

Approved: July 1, 2015 Updated: April 26, 2022





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

TABLE OF CONTENTS

Subject	Page
About the Fetal Heart Society Mission, aims, and structure	3
Articles of incorporation	8
Articles of amendment of the articles of incorporation	10
Bylaws of the Fetal Heart Society	16
Research collaborative research proposal and study implementation guidelines	27
Publication committee authorship and publication guidelines	36
APPENDIX 1: Fetal Heart Society concept research proposal form	41
APPENDIX 2: Fetal Heart Society full research proposal form	43
APPENDIX 3: Fetal Heart Society survey/questionnaire proposal form	49
APPENDIX 4: Membership dues	50
APPENDIX 5: Committees	52
APPENDIX 6: Recommended level of experience for governing board positions	53
APPENDIX 7: Cyber address & mailing address	54



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

ABOUT THE FETAL HEART SOCIETY

1. <u>Mission Statement:</u>

- To advance the art and science of fetal cardiovascular medicine
- To improve the understanding of in-utero cardiovascular physiology by fostering scientific research, organized research collaboration, and mentorship
- To educate medical and research professionals through scientific publications, education, and meetings

2. <u>Background:</u>

Cardiac abnormalities are the most common birth defect and ultrasound provides the opportunity to diagnose complex cardiovascular conditions, from the first trimester of pregnancy and onward. As a consequence, prenatal diagnosis and antenatal management is emerging as an important component of healthcare worldwide.

The concept of the fetus as a patient is now established. However, many of the conditions related to the cardiovascular system that the fetus faces are relatively uncommon. Variable treatment strategies and approaches exist amongst centers, leading to bias and a low evidence base for clinical practice. These factors impair the ability to advance knowledge in the field. Collaborative effort between institutions is essential in order to collect the evidence required to improve care for the fetus with a cardiovascular abnormality. Increased numbers will increase population volumes for better investigational power and quality of research. Better research can lead to conclusions and findings that will result in development of superior care strategies. Such care before birth could not only improve fetal and perinatal outcomes, but also potentially allow for life long benefits and better long-term outcome.

3. <u>Fetal Heart Society Aims:</u>

- Advance the cause of research and education relating to the field of fetal cardiology and other reasonably related medical or scientific pursuits
- Promote and encourage the development and advancement of the field of fetal cardiovascular diagnosis, management, and therapy

- Promote the establishment of mutually beneficial relationships among the Society's Members to enable sharing of ideas and research collaboration
- Foster and facilitate multicenter research and collaboration to advance the field of fetal cardiovascular science and clinical practice by establishment of a Fetal Cardiovascular Research Collaborative within the Fetal Heart Society

Through the creation of the **Fetal Heart Society**, we specifically hope to:

- Solicit and review proposed multicenter study protocols and provide feedback to investigators
- Provide access to a large number of study subjects to increase the power of observational studies and improve the capacity to perform comparative effectiveness research
- Take the opportunity created by strength in numbers to apply for resources to support multicenter efforts
- Establish regular meetings to review proposals, present research findings, and organize future research driven educational meetings
- Provide academic mentorship to young investigators
- Provide a voice to communicate evidence based decisions to caregivers to guidebest practice for the fetus with cardiovascular disease

4. Membership

Membership in the Fetal Heart Society is available to professionals and trainees with a research focus in fetal cardiovascular medicine. Membership will be conditioned upon an appropriate level of education and/or experience, participation in research projects, payment of Membership dues, and attendance at meetings. For further information regarding Membership, see the Bylaws.

5. Governance

Board of Directors:

The Fetal Heart Society will be managed by its Board of Directors. The number of Directors shall be not less than eight. The Board of Directors shall consist of the President, Vice President, Secretary, Treasurer, Research Officer, Publications Officer, Education Officer, and Immediate Past President (after the initial President completes a three (3) year term) who shall serve as *ex officio* Directors, and three (3) Directors elected at-large.

Directors will be elected by a plurality of the votes cast by the Active Members at which a quorum is present.

Directors shall serve staggered three (3) year terms. Directors may not serve more than two (2) consecutive terms in the same office. Directors may be re-elected for additional terms after three years have elapsed since their last term.

