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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.
- 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 - Details

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

Yes No [Clear](#)

If YES:

1.1 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.

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

Yes No [Clear](#)

If YES:

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

3 * Is the Principal Investigator for this protocol being changed?

Yes No [Clear](#)

If YES:

3.1 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.

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

Yes No [Clear](#)

Note: If YES, please revise the consent/assent forms or document used to obtain consent via another method as appropriate.

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

Yes No [Clear](#)

Note: If YES, please revise the recruitment documents in the protocol as appropriate.

6 Please enter any additional information if none of the questions above apply.

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Name: Details of
Amendment Change