Children's Hospital Boston

Edit: IRB Amendment - IRB-A00002828-1

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Title: Amendment 1 : International Fetal Cardiac Intervention Registry

Reason for Amendment

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

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

Clear

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

- [ ] The PI/Sponsor is requesting the change at a time other than continuing review.
- [ ] The PI/Sponsor is requesting a change at the same time as a continuing review.
- [ ] The IRB has requested that the PI change the protocol as a result of a continuing review or unanticipated problem.
- [x] The PI/Sponsor is requesting a change as a result of an unanticipated problem.
- [ ] The PI/Sponsor is requesting a change as a result of an EQuIP Review/Site monitoring visit.
- [ ] Other

If other, explain.

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

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Title: Amendment 1 : International Fetal Cardiac Intervention Registry

Amendment - Summary

1 * **Briefly describe the proposed modifications to this protocol.**

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

2 **Check all categories that apply to the proposed amendment.**

- ☐ New study aims that affect the study design or sub-study
- ☐ Changes in study design
- ☐ Changes in randomization methods or scheme
- ☐ Changes that affect risk/benefit ratio to subjects
- ☐ 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
- ☐ Submission of Interim Report
- ☐ Other

If Other Category:

3 * **Do the proposed modifications significantly change the original scientific design?**

○ Yes ○ No Clear

If YES:

3.1 **Have the modifications been submitted to a Scientific Review committee for review?**

○ Yes ○ No Clear

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.**

Add

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

○ Yes ◉ No Clear

If YES:

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

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

○ Yes ◉ No Clear

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Title: Amendment 1 : International Fetal Cardiac Intervention Registry

Amendment - Consent and Recruitment Changes

1 * **Does the proposed amendment require revisions to approved recruitment materials?**
○ Yes ◉ No Clear

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.

2 * **Does the proposed amendment require the addition of new recruitment materials, which support the currently approved recruitment methods?**
○ Yes ○ No Clear

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 Clear

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.

Note: Please revise the consent/assent documents in the protocol as appropriate.

4 * **Will the proposed modifications require re-consenting subjects who have already been enrolled?**
○ Yes ○ No Clear

4.1 * Please explain why or why not.

4.2 If it is necessary to re-consent, please describe how subjects will be re-consented.

5 * **Do the proposed modifications affect the risk/benefit assessment for subjects?**
○ Yes ○ No Clear

If YES:

5.1 Justify why these changes are appropriate.

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Name: Consent and Recruitment Changes

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 Clear

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.

7 * **Is a new cohort or subject population being added, is there a change in sample size or inclusion/exclusion criteria (e.g. increase/decrease in subjects to be enrolled or addition of a control group)?**

○ Yes ○ No Clear

If YES:

7.1 Please justify the revised sample size and/or new cohort or inclusion/exclusion criteria.

8 * **Do the proposed modifications require revisions to procedures, data collection or the study schedule?**

○ Yes ○ No Clear

Note: If YES, be sure to revise the protocol as necessary.

9 * **Do the proposed modifications require revisions to approved study materials (e.g. surveys)?**

○ Yes ○ No Clear

Note: If YES, be sure to revise the documents and upload them to the protocol.

10 * **Do the proposal modification require any additional patient care interaction?**

○ Yes ○ No Clear

Note: If YES, please contact the Clinical Trials Office (CTO) at extension 4-2721 or 4-2722.

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