Boston Children's Hospital

Date: Wednesday, April 29, 2020 2:38:03 PM Print Close

Title: Admin Update 1 : Another Sample New Research Activity

Administrative Update - Introduction

This protocol is due for an administrative update. Prompt completion of the report will reduce the possibility of the protocol expiring and the need to stop all research activities. There is no longer a separate completion form . You may use this form to request completion of your research at any time .

Please check the checkbox below and click 'Continue' to begin the administrative update report.

* ☑ **Start Administrative Update**

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Administrative Update Form

Protocol Status. Select the appropriate category to indicate the current status of the protocol.

1 * **Request for completion of research**

○ Yes ● **No**

1.1 Please select the reason for completion.

- ○ All research completed (includes all research activities and data analysis)
- ○ Data Analysis only of aggregate data (no identifiers or links to identifers are required)
- ○ Slow accrual
- ○ Investigator is no longer at Children's Hospital
- ○ Loss of interest
- ○ Never funded
- ○ Research never began
- ○ Other

2 * **Administrative Review. ONLY USE THIS CATEGORY FOR NON FDA REGULATED RESEARCH. If your research is FDA regulated you either need to select completion or activities continue.**

○ Yes ● **No**

Select one or both of these categories if applicable.

2.1 ☐ **Research involves data analysis only but access to private identifiable information and links to identifiers is still required.**

2.2 ☐ **The only remaining activity is accessing follow-up clinical data from procedures that already enrolled subjects would undergo as part of clinical care AND this long term follow is included in the approved protocol**
(DO NOT check this category if long term follow up is not included as part of the protocol- you will need to amend your protocol.)

3 * **Research Activities Continue**

● **Yes** ○ No

3.1 Select the appropriate category to indicate the current status of the protocol.

- ○ Currently enrolling subjects
- ● **Closed to enrollment - Subjects continue to undergo research interventions/interactions, and/or assessments included in the approved protocol**
- ○ Research on hold until decision made whether to continue
- ○ No subjects enrolled to date
- ○ Other

If Research on hold until decision made whether to continue

3.1.1 Please provide information about the hold.

If Other:

3.1.2 Please explain.

Deviations and Exceptions

4 * **Select all categories that apply (more than one may be checked).**

- [x] **No prior protocol deviations or exceptions have occurred since the original approval.**
- [ ] Prior deviation/exceptions occurred on this protocol, and already acknowledged or approved by the IRB.
- [ ] Unreported minor deviations or exceptions that have occurred since the last review, and significant deviations not yet reported, are attached for review.

4.1 Please upload the minor deviations/exceptions for review.

Name	Date Last Modified	Version	Owner
There are no items to display			

Note: If a significant deviation needs to be reported, please open a reportable event.

Protocol Reliance

5

If there are reliance agreements with other institutions as part of this protocol, the following is a list of those agreements that have been approved.
No approved reliances at this time.

5.1 Have there been any concerns or issues that have occurred regarding the reliance agreement or human subject activities at other sites?

○ Yes ○ No

If YES:

5.1.1 Please describe.

5.2 Are all reliance agreements listed above still active (i.e. are these sites still engaged in the research)?

○ Yes ○ No

If NO:

5.2.1 Please describe.

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Subject Enrollment

When your protocol was approved you indicated you would enroll the following number of subjects:

Target to enroll at Boston Children's Hospital, or at sites relying on BCH IRB review, to complete data analysis: 50

If applicable, number of subjects to account for screening failures and drop-outs at BCH or at relying sites needed for data analysis: 60

1 * **Please check one of the following categories:**

- ○ Enrollment remains in accordance with the approved protocol
- ● **I will be submitting an amendment to revise enrollment as necessary**

Please note over-enrollment may constitute an unanticipated problem that requires reporting . If you have any questions please call your IRB analyst to discuss at ext# 5-7052)

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Consent/Assent And IC Library

1 **This is a list of the currently active consent and assent forms:**

Consent/Assent Name
Assent Form.pdf
Consent form.pdf
Parent Consent.pdf

2 * **Please select one of the following:**

- ○ All consent and assent forms will be used in the coming year and should remain in the Informed Consent Library. Please note that although the study may be closed to enrollment, you may still need access to the consent forms for re-consent at age 18 or future amendments
- ● **Only some consent or assent forms will be used in the coming year and need remain in the Informed Consent Library**

○ No consent or assent forms are needed for the coming year and all can be removed from IC Library

2.1 Please specify which consent forms should be REMOVED from the IC Library. Please use the document titles as listed above for clarity.
Specify which consent forms should be REMOVED from the IC Library.