Officers:

The Officers of the Corporation shall be a President, Vice President, Secretary, Treasurer, Research Officer, Publications Officer, Education Officer, and Immediate Past President (after the initial President completes a three (3) year term), and such other Officers as may be determined by the Board of Directors of the Corporation.

Officer shall be elected by a plurality of the votes cast by the Active Members at which a quorum is present.

The Officers shall serve for a three (3) year term and shall serve until their successors have been duly elected and have qualified. Officers may not serve more than two (2) consecutive terms in the same office. Officers may be re-elected for additional terms after three (3) years have elapsed since their last term.

Committees:

The Board of Directors will designate committees, each of which shall consist of one or more Members of the Board of Directors. These committees will have the authority of the Board of Directors in the management of the Fetal Heart Society. Such committees, to the extent provided in said resolution, shall have and exercise the authority of the Board of Directors in the management of the Corporation Fetal Heart Society.

Other committees not having and exercising the authority of the Board of Directors in the management of the Corporation will be designated. Except as otherwise provided in such resolution, members of each committee may be Directors or Active Members, and shall be appointed for at least a (1) one year term.

The Board of Directors will appoint a Chairman for each Committee.

The Committee Chairman will put forth Committee Members who fulfill the qualifications to serve on the respective Committee to the Board of Directors for vote. Committee Members will be approved by a majority vote of the Board of Directors and will serve for at least a one year term and serve until his or her successor is appointed, unless the Committee is terminated.

Committees of the Board of Directors:

1. Executive Committee: The Executive Committee will act between meetings of the Board of Directors with all of the powers of the Board of Directors. The Executive Committee is comprised of President, Vice President, Secretary, Treasurer, and Immediate Past President (after the initial President completes a three year term).

Current Committees:

- <u>Research Collaborative Committee:</u> The Research Collaborative Committee will develop and maintain the guidelines for the Fetal Heart Society's research collaborative efforts including the process for research project review and acceptance, and data management, storage and sharing, will maintain a mechanism for support of facilitating multicenter collaborative research projects, and will oversees approved collaborative research projects. The Chairman of the Research Collaborative Committee is an elected Officer and an *ex officio* Member of the Board of Directors. In addition, one elected Board Member at Large will be appointed by the Board to serve on the Committee.
- Publication Committee: The Publication Committee will develop and maintain the guidelines for authorship and publication and oversees the publication of all works supported by the Fetal Heart Society. The Chairman of the Publication Committee is an elected Officer and *ex officio* Member of the Board of Directors. In addition, one elected Board Member will be appointed by the Board to serve on the Committee.
- <u>Education Committee</u>. The Education Committee will be responsible for Fetal Heart Society education initiatives including creating and maintaining a curriculum for web based and written educational materials for providers, nurses, coordinators and parent education. The Chairman of the Education Committee is an elected Officer and *ex officio* Member of the Board of Directors.
- 4. Other Committees:

Other committees not having the authority of the Board of Directors are designated by a resolution adopted by the Executive Committee. Except as otherwise provided in such resolution, Members of each committee may be Directors or Active Members, and shall be appointed for at least a one year term.

- 5. <u>Membership Committee</u>. The Membership Committee will develop and maintain requirements for Membership and determine benefits specific to level of Membership which will be reviewed and approved by the Board of Directors. The Committee will solicit and review Membership applications and make recommendations to the Board of Directors.
- 6. <u>Website Committee</u>. The Website Committee will oversee the design, implementation, maintenance, and continual improvement of the website.
- 7. <u>Finance Committee</u>. The Finance Committee is under the direction of the Treasurer. The Committee will be responsible for management of donation and sponsorship funds and administer the writing of grant applications
- 8. <u>Correspondence Committee</u>. The Correspondence Committee is under the direction of the Secretary. The Committee will be responsible for FHS correspondence including email announcements and newsletters, and be responsible for recording and distributing minutes for all meetings.
- 9. <u>Conferences Committee</u>. The Conference Committee is under the direction of the President. The Committee will be responsible for arranging all conferences (web based, conference calls, and in-person).
- 10. <u>Steering Committee</u>. The Steering Committee will participate in the initial formation and organization of the Fetal Heart Society and have the opportunity to contribute to the creation of the Society, the Bylaws and the Guidelines subject to the approval of the Board of Directors. The Steering Committee will be dissolved once the Society has been established and the Bylaws and Guidelines have been approved.

