Boston Children's Hospital

Date: Wednesday, April 29, 2020 2:29:08 PM Print Close

Title: Continuing Review 1 : Sample New Research Activity

Continuing Review/Completion - Introduction

Please use this form to submit continuing review/completion for your research protocol. Based on the responses the IRB will determine if continuing review is required or whether the protocol may be terminated or be transitioned to an "administrative check in process". Changes in the regulations permit some protocols to be transitioned to the new Common rule regulations. Differences between FDA and HHS regulations make this transition complex so the IRB carefully evaluates each protocol to this determination. ***There is no longer a separate completion form.*** *You may use this form to request completion of your research at any time. You will be informed if the protocol has been terminated, transitioned to an annual administrative check in or whether continuing review has been granted .*

Please check the checkbox below and click 'Continue' to begin the continuing review/completion report.

* ☑ **Start Continuing Review/Completion Form**

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Continuing Review Form

Note: To avoid any lapses in approval, please complete this form. If approval lapses, no research related activities may occur after the expiration date unless the investigator contacts the IRB office and the Chair determines that it is in the best interests of an individual subject to continue during the lapse of IRB approval.

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)
- ○ Completion due to toxicity/adverse event
- ○ Slow accrual
- ○ Investigator is no longer at Children's Hospital
- ○ Loss of interest
- ○ Never funded
- ○ Research never began
- ○ Other

2 * **Data Analysis or Collection of Clinical Data Only. Select one or both of these categories if applicable.**

○ Yes ● **No**

2.1 ☐ **Remaining activity limited to data analysis only but access to private identifiable information and links to identifiers is still required.**

2.1.1 Has it been 60 days after any last study visit?
(If the protocol does not involve study visits please answer NA)

- ○ Yes
- ○ No
- ○ NA

2.1.2 Do you anticipate any need to reactivate, revise or use any consent forms in the future?
(If the study does not involve any consent forms please answer NA)

- ○ Yes
- ○ No
- ○ NA

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).**

- ☐ 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
Minor Deviations Log.docx	4/29/2020 2:21 PM	0.01	PI Test

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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Overall Enrollment and IC Library

1 * **Did the enrollment of BCH subjects (including enrollment at study sites relying on BCH IRB review) proceed as expected this year? (Please note the Committee will look at the number indicated in the approved protocol and if recruitment is low, they will expect that you will indicate no and respond to the questions)**

● **Yes** ○ No

If NO:

1.1 Please specify the reason(s) why enrollment did not occur as anticipated (i.e. staffing concerns, low number of eligible patients).

1.2 Do you anticipate being able to enroll a sufficient number of subjects in a timely manner in order to reach study goals? Why or why not?

1.3 What efforts will be undertaken in order to increase enrollment in the coming year? Please note that any changes to the study will need to be submitted as an amendment and

approved by the IRB prior to implementation.

2 * **Is a written consent form used as the method of consent for this study?**

● **Yes** ○ No

If YES:

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

Consent/Assent Name
Consent Form.pdf

2.2 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

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

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Summary of Subject Enrollment

Note: If your protocol involves any approved method of obtaining informed consent (e.g. written consent, verbal consent, consent by voluntary completion of a survey), complete the following enrollment summary to provide the total number of enrolled subjects (individuals who provided consent, including those who did not complete study participation for any reason such as ineligibility, loss-to-follow-up, withdrawal).

1 Please provide the following information.

If Multi-Site Study, also complete the appropriate column.

	At BCH or sites relying on BCH IRB	**All other sites participating in this study**
1. Target Enrollment: Number needed to account for attrition (screening failures, lost to follow-up, etc).	**i. 125**	**ii. 600**
2. Target enrollment: Number needed for data analysis	**i. 100**	**ii. 500**
	# OF SUBJECTS WHO PROVIDED CONSENT	
3. Total number enrolled since last IRB review.	**i.** 40	**ii. 400**
4. Total number enrolled to date. *Please break down this total for CHB subjects as follows: items **a - h** below should equal total enrollment to date.*	**i.** 40	**ii. 400**
a. Subjects deemed ineligible (after screening)	2	
b. Subjects currently active on study	30	
c. Subjects who completed study without events leading to early termination	2	
d. Subjects withdrawn at their own/family request (*e.g. subject signed consent and then changed mind or stopped at their request)*	2	
e. Subjects withdrawn by PI due to toxicity or adverse events	2	
f. Subjects withdrawn by PI due to other reasons (*e.g. lack of compliance, pregnancy)*	2	
g. Subjects lost to follow-up	0	
h. Subjects no longer participating for other reasons	**Specify reasons:**	

2 If no subjects provided consent through BCH (including any reliance sites) since last continuing review (Enrollment Table, #3i), please specify why.

