histories), and instead paper case histories should be available to be monitored against the source. In the event that REDCap is being used for a purpose other than storage of research data (ie: operations support) and access is needed please contact clinical research IT at crit@childrens.harvard.edu.

Other Electronic Files

If you generally store your research documents in electronic files which are considered safe and secure (password protected file in department shared drive, Sharepoint Team Site), ensure they are available for review upon request, especially if you use electronic files like an electronic regulatory binder. Do not have electronic files duplicated in paper binders/files unless there is a reason. This creates extra work for everyone.

Appendix A

Access to Online Medical Records for non-BCH Personnel

Medical Records Auditor Access

This guidance outlines the process to obtain 'Medical Records Auditor' access to online medical records for non-Children's Hospital Boston personnel, such as outside study monitors and sponsors. MedRec Auditor access allows non-BCH individuals access to a **selected list of patients for a limited time**, or to selected encounters (e.g. specific visit dates) if necessary. The steps below need to be taken by a Department Administrator, or DA (person who typically completes access forms for new employees), once for each individual who requires access.

1. **Obtain "Associated Personnel" status and obtain a BCH ID # for the external auditor by following these steps:**

    1. Complete and submit the online version of the "Associated Personnel Data Form" at http://BCHshare.BCHoston.org/TS/hr/ap/Lists/AP%20Data/APDataNewForm.aspx *Form*'.

        Note: this online version of the form can *only be accessed by individuals who have completed the NetLearning training titled* "Associated Personnel Policy & Process Training Module". This would usually be the Department/Division Administrator, or DA.

        i. The research team member who will be providing the identified DA with the required information about the non-BCH Personnel should download a copy of the Associated Personnel (Non-Med Staff) Data Form from the HR website and gather the required information from the monitor.

        ii. The DA will then enter this information into the online version of the Associated Personnel Data Form to initiate the process. Once the request is processed, the DA will receive an email that provides the BCH ID# and instructions for obtaining a BCH ID Badge, if needed, for the monitor.

2. **Complete an '*Online Access Report*' (OAR) to request medical record system access for non-BCH Personnel (http://chwebapps.tch.harvard.edu/cfapps/secure/account_request/account_request.cfm?reqId=0). *This requires the BCH ID#, so step #1 must be completed prior to completing an OAR.***

    1. Request for the individual to be granted CHAMPS Access as 'Medical Records Auditor'. A printout, of the final access summary screen, should be sent to the Supervisor of Release of Information (currently Linda Lebel at (857)218-4529) to inform medical records that individuals will be requesting chart access.

The first two steps only need to be taken once for any individual non-BCH Personnel who needs access. The third step will need to occur for each instance (eg 3 day monitoring visit) that the individual will need access to medical records:

3. **Send an email with a list of charts that the individual will need to review to the BCH Supervisor of Release of Information (Linda Lebel) and cc Yvette Maxwell Yvette.Maxwell@childrens.harvard.edu and Omyra Nieves Omayra.Nieves@childrens.harvard.edu .**

    - This list should include:
        1. Medical Record Numbers
        2. Time period during which the external monitor should be able to access the records
        3. CCI/IRB protocol #
        4. Name of sponsor of the research – include a name and contact information (ph# and email) for the monitor).
    - A patient list will be created prior to the review dates. A minimum of 48 hours is required, although as much advance notice that can be reasonably provided is appreciated.

Reminder: The principal investigator is also responsible for ensuring that the Associated Personnel also receives the additional information outlined in the Associated Personnel Welcome Checklist

Who to Contact with Questions?

Supervisor, Release of Information – currently Linda Lebel at 857-218-4529
Health Information Management (HIM) Operations – currently Maureen Ryan at 857-218-4511
Director, Medical Record Services/Privacy Officer – currently Mary Radley at 617-730-0329

Children's Hospital Boston

IRB
Institutional Review Board

CHeRP
Children's Hospital
eResearch Portal

How do I...

View a Submission?

When viewing a submission workspace, you will have the '**View Submission Form'** activity available. This activity allows you to view all the smartforms and attached documents for the submission. The submission will be in a read only format. This activity is available for all submission types: Protocol, Continuing Review, Amendment and Reportable Events.

To view the protocols to which you have been given access, choose **IRB** from the blue bar at the top of the screen (**Figure 1**). You will then see a listing of the protocol(s) to which the auditor is given access (**Figure 2**).

