

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 Omyra.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

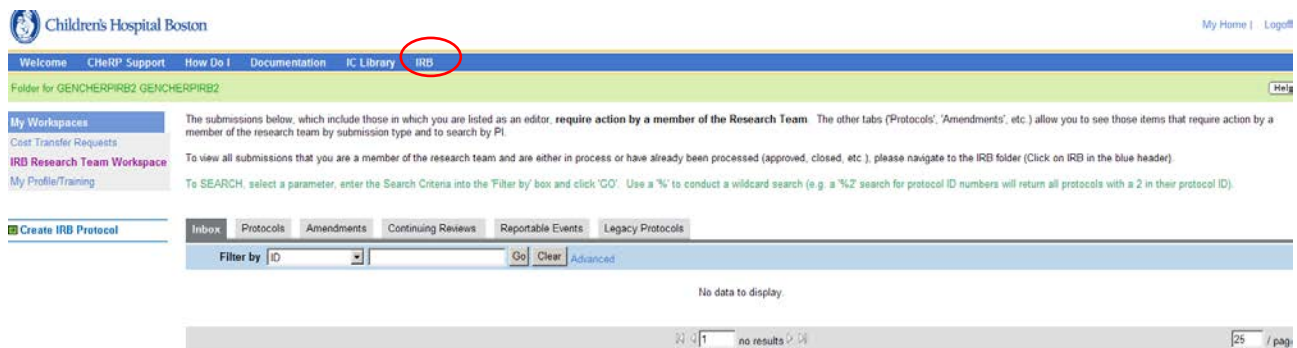
Appendix B

How do I...

View a Submission?

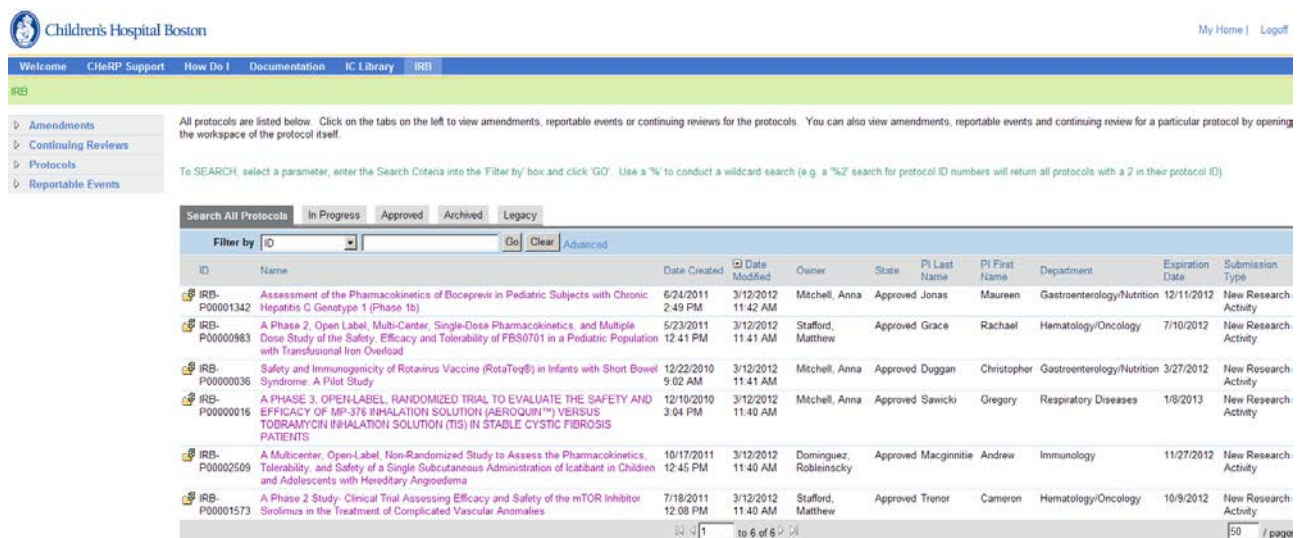
When viewing a submission workspace, you will have the '**View Submission Form**' activity available. This activity allows you to view all the smartforms and attached documents for the submission. The submission will be in a read only format. This activity is available for all submission types: Protocol,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



