Boston Children's Hospital

Date: Friday, March 21, 2025 3:45:35 PM Print Close

IRB-A00050051-1 Reason for Amendment

Title: Amendment 1 : Test removal of device question

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.
- [ ] This Amendment is requesting a change related to or as a result of an unanticipated problem.
- [x] **This Amendment is requesting a change related to or as a result of an EQuIP Review/Site monitoring visit.**
- [ ] 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

4 * **Does this amendment include adding participants/records or any change in data management plans?**
( ) Yes (●) **No**

IRB-A00050051-1 Summary

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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.
Test

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

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. The names of the documents must be listed below with the same name they were given in in the Smartform pages. Please hit the "Enter" button after each document title.
Test

Note: These documents must be present in the SmartForm at the time of approval, or they will not be listed.
Note: IRB Staff will check to ensure that the documents are as described before finalizing the approval letter. This means that the IRB Staff will look back in the protocol to make sure the document names are the same. If they are not, we will need to send the amendment back to you so that you can update this section with the correct names of each document.
Review this list carefully and compare it to pages on the SmartForm to avoid delays in approval.

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
- [ ] **Addition of a new cohort or sample
- [ ] Changes in sample size for enrollment
- [ ] Changes in eligibility/exclusion criteria
- [ ] 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.

There are no items to display

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.

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Ancillary Reviews

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Ancillary Reviews

Check all the statements which apply to this amendment to ensure the protocol is routed and reviewed by the relevant ancillary reviewer.

1 * **Amendment involves a change to the Financial Disclosure smartform.**
○ Yes ● **No**

2 * **Amendment involve the use of BCH pharmacy (IDS or oncology) and requires a change involving a drug (Investigational Product (IP) or supportive medication) in any of the following: dosing, frequency, route, administration guidelines, dispensing workflow, extension of study drug treatment, Investigator Brochure, pharmacy manual, or changes that affects medication orders in any way.**
○ Yes ● **No**

3 * **Amendment adds a new collection of a tissue removed for clinical purposes that would routinely go to pathology or are obtained directly from the operating room**
○ Yes ● **No**

4 * **Amendment modifies or alters any study product under the jurisdiction of the Biosafety committee with regards to how it's prepared (e.g. pharmacy) or administered to the study participant**
○ Yes ● **No**

5 * **Amendment includes the use of non-secure emails or non-secure texts with participants**
○ Yes ● **No**

6 * **Amendment includes additional data sources, devices, drug technologies, or any change in data storage plans.**
○ Yes ● **No**

7 * **Amendment involves the addition of or change to the use of a drug, biologic, nutritional supplement, herbal or homeopathic medicine, medical food, medical gas, inhalation therapy, topical cream, chemical or other compound that will be administered as part of the research protocol. Please do not check 'Yes' to this category if the only change is an updated investigator brochure.**
○ Yes ● **No**

8 * **Amendment involves the addition of or a change to a device that will be used, administered, implanted, or applied to the subjects, as the object of the protocol or is relevant to the objectives of the protocol. This includes investigational devices classified as both significant risk and non-significant risk, and also exempt devices, as well as FDA approved/marketed devices**
○ Yes ● **No**

9 * **Amendment involves the addition of MRI scans (including non-BCH equipment such as Hyperfine MRO or any other portable MR imaging system) or significant changes in the types of MRI scans and/or ancillary equipment involved with the MRI scans.**

○ Yes ● **No**

10 * **Amendment involves the addition or modification of radiological procedures that result in additional research radiation exposure or include a new a new population (e.g. minors).**

○ Yes ● **No**

11 * **Amendment involves a NEW device that emits laser radiation.**

○ Yes ● **No**

12 * **Does the amendment add tests, assessments or other clinical patient care charges that would pose a revision to the billing grid and/or budget?**

○ Yes ● **No**

13 * **Does your study amendment require updates to an existing research order built in EPIC or a request for new orders built in EPIC?**

○ Yes ● **No**

Note: Research orders are required for the following: All ETU supported studies, Research imaging, Medications dispensed by IDS, all Research Labs including custom lab panels or studies intending to use research collects for sample collection. Study teams must request order builds for any of the above. Using clinical orders and placing a note in Epic that the order is for research is not acceptable.

IRB-A00050051-1 Recruitment, Consent and Staff Changes

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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.

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.

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.

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.

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...).

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.

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.

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Link to Protocol Copy

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