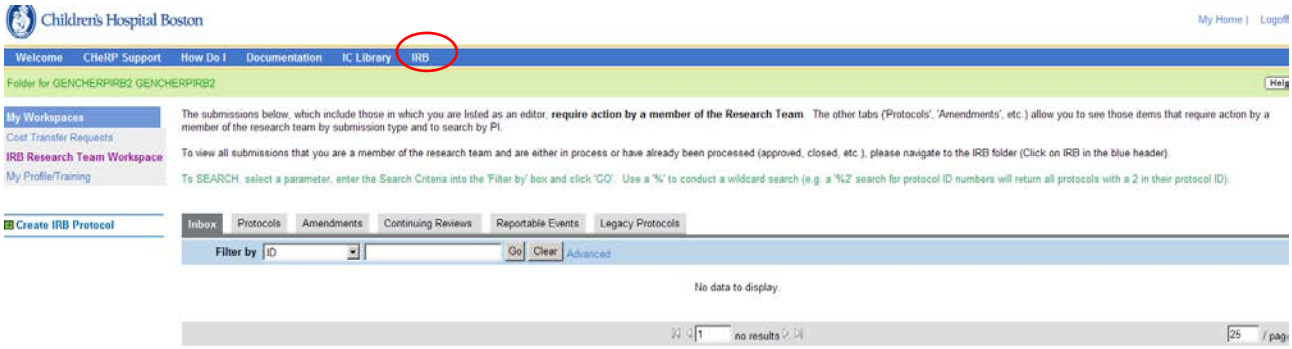

Figure 1

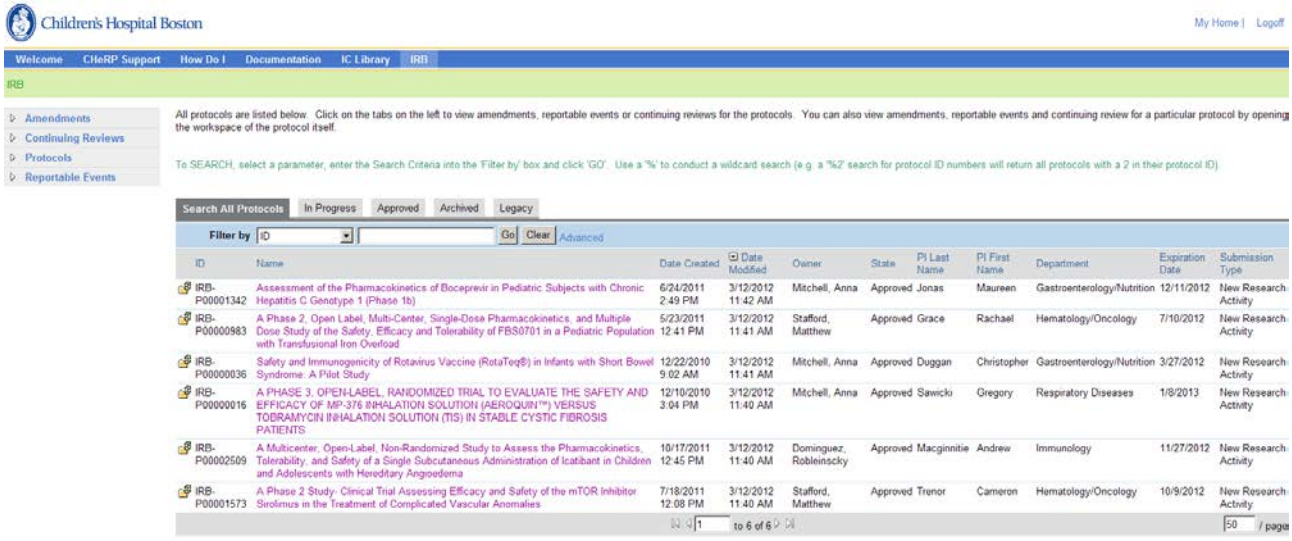

Figure 2

To enter a submission workspace, click on the study title. The top half of the page will have basic information about the protocol, and the bottom half of the page will show the **History Log** of all actions that have occurred since the protocol was first created in CHeRP.

