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

FETAL HEART SOCIETY <u>FULL RESEARCH PROPOSAL</u>

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)
Study Working Group Members: Attach proposed list (Please see FHS Authorship and Publication Guidelines)

Specific Aims: Please delineate specific research questions and hypotheses
Significance: Please provide background that justifies why this study is important
Innovation: Please describe what is novel about this study compared to prior studies
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 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

    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. Potential problems and alternative approaches
j. Timeline
k. Budget: (Include description of time commitment and personnel needs at participating FHS centers, and potential funding mechanisms outside of the FHS for this support)
l. 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
m. Please attach a proposed comprehensive data collection sheet or data collection tool(s) to be used in the study