The screenshot shows the CHeRP portal interface. At the top, there is a navigation bar with links: Welcome, CHeRP Support, How Do I, Documentation, IC Library, and IRB. The 'IRB' link is circled in red. Below the navigation bar, there is a section for 'My Workspaces' with links for 'Cost Transfer Requests', 'IRB Research Team Workspace', and 'My Profile/Training'. A search bar is visible with a 'Filter by' dropdown set to 'ID' and a 'Go' button. The main content area displays 'No data to display.' and a pagination bar showing '1 / no results' and '25 / pag'.

Figure 1



The screenshot shows the CHeRP portal interface with the 'IRB' link selected in the navigation bar. The main content area displays a list of protocols. The list has columns for ID, Name, Date Created, Date Modified, Owner, State, PI Last Name, PI First Name, Department, Expiration Date, and Submission Type. The protocols listed are:

ID	Name	Date Created	Date Modified	Owner	State	PI Last Name	PI First Name	Department	Expiration Date	Submission Type
IRB-P00001342	Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)	6/24/2011 2:49 PM	3/12/2012 11:42 AM	Mitchell, Anna	Approved	Jonas	Maureen	Gastroenterology/Nutrition	12/11/2012	New Research Activity
IRB-P00000983	A Phase 2, Open Label, Multi-Center, Single-Dose Pharmacokinetics, and Multiple Dose Study of the Safety, Efficacy and Tolerability of FBS0701 in a Pediatric Population with Transferrin Iron Overload	5/23/2011 12:41 PM	3/12/2012 11:41 AM	Stafford, Matthew	Approved	Grace	Rachael	Hematology/Oncology	7/10/2012	New Research Activity
IRB-P00000036	Safety and Immunogenicity of Rotavirus Vaccine (RotaTeq®) in Infants with Short Bowel Syndrome: A Pilot Study	12/22/2010 9:02 AM	3/12/2012 11:41 AM	Mitchell, Anna	Approved	Duggan	Christopher	Gastroenterology/Nutrition	3/27/2012	New Research Activity
IRB-P00000016	A PHASE 3, OPEN-LABEL, RANDOMIZED TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF MP-376 INHALATION SOLUTION (ABROQUIN™) VERSUS TOBRAMYCIN INHALATION SOLUTION (TIS) IN STABLE CYSTIC FIBROSIS PATIENTS	12/10/2010 3:04 PM	3/12/2012 11:40 AM	Mitchell, Anna	Approved	Sawicki	Gregory	Respiratory Diseases	1/8/2013	New Research Activity
IRB-P00002509	A Multicenter, Open-Label, Non-Randomized Study to Assess the Pharmacokinetics, Tolerability, and Safety of a Single Subcutaneous Administration of Icatibant in Children and Adolescents with Hereditary Angioedema	10/17/2011 12:45 PM	3/12/2012 11:40 AM	Dominguez, Roblesiescky	Approved	Macginnitie	Andrew	Immunology	11/27/2012	New Research Activity
IRB-P00001573	A Phase 2 Study: Clinical Trial Assessing Efficacy and Safety of the mTOR Inhibitor Sirolimus in the Treatment of Complicated Vascular Anomalies	7/18/2011 12:08 PM	3/12/2012 11:40 AM	Stafford, Matthew	Approved	Trenor	Cameron	Hematology/Oncology	10/9/2012	New Research Activity

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**).

Children's Hospital Boston My Home | Logout

Welcome CHERP Support How Do I Documentation IC Library IRB

IRB > Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)

Approved

[View Submission Form](#)
[Print Form](#)
[View Tracked Changes](#)

Title: Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) (IRB-P00001342)

PI:	Maureen Jonas	Date Modified:	4/24/2012 4:01 PM
PI's Department:	Gastroenterology/Nutrition	Date Submitted:	9/15/2011
IRB Analyst:	Anna Mitchell	Date IRB Received:	9/15/2011
IRB Review Path:	Full Committee Review	Initial Approval Date:	12/12/2011
Date of Activation:	1/12/2012	Latest Approval Date:	12/12/2011
Active Reliance:	No	Date of Expiration:	12/11/2012
Expedited Category:	Not Applicable	Risk/Benefit(s):	Greater than Minimal Risk/No Direct Benefit
Submission Type:	New Research Activity		
Pending Modules:	No pending modules at this time.		