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Sponsor/Funding Information

1 *The following sponsor information was listed on the approved protocol. Please review the current sponsor/funding information to make sure it is correct. If this information requires revision, please submit an amendment.*

Select one of the funding categories.
Externally sponsored (federal, state, corporate, foundations)

1.1 If internally sponsored - select as appropriate:
There are no items to display

1.2 If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

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Sponsor/Funding Information

1 *The following sponsor information was listed on the approved protocol. Please review the current sponsor/funding information to make sure it is correct. If this information requires revision, please submit an amendment.*

Currently approved sponsor/funding information.

	Sponsor	Funding Category
View	MERCK & CO, INC - 0929	Corporate/Industry

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Research Team

1 **<u>The PI is responsible for assuring all training requirements are up to date.</u>**

Please review the Research Team currently approved to work on this protocol. If anyone should be added or removed from the list of BCH research staff, please use the "Manage BCH Research Team" activity to make staff changes. Please only submit an amendment if you need to make changes to the non BCH research team.

PI:PI Test
Completed Training Courses:

	Training Program	Continuing Education Description	Training Completed	Date Created
View	Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/22/2018	
View	Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/12/2018	
View	Continuing Education	Continuing Education/Department Meeting	5/2/2018	
View	Continuing Education	Continuing Education/Department Meeting	6/13/2016	
View	Training Received at Another Institution		11/15/2015	
View	Continuing Education	Continuing Education/Department Meeting	10/26/2015	
View	Continuing Education	Research Protocol Case Discussions	11/15/2012	
View	Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/9/2012	5/9/2012
View	Continuing Education	Continuing Education/Department Meeting	9/30/2011	
View	CHeRP Training		12/19/2010	

	Training Program	Continuing Education Description	Training Completed	Date Created
View	Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/15/2009	11/8/2010
View	Collaborative IRB Training Initiative (CITI Behavioral)		8/2/2006	11/8/2010
View	Collaborative IRB Training Initiative (CITI Biomedical)		8/2/2006	11/8/2010
View	Collaborative IRB Training Initiative (CITI Non-Interventional)		4/11/2006	11/8/2010
View	Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	4/5/2006	11/8/2010

Research Staff - Children's Hospital Employees only:

	Last Name	First Name	Role	Editor	CC on Correspondence	Required Training Completed	CHeRP Training	Date Modified	Date Created
View	Kuniholm	Ashley	Co-Investigator	yes	yes	yes	yes	4/29/2020	4/29/2020

Research Staff - Non Children's Hospital Employees only:

Last Name	First Name	Role	Email	Required Training Completed
There are no items to display				

Note: If you are adding new Research Team Members, please consider whether you need to revise the Financial Disclosure section of the protocol through the submission of an amendment.

2 Research Staff at Reliance Sites

Reliance PIs - Employees who are listed on existing Reliance on BCH protocols:

Last Name	First Name	Institution	Completed Training
There are no items to display			

Research Team Members - Employees who are listed on existing Reliance on BCH protocols:

Last Name	First Name	Employee ID	Role
There are no items to display			

3 Not Active BCH Team Members:

All BCH Team members are 'Active'

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Additional Documents

1 Please upload any additional documents if it is necessary.

Name	Date Last Modified	Version	Owner
There are no items to display			

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Principal Investigator Responsibilities

*** The PI accepts responsibility for assuming adherence to DHHS, FDA, and Children's Hospital policies relative to the protection of the rights and welfare of patients/subjects participating in this study. Any revisions/amendments will be submitted prior to implementation unless to ensure the safety of a research subject. The information obtained as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time, it is desired to reuse this information for other purposes or disclose the information to other individuals or entity, approval will be obtained from the Institutional Review Board.**

● **Yes** ○ No

Note: As a result of reviewing and submitting this admin check in form, you may realize there are revisions /amendments you wish to make at this time. Any revisions or amendments must be submitted separately as an amendment. To create an amendment, you must go back to the protocol workspace after completing the admin check in form.