



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

FETAL HEART SOCIETY FULL RESEARCH PROPOSAL

Format: 11 point font, single line spacing and not to exceed 7 pages

Date:

Study Title:

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

Proposed authors: The planned first and last author, as well as any additional planned authors (Please see FHS Authorship and Publication Guidelines). Must include "for the Fetal Heart Society"

Study Working Group Members: Use form at end of this document (Please see FHS Authorship and Publication Guidelines for more information)

Overview: Start proposal with an overview abstract (no more than 1-2 paragraphs) that leads up to objectives and hypotheses

Specific Aims: Please delineate specific research questions and hypotheses for each of the aims. Each aim should be related but success of one should not depend on success of another. Each aim should have a hypothesis to be tested

Background: Please provide background that justifies why this study is important. Background needs to be sufficiently detailed and organized with a full review of the literature that leads up to the hypotheses to be tested and to the aims (1-2 pages minimum). Please describe what is **novel** about this study compared to prior studies. How will the study build on our understanding/experience/care of patients. Comprehensive literature review with references should be provided.

Approach: Please describe specific methodology planned, including:

1. Study design
 - a. Specify retrospective or prospective, and case series, case control, cohort, experimental (e.g. pilot or randomized control), or other (with detail)
 - b. If randomized controlled trial, specify method of randomization, including whether central or center-specific randomization will be used, as well as stratification variables if used and concealment methods
2. Study population/Inclusion criteria/Exclusion criteria Please be sure to specify the following:
 - a. Main Study (new data) or Ancillary Study (secondary analysis or extension of prior study)
 - i. Main Study: Study proposed by a FHS Active Member that requires new collection of retrospective or prospectively collected data from Member sites
Main Studies are hypothesis driven and address questions related to the primary hypothesis stated in the study protocol
 - ii. Ancillary Study: Observational study performed as a supplement to a prior Main Study, involving either previously collected data or additional data for existing patient entries
Ancillary Studies may be proposed during an ongoing study, begun at the onset of data collection, or any time after completion of a Main Study
Each Ancillary Study must be proposed using a new Concept Research



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

Proposal as outlined in the FHS Research Collaborative Guidelines
pertaining to research proposals

- b. Clear and precise Inclusion/Exclusion criteria, including but not limited to



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

- i. If study is limited to patients with prenatal diagnosis, or will also include neonates
 - ii. If a study will include maternal data
 - iii. How controls will be defined if part of the study
 - iv. How patients/fetuses with genetic and/or other anomalies will be treated
 - c. Time period to be studied, specifying if dates are of fetal echocardiogram, referral ultrasound, intervention, etc.
 - d. Independent /Intervention variables:
 - i. List variables to be studied
 - ii. 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)?
 - iii. If the variables are ones in which there may be more than one collection (e.g. echocardiographic measures, maternal weight) specify how many repeated measures are planned and which ones should be collected
 - iv. Will imaging data be collected?
For images, a plan for image archiving and analysis will need to be specified unless specific exemption is granted by the Research Collaborative Committee
 - e. Outcomes/Dependent variables:
 - i. List primary and secondary outcomes
 - ii. Define the primary study outcome in sufficient detail to demonstrate that it is clinically relevant, free of bias and measurable
 - f. Analytic Plan:
 - i. If experimental design, will there be interim analysis?
 - g. Sample size calculation
 - h. Safety:
 - i. Are there any potential maternal or fetal ethical concerns regarding this study?
 - ii. If experimental study:
 1. How will adverse events be reported?
 2. Will there be a data and safety-monitoring plan?
If so, include formation, location, frequency of review, and criteria to terminate the study
 - i. Please attach a proposed comprehensive data collection sheet or data collection tool(s) to be used in the study



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

Study Timeline

Potential Problems/Alternative approach

Clinical Relevance/Significance: Clinical relevance section may be redundant from introduction/background but hits message again-how much of an impact will the findings have?

Future Directions: where can you go from here? What spin-offs or next directions can you take the findings of this study.

Sponsorship: Is any part of this study being sponsored by an outside agency? If yes, specify all real or perceived conflicts of interest for each of the proposed authors

Budget: consider what may be necessary

- a. Personnel -should include multicenter project director, local study coordinator (may be necessary for some studies -otherwise could plan a certain \$/patient- for patient recruitment, coordination, data upload etc), statistician (can also be in services section), database developer, research sonographer or nurse.
- b. Supplies/Services/Consumables-e.g. imaging server set up fee, image upload/storage fee (1.75 per study x patient number x number of studies per patient), image deidentification and cataloguing with DCC
- c. Other costs – e.g. KT costs -publication fees, abstract submission, posters, travel, patient enticement costs for parking or \$ for participation

Appendices: must include authorship form, and can include references, data collection sheets, study timeline, representative publications (no more than 2-3) diagrams demonstrating measurements etc



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

FHS Authorship Attachment (must be revised if changes are made, subject to Publication Committee and/or Board Approval)

Gathering data takes a lot of work, and in many sites, more than one person collects the data. In most journals, authorship criteria do include "data collection and analysis" in addition to input on the final manuscript (writing, editing, feedback). Remember, though, that collaborators can also get a Pubmed citation. Please also keep in mind that the FHS written policy (see MOO) states clearly that "submission of case materials alone does not satisfy the ICMJE authorship requirement".

To that end, please complete below and update as necessary. Updated attachment versions should be sent to the FHS Publications Committee Chair, publications@fetalheartsociety.org.

Project Name/Working title:

Version of this form:

Date submitted to Publications Committee:

Date approved:

I. Current paper proposed listings, in order:

AUTHORS with institution (meets ICMJE criteria)

(First author)

(Other authors...)

(Senior Author)

for the Fetal Heart Society.

COLLABORATORS with institution (PUBMED searchable, but name will not be listed on author list):

others

II. Next paper, working title (if a project is anticipating more than one publication):

AUTHORS with institution (meets ICMJE criteria)

(First)

(Other authors...)

Senior

for the Fetal Heart Society

COLLABORATORS with institution:

others