History Log | Sticky Notes | Initial Review | Documents | Reportable Events | Amendments | Continuing Reviews | Review Status | Protocol Versions

Activity	Author	Activity Date
Consent Forms Finalized The following consent forms were finalized Merck P07164 Consent- Genetic testing.pdf	Mitchell, Anna	3/29/2012 12:36 PM EDT
Consent Forms Administratively Edited	Mitchell, Anna	3/29/2012 12:36 PM EDT
Notification Sent to Research Team Dear Dr. Jonas, During an internal review of protocols that require two parent signatures we found that the 2nd parent signature line was not included in your consent form even though this requirement was included in the approval letter released. We apologize for this omission and we are working to correct the problem. We have modified the con...	Mitchell, Anna	3/29/2012 12:31 PM EDT
Consent Forms Finalized The following consent forms were finalized Merck P07164 Consent revised.pdf	Mitchell, Anna	3/29/2012 12:31 PM EDT
Consent Forms Administratively Edited	Mitchell, Anna	3/29/2012 12:30 PM EDT
Amendment Approved	Mitchell, Anna	1/20/2012 3:03 PM EST

Amendment 1: Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) and closed by Anna Mitchell

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).

Children's Hospital Boston | My Home | Logout

Welcome | CHeRP Support | How Do I | Documentation | IC Library | IRB

IRB > Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)

Approved

[View Submission Form](#)
[Print Form](#)
[View Staff Changes](#)

Title: Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) (IRB-P00001342)

PI: Maureen Jonas | Date Modified: 4/24/2012 4:01 PM
 PI's Department: Gastroenterology/Nutrition | Date Submitted: 9/15/2011
 IRB Analyst: Anna Mitchell | Date IRB Received: 9/15/2011
 IRB Review Path: Full Committee Review | Initial Approval Date: 12/12/2011
 Date of Activation: 1/12/2012 | Latest Approval Date: 12/12/2011
 Active Reliance: No | Date of Expiration: 12/11/2012
 Expedited Category: Not Applicable | Risk/Benefit(s): Greater than Minimal Risk/No Direct Benefit
 Submission Type: New Research Activity
 Pending Modules: No pending modules at this time.

History Log | Sticky Notes | Initial Review | Documents | Reportable Events | **Amendments** | Continuing Reviews | Review Status | Protocol Versions

Link to Original Version of this Submission: No original version available

Filter by ID | Go | Clear | Advanced

ID	Name	Date Modified	Owner	State	Protocol Copy
IRB-A00001342-1	Amendment 1 - Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)	1/20/2012 3:03 PM	Mitchell, Anna	Approved Amendment	IRB-P00001342_1

25 / page

Figure 4

Children's Hospital Boston | My Home | Logout

Welcome | CHeRP Support | How Do I | Documentation | IC Library | IRB

IRB > Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) > Amendment 1 : Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)

Approved Amendment

[New Amendment Form](#)
[Print Amendment Form](#)

Title: Amendment 1 : Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) (IRB-A00001342-1)

PI: Maureen Jonas | Date Approved: 1/20/2012
 PI's Department: Gastroenterology/Nutrition | Date Modified: 1/20/2012 3:03 PM
 IRB Analyst: Anna Mitchell | Date Submitted to IRB: 1/20/2012
 IRB Review Path: Expedited Review | Expedited Category: Not Applicable
 Link to Protocol Copy: SmartForm | Risk/Benefit(s): Greater than Minimal Risk/No Direct Benefit
 Active Reliance: No
 Submission Type: New Research Activity
 Pending Modules: No pending modules at this time.