To view or print the currently approved version of the CHeRP **Submission Form** for the study, click on the **View Submission Form** or **Print Form** wording in the upper left corner of the screen and the entire form will be displayed either in sections**,** or in entirety (see **Figure 6**)**.**

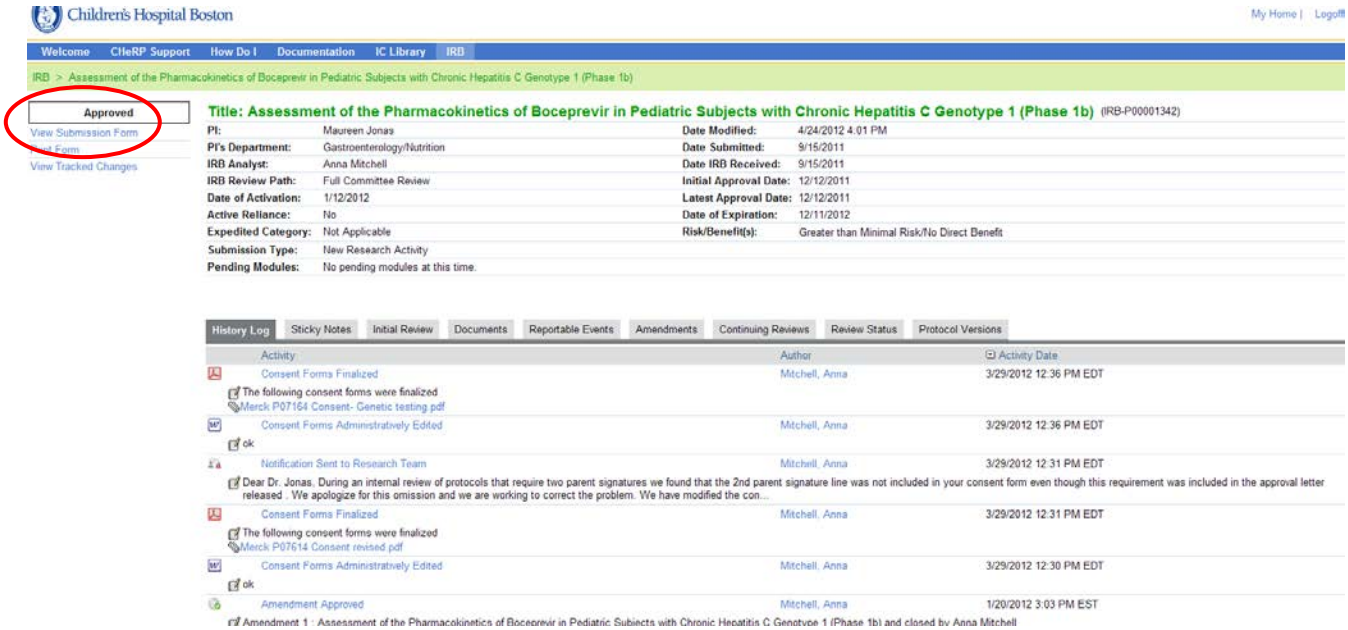

Figure 3

Click on any of the **gray shaded tabs** to access more detailed information about:

- **History Log –** Includes a complete history, most recent at the top, of all actions taken since the study was first entered into the CHeRP system.
- **Sticky Notes –** communication between IRB staff and Research staff requesting revisions to submissions
- **Initial Review –** the initial study review and approval, including links to approval (called Report of Action) letters.
- **Documents –** all study documents that have been approved by the IRB over the time period the study has had IRB approval.
- **Reportable Events –** all Reportable Events that have been created and/or submitted to the IRB, including review process and outcome.
- **Amendments -** all Amendments that have been created and/or submitted to the IRB, including review process and outcome.
- **Continuing Reviews -** all Continuing Reviews that have been created and/or submitted to the IRB, including review process and outcome.
- **Review Status –** lists all individuals who have been assigned to review the protocol, and provides statistics on review times.
- **Protocol Versions –** lists each final version of the protocol (smart form) and consent documents that has been approved.

For example, to view an amendment submission, click on **Amendments,** then click on the amendment name to see details about the submission components, IRB review, and outcome (**Figures 4 and 5**), including whatever consents were approved (click on **Consents** tab).