For more information regarding the Committees, see the Bylaws.



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

ARTICLES OF INCORPORATION

FETAL HEART SOCIETY, INC.

A VIRGINIA NONPROFIT AND NONSTOCK CORPORATION

The undersigned, pursuant to Chapter 10 of Title 13.1 of the Code of Virginia, state as follows:

1. The name of the corporation is the FETAL HEART SOCIETY, INC. d.b.a Fetal Heart Society.

This organization is a nonprofit public benefit corporation and is not organized for the private gain of any person. It is organized under Chapter 10 of Title 13.1 of the Code of Virginia for charitable purposes.

The properties and assets of this non-profit Corporation are irrevocably dedicated to fulfillment of the objectives of this corporation. No part of the net earnings, properties, or assets of this Corporation, on dissolution or otherwise, shall inure to the exclusive benefit of any private person or individual, or any member or director, or other officer of this Society except in fulfillment of said objectives. On a liquidation or dissolution, all Properties and assets and obligations shall be distributed pursuant to the nonprofit provisions of the Virginia Corporation code then in effect.

The Specific purposes for which this corporation is organized include, but are not limited to: advancement of the art and science of fetal cardiology through scientific research, scientific publication, scientific education, and scientific meeting.

The organization will not, as a substantial part of its activities, attempt to influence legislation or participate to any extent in a political campaign for or against any candidate for public office.

The organization is formed exclusively for literary and scientific purposes within the meaning of Internal Revenue Code Section 501(c)(3).

The corporation shall have one or more classes of members with such designations, qualifications and rights as set forth in the bylaws.

2. The directors shall be elected by the members.

3. A. The name of the corporation's initial registered agent is Mary Teresa Donofrio.

B. The initial registered agent is an individual who is a resident of Virginia and an initial director of the corporation.

4. A. The corporation's initial registered office address, including the street and number, if any, which is identical to the business office of the initial registered agent, is 4015 Ellicott Street, Alexandria, Virginia 22304.

B. The registered office is located in the independent city of Alexandria, Virginia.

5. The initial directors are:

Mary Teresa Donofrio (President)

Anita Moon-Grady (Vice President)

Jack Rychik (Secretary)

Michael Puchalski (Treasurer)

Wayne Tworetzky (Research Chair)

ARTICLES OF AMENDMENT

OF THE

ARTICLES OF INCORPORATION OF

FETAL HEART SOCIETY, INC.

The undersigned, on behalf of the nonstock corporation set forth below, pursuant to Title 13.1, Chapter 10, Article 10 of the Code of Virginia, states as follows:

- 1. The name of the corporation is Fetal Heart Society, Inc.
- 2. The following Articles of the Articles of Incorporation are hereby amended and added as follows:

A. Article (1) is hereby amended to read in its entirety:

- 1(a). The name of the corporation is the Fetal Heart Society, Inc. (the "Corporation").
- 1(b). The Corporation is hereby organized for the following purposes:
- A. To advance the art and science of fetal cardiovascular medicine, including diagnosis, management and treatment of cardiovascular conditions before birth and in the perinatal period.
- B. To improve the understanding of in-utero cardiovascular physiology by fostering scientific research, organized research collaboration, and mentorship for the benefit of patients.
- C. To educate medical and research professionals through scientific publications, education and meetings.
- D. To exercise any other powers conferred upon corporations organized pursuant to the provisions of the Virginia Nonstock Corporation Act(the "Act") provided, however, that