History Log | Sticky Notes | Consents

Activity	Author	Activity Date
Notification Sent	Mitchell, Anna	1/20/2012 3:03 PM EST
Report of Action Sent	Mitchell, Anna	1/20/2012 3:03 PM EST
Motion: Approved Motion Reported to Committee on: 1/23/2012 Analyst Comments: Dear Dr. Jonas, This study staff amendment has been approved through expedited procedures, please see the attached letter. Thanks, Anna		
Report of Action for amendment: IRB-A00001342-1		
Amendment Submitted	Raza, Roshan	1/20/2012 1:40 PM EST
Amendment Created	Raza, Roshan	1/20/2012 12:11 PM EST

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.

Children's Hospital Boston | View: IRB Amendment - IRB-A0000

Exit | Hide/Show Errors | Print... | Jump To: | Search for Amendment

Title: Amendment 1 : Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)

Reason for Amendment

1 * What is the current status of protocol?
 Currently enrolling
 Closed to enrollment but treatment and/or follow-up continues
 Closed to enrollment, data analysis only
 No subjects have been enrolled

2 * Why is this amendment being submitted? Select as many as relevant.
 The PI/Sponsor is requesting the change at a time other than continuing review.
 The PI/Sponsor is requesting a change at the same time as a continuing review.
 The IRB has requested that the PI change the protocol as a result of a continuing review or unanticipated problem.
 The PI/Sponsor is requesting a change as a result of an unanticipated problem.
 The PI/Sponsor is requesting a change as a result of an EQulP Review/Site monitoring visit.
 Other

If other, explain.

3 * Does this amendment involve STAFF CHANGES ONLY? Yes No

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**).

Children's Hospital Boston My Home | Logoff

Welcome CHERP Support How Do I Documentation IC Library IRB

IRB > Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b)

Approved

Title: Assessment of the Pharmacokinetics of Boceprevir in Pediatric Subjects with Chronic Hepatitis C Genotype 1 (Phase 1b) (IRB-P00001342)

PI: Maureen Jones Date Modified: 4/24/2012 4:01 PM
 PI's Department: Gastroenterology/Nutrition Date Submitted: 9/15/2011
 IRB Analyst: Anna Mitchell Date IRB Received: 9/15/2011
 IRB Review Path: Full Committee Review Initial Approval Date: 12/12/2011
 Date of Activation: 1/12/2012 Latest Approval Date: 12/12/2011
 Active Reliance: No Date of Expiration: 12/11/2012
 Expedited Category: Not Applicable Risk/Benefit(s): Greater than Minimal Risk/No Direct Benefit
 Submission Type: New Research Activity
 Pending Modules: No pending modules at this time

History Log Sticky Notes Initial Review Documents Reportable Events Amendments Continuing Reviews Review Status **Protocol Versions**

Links to the Protocol Versions:
 Original IRB-P00001342 - Created Date: 1/17/2012
 IRB-P00001342_1 - Created Date: 1/20/2012

Protocol Consents History:
 Name:
 Merck P07164 Assent.pdf | history
 Merck P07164 Consent- Genetic testing.pdf | history
 Merck P07614 Consent revised.pdf | history

Figure 7

Resource History for Merck P07614 Consent revised.pdf

Title: Merck P07614 Consent revised.pdf
 File: 7HLI9GPMGU5KB0GLEH2HSVVHFE.pdf
 Owner: Anna Mitchell
 Author: Anna Mitchell
 Content Type:
 Version: 0.02
 Description: http://rc-cherp.tch.harvard.edu/CHERP/Doc/0/10Q1H83SQ0I4R182UNTGDFJHA3/R5ABGPQ2SEI4NFB325EBNE1A31

History:

Date	Version	Person	Action	Notes	Uploaded File
3/29/12 12:31 PM	0.02	Anna Mitchell	Edited		7HLI9GPMGU5KB0GLEH2HSVVHFE.pdf
1/17/12 11:02 AM	0.01	Anna Mitchell	Created		R5ABGPQ2SEI4NFB325EBNE1A31.pdf

1-2 of 2

Figure 8