Boston Children's Hospital

Date: Wednesday, April 29, 2020 2:44:25 PM Print Close

Title: Continuing Review 3 : Another 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
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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Completion Form

1 * **Were there any serious adverse or unexpected effects or unanticipated problems that involve risks to subjects or others since the last continuing review?**

○ Yes ● **No**

If YES:

1.1 Please describe.

1.2 If there were events likely related to the research protocol, please summarize the events and indicate if changes were made to the protocol as a result.

1.3 Did the serious adverse/unexpected events or unanticipated problems change the risk/benefit ratio?

○ Yes ○ No

If YES:

1.3.1 Please describe.

2 * **Were there any minor deviations that have not been reported since the last continuing review**

○ Yes ● **No**

If YES:

2.1 Please upload a deviation log:

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

3 *If your protocol involved any IRB-approved method of obtaining informed consent (e.g. written consent, verbal consent, consent by voluntary completion of a survey), please complete the following enrollment summary to provide an accurate breakdown of 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) at CHB.*

* **Select YES if your protocol only involved a waiver of informed consent (no methods used to obtain consent, e.g. medical record review, submission to a registry without informed consent). Then skip to question 4.**

○ Yes ● **No**

Was this a Multi-Site study?

○ Yes ● **No**

If YES:

3.1 Was Children's Hospital the coordinating center?

○ Yes ○ No

		If Multi-Site Study, also complete the appropriate column:	
	at CHB only	**for all sites**	if CHB was not coordinating center **for all sites (to be removed)**
1. Target Enrollment: number approved by IRB (N) for entire duration of study:	60		
	# SUBJECTS WHO PROVIDED CONSENT		
2. **Total number enrolled** Please break down this total for CHB subject as follows: (items a-g below should equal total number enrolled)	60	60	
a. subjects deemed ineligible (after screening)	3		
b. subjects who completed study *without events leading to early termination*	50		
c. subjects withdrawn at their own/family request *e.g. subject signed consent and then changed mind or stopped at their request*	2		
d. subjects withdrawn by PI due to toxicity or adverse events	0		
e. subjects withdrawn by PI due to other reasons *e.g. lack of compliance, pregnancy*	0		
f. subjects lost to follow-up	5		
g. subjects who ended participation for other reasons (please specify reasons)	0		

4 * **Please provide a brief summary of the results of the research.**

Brief summary of the results of the research.

If applicable, please attach copies of any associated publications

Name	Date Last Modified	Version	Owner
JAMA publication.docx	4/29/2020 2:44 PM	0.01	PI Test
Poster presentation abstract.docx	4/29/2020 2:44 PM	0.01	PI Test

5 Things to remember when closing a study:

1. **PLEASE NOTE THAT YOU WILL RECEIVE NOTIFICATION FROM CHeRP AFTER THE FORM IS PROCESSED. THIS IS THE FORMAL ACKNOWLEDGEMENT OF THE PROTOCOL COMPLETION. PLEASE SAVE THIS FOR YOUR RECORDS AND FOR SPONSORS.**
2. Case Report Forms (CRFs) and other data collection forms: all data collection forms must be completed, reviewed, corrected (as needed) and submitted as indicated in the protocol.
3. Investigational Drug/Device Accountability: if applicable, complete inventory for drug and devices – all drugs and devices must be accounted for. All investigational drugs and devices should be disposed or returned according to Sponsor's directives.

4. Principal Investigator (PI) Files: ensure that all pertinent documents are on file, completed and signed as required. The PI should have the signed consent form for all enrolled subjects.
5. PLEASE NOTE: Even if this protocol is being closed, the Principal Investigator is responsible for maintaining certain study documents for 6 or more years depending on the study. To determine what document retention responsibilities apply to this protocol, please see http://www.childrenshospital.org/~/media/research-and-innovation/office-of-clinical-investigation/cipp_031_009_records.ashx?la=en.
6. Also, ask the study sponsor for any specific requirements for storing study related materials.