3 If the total number of subjects enrolled for the study (Enrollment Table, #4i) has exceeded the Target Enrollment as initially approved by the IRB (Enrollment Table, #1i), please specify why.
Note: To continue enrollment, you must submit an amendment to increase the Target

Enrollment.

4 **If subjects were withdrawn due to toxicity or adverse events (Enrollment Table, #4e), please explain.**
Explain why subjects were withdrawn due to toxicity or adverse events.

5 **If subjects were withdrawn by PI due to other reasons (Enrollment Table, #4f), please explain.**
Explain why subjects were withdrawn by PI due to other reasons.

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Summary of Subject Enrollment - Continue

1 * **Is the overall enrollment from <u>all participating sites</u> proceeding as expected in order to reach the study goals?**
● **Yes** ○ No

If NO:
1.1 Specify the reason(s) why and what steps will be taken to increase enrollment.

2 **If the total number of subjects enrolled from all participating sites (Enrollment Table, #3ii) has exceeded the Target Enrollment (Enrollment Table, #1ii) as initially approved by the IRB, please specify why.**

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Serious Adverse/Unexpected Events and Unanticipated Problems Causing Risk to Subjects or Others

Note: Adverse event is defined here as any untoward or undesired outcome of the research, including both serious and non-serious events, expected and unexpected events and events not related to the research.

1 * **Has the frequency or severity of the adverse event profile differed from that expected?**
○ Yes ● **No**

If YES:
1.1 Please describe.

2 * **Has the adverse event profile experience changed the risk/benefit assessment?**
● **Yes** ○ No

If YES:
2.1 Please describe.
Describe how the adverse event profile experience changed the risk/benefit assessment.

3 * **Have there been any other unanticipated problems involving risk, for example medication or laboratory errors, unintended disclosure of confidential information.**
● **Yes** ○ No

If YES:
3.1 Please describe.
Describe any other unanticipated problems involving risk, for example medication or laboratory errors, unintended disclosure of confidential information.

4 * **Are informed consent changes required as a result of the adverse event profile, unexpected events or unanticipated problems involving risk?**
● **Yes** ○ No

Note: If YES, please submit an amendment.

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Data and Safety Monitoring

Please click here to view the Approved Data and Safety Monitoring Information.

1 * **Is there a Data and Safety Monitoring Plan for this study?**

● **Yes** ○ No

If YES:

1.1 Has the Data and Safety Monitoring Plan been followed?

● **Yes** ○ No

If NO:

1.1.1 Explain why.

1.2 Does the Data and Safety Monitoring Plan indicate that meetings will occur and a report will be generated for the IRB to review?

● **Yes** ○ No

If YES:

1.2.1 Has a DSM meeting occurred since the last continuing review?

● **Yes** ○ No

If YES:

1.2.1.1 Please upload reports or communications that have not yet been submitted to the IRB.

Name	Date Last Modified	Version	Owner
DSMB Report January 2020.doc	4/29/2020 2:26 PM	0.01	PI Test
DSMB Report September 2019.doc	4/29/2020 2:26 PM	0.01	PI Test

If NO:

1.2.1.2 Please explain why a meeting has not yet taken place or why a report is not available. Additionally, please explain when the next meeting will occur or when a DSMB report will be available.

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Drug and Device Studies

1 * **Since the time of the last continuing review, has the study been inspected by the FDA?**

● **Yes** ○ No

If YES:

1.1 Upload a copy of any FDA report you received and response you provided.

Name	Date Last Modified	Version	Owner
FDA Report.docx	4/29/2020 2:27 PM	0.01	PI Test

Drug/Device accountability: the PI is responsible for assuring there are adequate records for the disposition for all study drugs and devices, including the dates and quantity received, batch or code mark of each shipment, the dates/quantity used by each subject and for the final return or disposal (according to sponsor instructions) of unused drugs and devices. For investigational drugs, the research pharmacy provides this service. For investigational devices, the PI must assume this responsibility.

2 * **Have there been any problems or concerns related to drug and/or device accountability?**

○ Yes ● **No**

If YES:

2.1 Explain why and specify what drugs and/or devices cannot be accounted for.

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Drug and Device Studies - Continue

For Sponsor-Investigators (IND or IDE-holders): Investigators who also serve as sponsors and hold the IND/IDE have the responsibility to provide adequate monitoring of all clinical investigations conducted under the IND or IDE by a qualified monitor. In addition, investigators holding an IND or an IDE for a significant risk device are responsible for submitting annual progress reports to the FDA within 60 days the anniversary date when the IND or IDE went into effect.

