

## APPENDIX 1



*Advancing the Field of Fetal Cardiovascular Care and Science Through Collaborative Research, Education and Mentorship*

### **FETAL HEART SOCIETY CONCEPT RESEARCH PROPOSAL**

**Deadline:** 2 weeks prior to quarterly FHS Research Collaborative Committee Meeting

**Format:** 11 point font, single line spacing and not to exceed 2 pages

**Date:**

**Main Study (new data) or Ancillary Study (secondary analysis or extension of prior study)**

**Study Title:**

**Principal Investigator and hospital/program affiliation:** Should be a Fetal Heart Society (FHS) Active Member

**Specific Aims:** Please delineate specific research questions and hypotheses

**Significance/Background:** Please provide background that justifies why this study is important

**Brief Approach:**

1. Study design
2. Study population
3. Time period to be studied
4. Independent /Intervention variables: List variables to be studied  
Are there any special skills that will be necessary at centers that enroll patients? How will the Principal Investigator “certify” centers regarding these skills (e.g. novel measurement or intervention)?
5. Outcomes/Dependent variables: List primary and secondary outcomes Define the primary study outcome in sufficient detail to demonstrate that it is clinically relevant, free of bias and measurable
6. Timeline
7. Budget details. Cost may be incurred for the study regarding project coordination (IRB communication/assistance, site communication, study training), building and reviewing clinical databases (Open Clinica or RedCap), and image processing.

***If the proposal is deemed to be something that the FHS is interested in, how we move forward will depend on the estimated cost, available FHS resources, and funding that the PI can provide.***

Given this, please provide:

Number of US Sites
Number of foreign sites
Number of Data elements in the clinical database: 0-500=1, 500-1000=2, 1000-1500=3, >1500=4
Number of Patients: <500=0, 500-1500=1, 1500-3000=2, >3000=3
Number of Echocardiograms to be collected:

- A. Will the Investigators need the FHS Data Coordinating center to build and maintain the clinical database (typically Open Clinica or RedCap)?
- B. Will echocardiographic images be needed for this study?
- C. Do the investigators have access to funding to potentially provide to cover/offset costs of the project? If so, please describe
- D. Budget estimating form (we will provide an estimate for you based on this data)