- a. The Corporation is organized exclusively for charitable, educational, scientific, and religious purposes, including, for such purposes, the making of distributions to organizations exempt from federal income tax under Internal Revenue Code ("IRC") Section 501(c)(3); and
- b. Notwithstanding any other provision of these Articles of Incorporation, the Corporation shall not carry on any other activities not permitted to be carried on: (i) by a corporation exempt from federal income tax under IRC Section 501(c)(3); or (ii) by a corporation contributions to which are deductible under IRC Section 170(c)(2).
- B. A new Article 6 is hereby added to the Articles of Incorporation and shall read in its entirety:
 - 6. The Corporation shall have one or more classes of members, with such designations, qualifications and rights as set forth in the bylaws.
- C. A new Article 7 is hereby added to the Articles of Incorporation and shall read in its entirety:
 - 7. Other lawful provisions for the conduct and regulation of the business and affairs of the Corporation, for its voluntary dissolution, or for limiting, defining or regulating the powers of the Corporation or its directors are as follows:
 - A. No part of the net earnings of the Corporation shall inure to the benefit of, or be distributable to, its directors, officers, employees, or other private persons, except that the Corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of IRC Section 501(c)(3) purposes. No substantial part of the activities of the Corporation shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the Corporation shall not participate in, or intervene in (including the publishing or distribution of statements), any

political campaign on behalf of, or in opposition to, any candidate for public office.

- B. Upon the dissolution of the Corporation, and after paying or making provision for the payment of all of the liabilities of the Corporation, all assets of the Corporation shall be distributed for one (1) or more of the Corporation's exempt purposes within the meaning of IRC Section 501(c)(3), or shall be distributed to the federal government, or to a state or local government, for a public purpose, in such manner as the Board of Directors shall determine.
- C. The personal liability of the officers and directors of the Corporation is hereby eliminated to the fullest extent permitted by law and by the provisions of the Act.
- 3. The foregoing amendments were adopted by the corporation on 1/8/2015.
- 4. The adoption of the amendments was duly approved by the unanimous written consent of the directors. Member approval of the amendments was not required because the corporation has not yet completed its organization and there are no members.

Executed in the name of the corporation by:

Mary T. Donofrio, President

ARTICLES OF RESTATEMENT OF THE ARTICLES OF INCORPORATION OF FETAL HEART SOCIETY, INC.

The undersigned, on behalf of the nonstock corporation (the "Corporation") set forth below, pursuant to Title 13.1, Chapter 10, Article 10 of the Virginia Nonstock Corporation Act (the "Act"), states as follows:

- 1. The name of the Corporation is Fetal Heart Society, Inc.
- 2. This restatement contains amendments to the Articles of Incorporation of the Corporation.
- 3. The Articles of Incorporation of the Corporation are hereby amended and restated by deleting the existing Articles of Incorporation in their entirety and by inserting in lieu thereof the Amended and Restated Articles of Incorporation of the Corporation attached as <u>Exhibit A</u> hereto (the "Amended and Restated Articles of Incorporation.").
- 4. The Amended and Restated Articles of Incorporation were adopted by the Corporation on February 23, 2018.
- 5. The Amended and Restated Articles of Incorporation were proposed by the board of directors and submitted to the members in accordance with the provisions of Title 13.1, Chapter 10 of the Act, and at a meeting of the members at which quorum of each voting group was present.

The total number of votes cast for and against the amendment by each voting group entitled to vote separately on the amendment was:

Voting Group	Total Votes FOR	Total Votes AGAINST
Active Membership	21	0

and the number cast for the restatement by each voting group was sufficient for approval by that voting group.

Executed in the name of the Corporation by:

Fetal Heart Society, Inc. (SCC ID: 07834385)

By: Mary T. Donofrio Title: President, Fetal Heart Society

Exhibit A

AMENDED AND RESTATED ARTICLES OF INCORPORATION OF FETAL HEART SOCIETY, INC.

A VIRGINIA NONPROFIT AND NONSTOCK CORPORATION

These Amended and Restated Articles of Incorporation are presented for filing pursuant to § 13.1-889 of the Virginia Nonstock Corporation Act (the "Act").

- 1(a). The name of the corporation is the Fetal Heart Society, Inc. (the "Corporation").
- 1(b). The Corporation is hereby organized for the following purposes:
 - A. To advance the art and science of fetal cardiovascular medicine, including diagnosis, management and treatment of cardiovascular conditions before birth and in the perinatal period.
 - B. To improve the understanding of in-utero cardiovascular physiology by fostering scientific research, organized research collaboration, and mentorship for the benefit of patients.
 - C. To educate medical and research professionals through scientific publications, education and meetings.
 - D. To exercise any other powers conferred upon corporations organized pursuant to the provisions of the Act provided, however, that
 - a. The Corporation is organized exclusively for charitable, educational, scientific, and religious purposes, including, for such purposes, the making of distributions to organizations exempt from federal income tax under Internal Revenue Code ("IRC") Section 501(c)(3); and
 - b. Notwithstanding any other provision of these Articles of Incorporation, the Corporation shall not carry on any other activities not permitted to be carried on: (i) by a corporation exempt from federal income tax under IRC Section 501(c)(3); or (ii) by a corporation contributions to which are deductible under IRC Section 170(c)(2).
 - 2. The Corporation shall have one or more classes of members, with such designations, qualifications and rights as set forth in the bylaws.