1 * **Does this study involve the use of an investigational drug?**

● **Yes** ○ No

If YES:

1.1 Since the last review, has the study progress been monitored by a qualified monitor?

● **Yes** ○ No

If YES:

1.1.1 Attach copies of monitoring reports/letters since the last review.

Name	Date Last Modified	Version	Owner
CRO Monitoring Visit Report.docx	4/29/2020 2:27 PM	0.01	PI Test

If NO:

1.1.2 Explain why this study has not been monitored.

1.2 Has an annual report been submitted to the FDA within the last year?

○ Yes ● **No**

If YES:

1.2.1 Attach a copy of the FDA annual report submitted within the last year.

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

If NO:

1.2.2 Explain why and specify the date the last annual report was submitted to the FDA.

Why FDA report FDA annual report has not been submitted within the last year and the date the last annual report was submitted to the FDA.

2 * Does this study involve the use of a significant risk device?

● **Yes** ○ No

If YES:

2.1. Since the last review, has the study progress been monitored by a qualified monitor?

● **Yes** ○ No

If YES:

2.1.1 Attach copies of monitoring reports/letters since the last review.

Name	Date Last Modified	Version	Owner
CRO Monitoring Visit Report.docx	4/29/2020 2:28 PM	0.01	PI Test

If NO:

2.1.2 Explain why this study has not been monitored.

2.2. Has an annual report been submitted to the FDA within the last year?

● **Yes** ○ No

If YES:

2.2.1 Attach a copy of the FDA annual report submitted within the last year.

Name	Date Last Modified	Version	Owner
FDA Report.docx	4/29/2020 2:28 PM	0.01	PI Test

If NO:

2.2.2 Explain why and specify the date the last annual report was submitted to the FDA.

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Progress Information - IND/IDE

1 * Have there been any subject or staff concerns or complaints?

○ Yes ● **No**

If YES:

1.1 Describe the event(s) and explain how it was resolved.

2 * Are there any preliminary findings?

○ Yes ● **No**

If YES:

2.1 Please explain.

3 * **Is there any new literature that is applicable to this research and impacts the risk/benefit assessment?**

○ Yes ● **No**

If YES:

3.1 Please explain.

4 * **Have the participants experienced any benefit?**

○ Yes

● **Data Not Available**

○ No

If YES:

4.1 Please describe.

5 * **Has there been any change in the risk/benefit assessment?**

○ Yes ● **No**

If YES:

5.1 Please explain.

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Informed Consent, Recruitment Materials and Study Protocol

1 **Currently Approved Consent Forms/Documents**

Method of consent:

Written informed consent/assent/authorization will be obtained from subjects.

Informed consent/assent/authorization will be obtained through a method other than a written document (i.e. verbal, survey completion).

*Waiver of informed consent and authorization are requested. No consent/authorization will be obtained.

*Waiver of parental permission is requested.

Currently approved consent forms/documents:

Name			
Consent Form.doc	4/29/2020 1:18 PM	0.02	Ashley Kuniholm

Note: Please review the currently approved consent materials listed above. If these documents are not up to date or no longer in use, you must submit an amendment to either revise or remove the documents. Your renewal application cannot not be approved until all consent forms are current and any consent that are no longer used have been removed. If there is a possibility that subjects may turn 18 and will need to be re-consented please make sure you keep the consents approved and included with the protocol.

2 **Recruitment Materials**

Please review the currently approved recruitment materials. If these documents are not up to date, please submit an amendment to revise the documents.

Currently approved recruitment materials.

Name	Date Last Modified	Version	Owner
Recruitment Letter.docx	11/22/2019 2:37 PM	0.01	Ashley Kuniholm

3 **Currently Approved Study Protocol**

Please review the currently approved protocol. If these documents are not up to date, please submit an amendment to revise the documents.

Study Protocol.

Name	Date Last Modified	Version	Owner
Protocol.docx	11/22/2019 3:25 PM	0.01	Ashley Kuniholm

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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	NATIONAL HEART, LUNG, AND BLOOD INSTITUT - 1049	Federal

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Research Team

1 **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 update recruitment or consent documents, or 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	
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	Admin Contact	yes	yes	yes	yes	11/22/2019	11/22/2019

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 review 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 continuing review form.