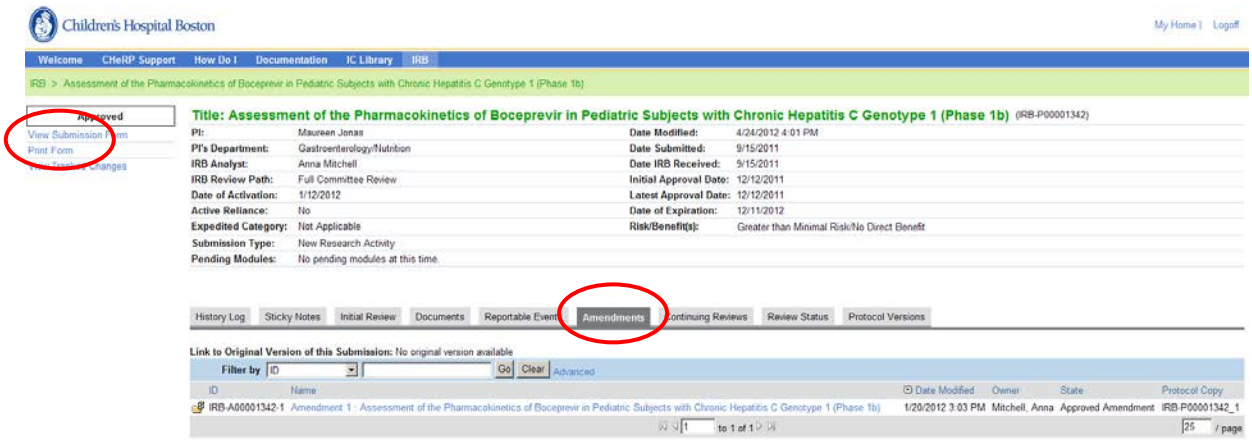

Figure 4

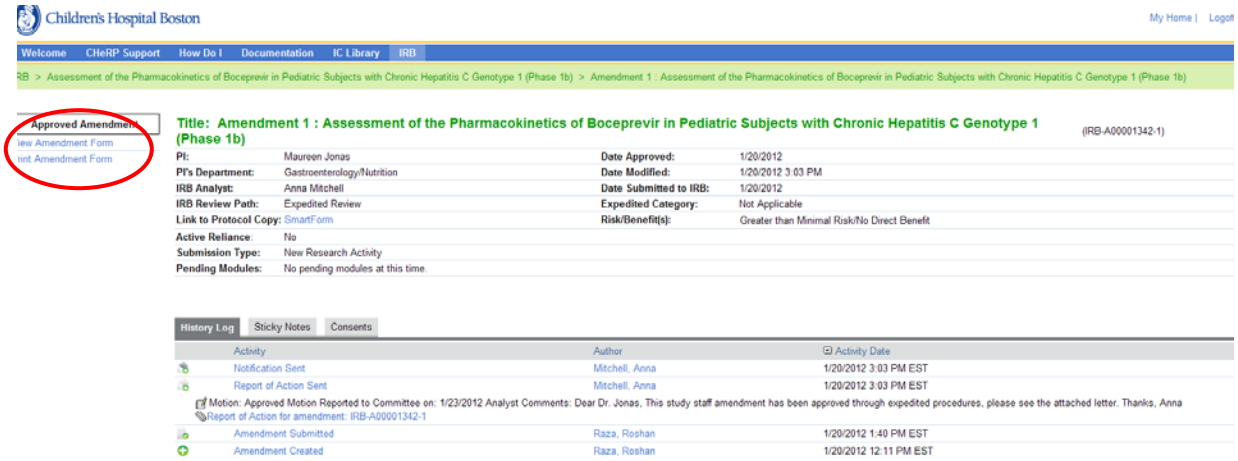

Figure 5

To view or print a copy of the actual submission form for the amendment, click on **View Amendment Form** or **Print Amendment Form (Figure 5)** in the upper left side of the screen and the entire submission form will be displayed either in sections **(Figure 6),** or in entirety**.**