- 3. The Directors shall be elected by the Active Members for staggered three (3) year terms.
- 4. Corporate action may be taken without a meeting of the members and without prior notice if the corporate action is taken by members who would be entitled to vote at a meeting of members having voting power to cast not fewer than the minimum number of votes that would be necessary to authorize or take the corporate action at a meeting at which all members entitled to vote thereon were present and voted.
- 5. The name of the Corporation's registered agent is Virginia Registered Agent Services. The registered agent is an individual who is a resident of Virginia and a director of the Corporation. The Corporation's registered office address, including the street and number is 3850 Gaskins Rd., Suite 120, Richmond Virginia 23233. The registered office is located in the independent city of Richmond, Virginia.
- 6. Other lawful provisions for the conduct and regulation of the business and affairs of the Corporation, for its voluntary dissolution, or for limiting, defining or regulating the powers of the Corporation or its directors are as follows:
 - A. No part of the net earnings of the Corporation shall inure to the benefit of, or be distributable to, its directors, officers, employees, or other private persons, except that the Corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of IRC Section 501(c)(3) purposes. No substantial part of the activities of the Corporation shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the Corporation shall not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of, or in opposition to, any candidate for public office.
 - B. Upon the dissolution of the Corporation, and after paying or making provision for the payment of all of the liabilities of the Corporation, all assets of the Corporation shall be distributed for one (1) or more of the Corporation's exempt purposes within the meaning of IRC Section 501(c)(3), or shall be distributed to the federal government, or to a state or local government, for a public purpose, in such manner as the Board of Directors shall determine.
 - C. The personal liability of the officers and directors of the Corporation is hereby eliminated to the fullest extent permitted by law and by the provisions of the Act.
- 7. These Articles of Incorporation may be amended from time to time in any and as many respects as may be desired; provided: (i) that the Articles of Incorporation as amended may contain only such provisions as might be lawfully contained in the original Articles of Incorporation; and (ii) that any such amendments are made in the manner and pursuant to the procedures and requirements prescribed by the Act.



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

BYLAWS

OF

FETAL HEART SOCIETY, INC.

(A Virginia Nonstock Corporation)

Approved 2/22/2018

ARTICLE I <u>Name</u>

The name of this corporation (hereinafter referred to as the "Corporation") is:

FETAL HEART SOCIETY, INC.

ARTICLE II <u>Purposes</u>

Section 1. The Corporation is organized and shall be operated exclusively as a nonstock organization within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, and the Regulations thereunder, as they now exist or may hereafter be amended (hereinafter collectively referred to as the "Code"). The Corporation may exercise any other powers conferred upon corporations organized pursuant to the provisions of the Virginia Nonstock Corporation Act (the "Act"). The Corporation is organized and shall be operated for such specific purposes as are set forth in the Corporation's Articles of Incorporation.

ARTICLE III Offices

The Corporation shall maintain in the Commonwealth of Virginia a registered office and a registered agent at such office, and may have other offices within or without the Commonwealth of Virginia as shall be determined by the Board of Directors.

ARTICLE IV <u>Members</u>

Section 1. Members. The Corporation shall have four classes of members, with such qualifications and rights as are set forth in Section 2 of this Article IV. Membership is generally available to professionals and trainees with a research focus in fetal cardiovascular medicine. Membership will be conditioned upon an appropriate level of education and/or experience, participation in research projects, payment of membership dues, and attendance at meetings. The Membership Committee shall be responsible for formulating and making available additional and specific requirements for membership.

