Boston Children's Hospital

Date: Wednesday, April 29, 2020 1:55:57 PM Print Close

Title: Amendment 1 : Sample New Research Activity

Reason for Amendment

1 * **What is the current status of protocol?**

- (●) **Currently enrolling or collecting data**
- ( ) Closed to enrollment but treatment and/or follow-up continues
- ( ) Closed to enrollment and data collection, data analysis only
- ( ) No subjects have been enrolled

2 Please specify:

2.1 * **Who is primarily responsible for asking that this amendment be submitted?**
The Principal Investigator

If Other, please specify:

2.2 * **Why is this amendment being submitted? Select as many as relevant.**

- [ ] This Amendment is requesting a change related to or as a result of a continuing review.
- [x] **This Amendment is requesting a change related to or as a result of an unanticipated problem.**
- [ ] This Amendment is requesting a change related to or as a result of an EQuIP Review/Site monitoring visit.
- [x] **PI and/or Sponsor are requesting changes for scientific or logistical reasons.**
- [ ] Other

If Other, explain.

Note: If adding a research site via a reliance agreement, please complete the 'Add Reliance on BCH' activity rather than the 'Amendment' activity.

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

Note: If the staff amendment is ONLY to add/remove BCH personnel from The Research Team page (without other changes e.g. documents, consents), please use the "Manage BCH research team" activity in the main protocol workspace instead of this form

Title: Amendment 1 : Sample New Research Activity

Amendment - Summary

1 * **Briefly describe the proposed modifications to this protocol. Describe the amendment in sufficient detail for IRB staff and reviewers, and as it should appear in the IRB approval letter.**
Note that IRB staff will have license to edit the final letter to ensure that it is accurate per the IRB review and approval of the amendment.
Describe the amendment in sufficient detail for IRB staff and reviewers, and as it should appear in the IRB

approval letter.

1.1 * **Provide the rationale and justification for these proposed changes.**
Rationale and justification for these proposed changes.

1.2 **Please list any documents that need to be listed in the final approval letter exactly as they should be named in the final approval letter.**
Please hit the "Enter" button after each document title.
Note that these documents must be present in the SmartForm at the time of approval or they will not be listed.
Note that IRB Staff will check to ensure that the documents are as described before finalizing the approval letter.
Review this list carefully and compare it to pages on the SmartForm to avoid delays in approval
List any documents that need to be listed in the final approval letter exactly as they should be named in the final approval letter.

2 **Check all categories that apply to the proposed amendment. If any categories are notated with **, please discuss these changes with your scientific review committee to determine if your department will require scientific review of this amendment. These are categories of changes that the IRB commonly requests scientific review of in order to approve.**

- [x] ****New study aims that affect the study design or sub-study**
- [ ] **Changes in study design
- [ ] **Changes in randomization methods or scheme
- [ ] **Changes in study procedures or measurement tools
- [ ] **Changes in the intervention or treatment for trial visits
- [x] ****Addition of a new cohort or sample**
- [ ] Changes in sample size for enrollment
- [x] **Changes in eligibility/exclusion criteria**
- [x] **Changes in data collection or visit schedule**
- [ ] Changes in recruitment strategy
- [ ] Changes that affect risk/benefit ratio to subjects
- [ ] Submission of Interim Report
- [ ] Other

If Other Category:

3 * **Are any of the proposed modifications notated by ** checked off in this amendment form?**
● **Yes** ○ No

If YES:

3.1 **Have the modifications been submitted to a Scientific Review committee for review?**
● **Yes** ○ No

if YES:

3.1.1 **The proposed modifications have been reviewed and approved by the appropriate Scientific Review committee, and the corresponding documentation is attached. Upload relevant documents here.**
SRC approval of proposed changes.doc 4/29/2020 1:54 PM 0.01 PI Test

If NO:

3.1.2 The appropriate Chair/Chief/Individual responsible for Scientific Review did not deem Scientific Review necessary for the proposed modifications.

☐

4 * **Do the proposed modifications affect the risk/benefit assessment for subjects?**

● **Yes** ○ No

If YES:

4.1 Justify why these changes are appropriate.

Why these changes are appropriate.

5 * **Does this amendment add any test, assessments or other clinical patient care charges that would pose a revision to the study tracking sheet and/or industry sponsored budget?**

● **Yes** ○ No

NOTE: You may contact the Clinical Trials Office (CTO) at extension 4-2739 or 4-2722 for any questions.

Title: Amendment 1 : Sample New Research Activity

Amendment - Recruitment, Consent and Staff Changes

1 * **Does the proposed amendment require revisions to approved recruitment materials?**

● **Yes** ○ No

If YES:

1.1 Please explain the reason for the edits and be sure to upload the revised materials in the recruitment section of the protocol. Please use track changes when revising these documents.

Explain the reason for the edits.

2 * **Does the proposed amendment require the addition of new recruitment materials, which support the currently approved recruitment methods?**

● **Yes** ○ No

If YES:

2.1 Please explain the reason for the addition of the new materials and how they support the currently approved recruitment methods. Be sure to upload the proposed recruitment materials in the recruitment section of the protocol.

Explain the reason for the addition of the new materials.

3 * **Does the proposed amendment require changes to the consent/assent forms or the documents used to obtain consent via another method?**

● **Yes** ○ No

If YES:

3.1 Please explain the proposed revisions to the consent/assent forms or the documents used to obtain consent via another method. Please revise the consent/assent documents in the protocol as appropriate, using track changes.

Explain the proposed revisions to the consent/assent forms.

3.2 **Will the proposed modifications require re-consenting subjects who have already been enrolled? This is generally required when changes may relate to subjects' willingness to continue participation.**

● **Yes** ○ No

3.2.1 **Please explain why or why not.**

Explain why or why not.

3.2.2 **If it is necessary to re-consent, please describe how subjects will be re-consented (sign the revised consent, sign a consent addendum, documentation of verbal re-consent, etc...).**

Describe how subjects will be re-consented.

4 * **Is the Principal Investigator for this proposal being changed?**

○ Yes ● **No**

If YES:

4.1 **Please provide the name of the new Principal Investigator and be sure to update the Principal Investigator (PI) section of the protocol copy and consent forms, using track changes. Additionally, the Financial Disclosure section should be updated as necessary.**

5 * **Does this amendment involve the addition of study personnel?**

● **Yes** ○ No

If YES:

5.1 **Please list which members will be added to the protocol and be sure to update the Research Team section of the protocol copy. Additionally, the Financial Disclosure section should be updated as necessary.**

List which members will be added to the protocol.

6 * **Does this amendment involve the removal of study personnel?**

● **Yes** ○ No

If YES:

6.1 **Please list which members will be removed to the protocol and be sure to update the Research Team section of the protocol copy.**

List which members will be removed to the protocol.

Title: Amendment 1 : Sample New Research Activity