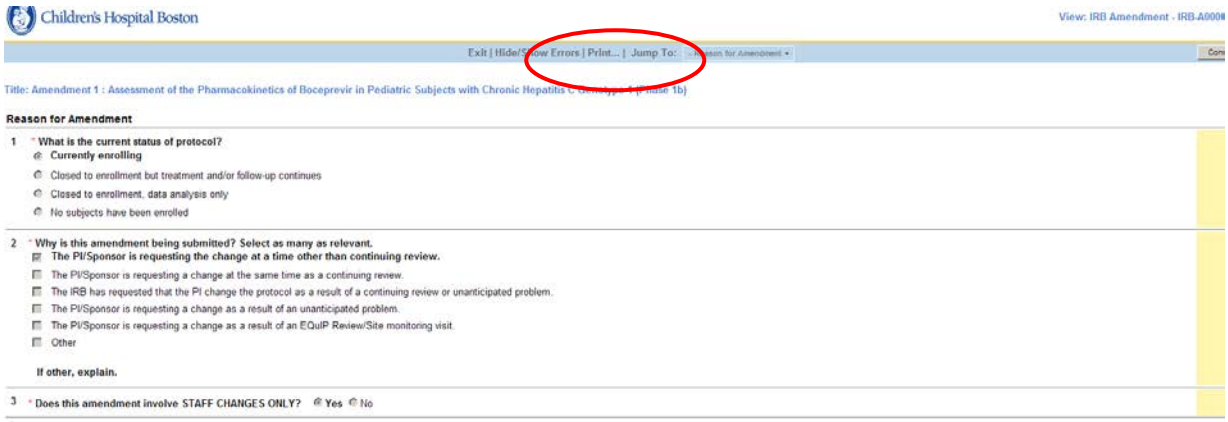

Figure 6

To see a historical list of all approved versions of the Protocol and Protocol Consents for a study, click on **Protocol Versions (Figure 7).** Then click on the individual **Links to the Protocol Versions**, or Click on **History** next to each type of consent to see a list of each version of that type of consent approved over the time the study has been active in the CHeRP system **(Figure 8).**

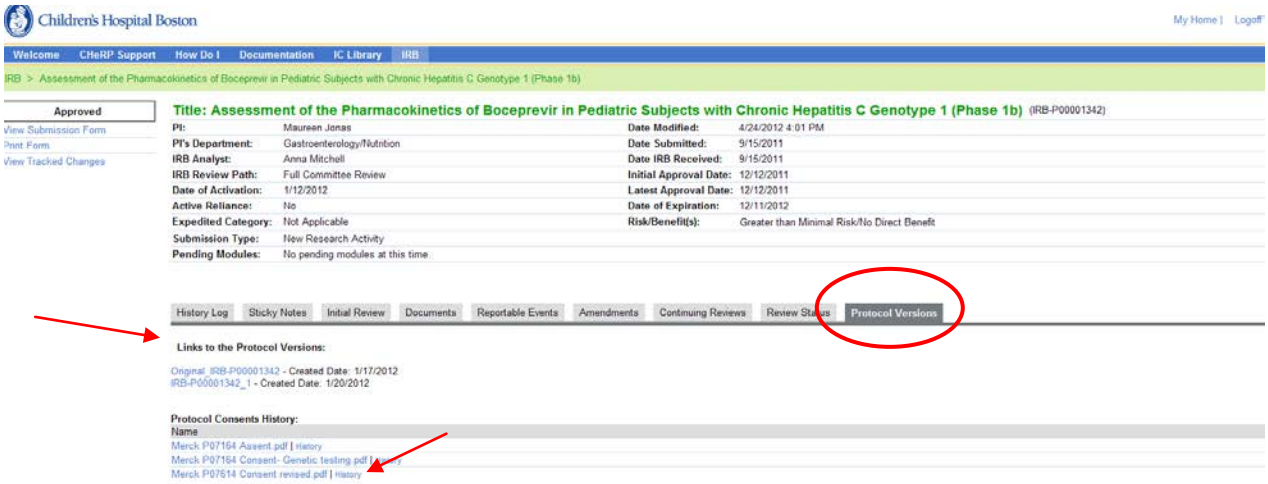

Figure 7

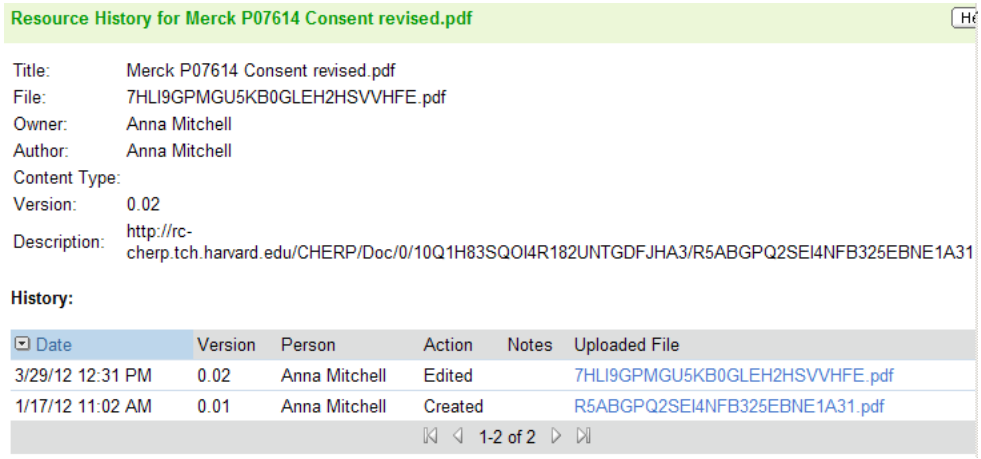

Figure 8