Section 2. Classes of Membership

- A. <u>Active Membership</u>. Active Membership is available to individuals holding a M.D., D.O., Ph.D., or equivalent, or allied health care professionals. Admission to Active membership is conditioned upon dues payment and participation in meetings and research collaborative projects. Each Active Member shall have a right to cast one (1) vote on every matter brought before the members.
- B. <u>Affiliate Membership</u>. Affiliate Membership is available to individuals holding a M.D., D.O., appropriate Ph.D., or equivalent, allied health care professionals, or trainees. Admission to Affiliate membership is conditioned upon payment of dues. Participation in meetings and research collaborative projects is encouraged but not required. Affiliate Members do not have the right to vote.
- C. <u>Emeritus Membership</u>. The Board of Directors may grant Emeritus Membership to individuals approved by the Board. Emeritus Members shall not be required to pay dues, and will not have the right to vote.
- D. <u>Honorary Membership</u>. The Board of Directors may grant Honorary Membership to individuals approved by the Board. Honorary Members shall not be required to pay dues, and will not have the right to vote.

Section 3. Membership Applications. Application for membership shall be made in writing on a form as prescribed by the Board of Directors. Applications for membership shall be approved by the Board of Directors. The Board of Directors retains the right to reject an application for membership when it considers such action to be in long-term best interest of the Corporation, consistent with its tax-exempt mission.

Section 4. Determination of Membership Dues and Obligation to Pay. The Board of Directors shall fix the amount of membership dues and/or assessments (if any) for Active and Affiliate Membership. Membership in the Corporation (other than Emeritus or Honorary Membership described in Section 2.C and 2.D of this Article IV) carries a definite obligation to pay membership dues and any assessments established by the Board of Directors. Membership dues and assessments are not refundable for any reason. Membership dues shall be levied by the Treasurer during the month of July of each year.

Section 5. Duration of Membership. The term of membership in the Corporation shall be determined by the Board of Directors from time to time.

Section 6. Termination of Membership. Membership in the Corporation shall be suspended or terminated if a member does not pay all required membership dues, in full, by the due date established by the Board of Directors, pursuant to procedures established by the Board of Directors. In addition, the Board of Directors may, by the affirmative vote of a majority of the Directors present at a meeting of the Board of Directors at which a quorum is present, terminate a member's membership for cause after an appropriate hearing. Grounds constituting "cause" shall be determined by the Board of Directors in its sole discretion. Such member shall be given reasonable notice thereof and shall be entitled to a hearing before the Board of Directors) submission of written notice of membership resignation or non-renewal, or by the failure of a member to continue to satisfy the relevant membership requirements. However, termination of membership shall not extinguish such members' financial obligations, if any, as more fully described elsewhere in these Bylaws.

Section 7. Annual and Regular Meetings. Annual meetings of the membership may be held at such time and place, either within or without the Commonwealth of Virginia, as may be designated by resolution of the Board of Directors, provided that appropriate notice is provided to all members.

Section 8. Special Meetings. Special meetings of the membership may be called by or at the request of the President or the majority of the entire Board of Directors or at the written demand of at least 25% of all Active Members entitled to vote on issues to be considered at the proposed meeting. The person or persons authorized to call special meetings of the voting membership may fix any place, either within or without the Commonwealth of Virginia, as the place for holding any special meeting called by them. Special meetings of the emeritus or honorary (non-voting) members are permitted but not required.

Section 9. Notice. Notice of any special meeting of the voting membership shall be received by each member by mail, overnight courier, telecopier, electronic mail, or other mode of written transmittal, not less than ten (10) days and not more than sixty (60) days before the date set for such a meeting, and must include the time, date, place and purpose of such meeting. Any members may waive notice of any meeting before, at or after such meeting.

Section 10. Quorum. Ten percent (10%) of the Active Members present in person or by proxy shall constitute a quorum for the transaction of business at any meeting of the membership, provided, that if less than ten percent (10%) of the Active Members are present at said meeting, a majority of the Active Members present may adjourn the meeting from time to time without further notice.

Section 11. Chairman. The President shall preside as Chairman at all meetings of the voting membership. In the absence of the President from any meeting of the voting members, the Vice President shall serve as temporary Chairman.

