*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:**

**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 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. If the Study is an ancillary study, please clearly specify in the proposal the name of the original study.
    b. Clear and precise Inclusion/Exclusion criteria, including but not limited to:
        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 willbe 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. If the study is an ancillary study, clearly delineate which already collected data will be needed, and if any new data will need to be collected from sites.
        iii. 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)?
        iv. 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

v. 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

**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

1. 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.
2. 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 de-identification and cataloguing with DCC
3. 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.

**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 Manual of Operations) 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):**
Collaborators:

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

**FHS Planned Authorship and Participation**
**Please list roles of each person that will work on this project. Please submit 2 charts if two papers are anticipated from this project**

**Project name/short title:**

Authorship will be based on the following 4 criteria (ICMJE)

1. Substantial contributions to the conception or design of the work or acquisition, analysis, or interpretation of data for the work AND
2. Drafting the work or revising it critically for important intellectual content AND
3. Final approval of the version to be published AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

| **Date:** | **Role** | **Project title:** | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Name** | Author=A Collabor-ator=C None=N | Concept/ Design | IRB/ database | Recruit-ment | Data acquire/ entry/ Upload | Data analysis | Primary manuscript drafting | Manuscript editing/ revision |
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(Attach additional pages as necessary)