Section 12. Manner of Acting. The act of a majority of the Active Members present at a duly called meeting of the Active Members at which a quorum is present shall be the act of the voting membership, except as otherwise provided by law, by the Corporation's Articles of Incorporation, or by these Bylaws. Where and in the manner authorized by the Board of Directors, any action required to be taken at a meeting of the Active Members or any action which may be taken at a meeting of the voting members may be conducted by U.S. mail ballot, fax ballot, electronic mail ballot, or any other method of voting provided for by the Act. Voting conducted by electronic transmission shall either set forth or be submitted with information from which it may be determined that the electronic transmission was authorized by the Active Member or the Active Member's proxy. Such voting shall be subject to the same quorum and notice requirements as a meeting held in person. Proxy voting by Active Members shall be permitted.

Section 13. Remote Participation in Meetings. Where and in the manner authorized by the Board of Directors and to the extent permitted by the Act, any member may participate in a meeting of the members by remote communication. Members participating by remote communication shall be deemed present and may vote at such meeting if the Corporation has implemented reasonable measures to: (a) verify that each person participating remotely is a member; and (b) provides such members a reasonable opportunity to participate in the meeting and to vote on matters submitted to the members, including an opportunity to communicate, and to read or hear the proceedings of the meeting substantially concurrent with such proceedings.

ARTICLE V Board of Directors

Section 1. General Powers. The affairs of the Corporation shall be managed by its Board of Directors. It shall be the duty of the Board of Directors to carry out the objectives and purposes of the Corporation, and to this end, the Board of Directors may exercise all powers of the Corporation. The Board of Directors shall be subject to the restrictions and obligations set forth by statute and in the Corporation's Articles of Incorporation and these Bylaws.

Section 2. **Composition, Appointment, Tenure, and Qualifications.** The number of Directors shall be not less than eight (8), such number which shall be fixed from time to time by the Board of Directors. The Board of Directors shall consist of the President, Vice President, Secretary, Treasurer, Research Officer, Publications Officer, Education Officer and Immediate Past President (after the initial President completes a three (3) year term) who shall serve as *ex officio* Directors, and three (3) Directors elected at-large. Directors shall be at least twenty-one (21) years of age but need not be residents of the Commonwealth of Virginia. Directors shall be active members of the Society and to be nominated should have at minimum three (3) years experience serving on the Board or on a Committee, or be invited to submit a nomination by a majority vote of the current Board of Directors. Specific requirements for level of experience will be determined prior to each elections by majority vote of the current Board of Directors. Once nominated, a ballot will be created and Directors shall be elected by a plurality of the votes cast by the Active Members entitled to vote in the election at a meeting at which a quorum is present. Such election may also be conducted by mail or by electronic ballot. In the event of a tie for a Director position, a runoff election shall be held between the two candidates. Directors shall serve staggered three (3) year terms. Directors may not serve more than two (2) consecutive terms in the same office. Directors may be re-elected for additional terms after three (3) years have elapsed since their last term.

Section 3. Annual and Regular Meetings. Annual meetings of the Board of Directors shall be held at such time and place, either within or without the Commonwealth of Virginia, designated by resolution of the Board of Directors, without notice other than this Bylaw and such resolution. The Board of Directors may provide by resolution the time and place, either within or without the Commonwealth of Virginia, for the holding of additional regular meetings of the Board of Directors without notice other than this Bylaw and such resolution.

Section 4. Special Meetings. Special meetings of the Board of Directors may be called by or at the request of the Chairman or any two (2) Directors. The person or persons authorized to call special meetings of the Board of Directors may fix any place, either within or without the Commonwealth of Virginia, as the place for holding any special meeting of the Board called by them.

Section 5. Notice. Notice of any special meeting of the Board of Directors shall be received by each Director by mail, overnight courier, facsimile, or other mode of written transmittal, not less than three (3) days before the time set for such a meeting, and must include the time, date, place, and purpose of such meeting. Any Director may waive notice of any meeting before, at or after such meeting.

Section 6. Quorum. A majority of the Board of Directors in office shall constitute a quorum for the transaction of business at any meeting of the Board, provided, that if less than a majority of the Directors are present at said meeting, a majority of the Directors present may adjourn the meeting from time to time without further notice.

Section 7. Manner of Acting. The act of a majority of the Directors present at a meeting at which a quorum is present shall be the act of the Board of Directors, except as otherwise provided by law or by these Bylaws.

Section 8. Teleconferencing. To the extent permitted by the Act, any person participating in a meeting of the Board of Directors may participate by means of conference telephone or by any means of communication by which all persons participating in the meeting are able to hear one another and otherwise fully participate in the meeting. Such participation shall constitute presence in person at such meeting.

Section 9. Action by Unanimous Written Consent. Any action required to be taken at a meeting of the Board of Directors or any action which may be taken at a meeting of the Board of Directors may be taken without a meeting if a consent in writing, setting forth the action so taken, shall be signed by all of the Directors entitled to vote with respect to the subject matter thereof.

Section 10. Minutes and Parliamentary Procedure. Minutes of each meeting of the Board of Directors shall be recorded by the Secretary. The minutes shall be submitted to the Board of Directors for approval at the subsequent meeting of the Board of Directors. All meetings shall be conducted in accordance with the latest edition of <u>Robert's Rules of Order</u>.

Section 11. Removal or Resignation of Directors. Any Director may be removed from office at any time by a majority vote of the Active Members present and voting at a meeting where a quorum is present, whenever in their judgment the best interests of the Corporation would be served thereby. A Director may be removed only at a meeting called for the purpose of removing the Director, and the meeting notice must state that the purpose of the meeting is removal of the Director.

Any Director may resign at any time by giving written notice to the Chairman, Secretary or to the Board of Directors. Such resignation shall take effect at the time specified in such notice, or, if no time is specified, at the time such resignation is tendered.

Section 12. Vacancies. Any vacancy occurring in the Board of Directors or any Directorship to be filled by reason of an increase in the number of Directors shall be filled by election during a special meeting of the Active Members called to fill the vacant position. A Director or member elected by plurality vote of the Active Members to fill a vacancy shall be elected for the unexpired term of his or her predecessor in office. Such action shall be effected by the affirmative vote of a majority of the Directors in office.

ARTICLE VI Officers

Section 1. Officers. The Officers of the Corporation shall be a President, Vice President, Secretary, Treasurer, Research Officer, Publications Officer, Education Officer and Immediate Past President (after the initial President completes a three (3) year term), and such other Officers as may be determined by the Board of Directors of the Corporation. The officers will be vested with such authority and to be obligated to perform such duties as shall be prescribed by the Board of Directors. The offices of President and Secretary shall not be held by the same person. Officers shall be at least twenty-one (21) years of age but need not be residents of the Commonwealth of Virginia.

Section 2. Election and Term of Office. The offices of President, Vice President, Secretary, Treasurer, Research Officer, Publications Officer, and Education Officer shall be elected by a plurality of the votes cast by the Active Members of the Corporation. In the event of a tie for an officer position, a runoff election shall be held between the two candidates with the highest number of votes in the initial election. Such election of officers shall be subject to the approval by the affirmative vote of a majority of the Board of Directors. The Officers shall serve for a three (3) year term and shall serve until their successors have been duly elected and have qualified. Officers may not serve more than two (2) consecutive terms in the same office. Officers may be re-elected for additional terms after three (3) years have elapsed since their last term.

Section 3. Removal. Any Officer may be removed from office at any time by the affirmative vote of a majority of the Directors in office whenever in their judgment the best interests of the Corporation would be served thereby.

Section 4. Vacancies. A vacancy in any office because of death, resignation, removal, disqualification, or otherwise, may be filled for the unexpired portion of the term of such office. Vacancies may be filled or new offices created and filled by a majority vote of Active Member during a special meeting called to fill the vacant position. Such election shall be subject to the approval by the affirmative vote of a majority of the Board of Directors.

ARTICLE VII Committees

Section 1. Committees of Directors. The Board of Directors, by resolution adopted by a majority of all Directors, may designate one (1) or more committees, each of which shall consist of

two (2) or more members of the Board of Directors and appoint Directors to serve on them. Such committees, to the extent provided in said resolution, shall have and exercise the authority of the Board of Directors in the management of the Corporation; but the designation of such committees and the delegation thereto of authority shall not operate to relieve the Board of Directors, or any individual Director, of any responsibility imposed upon them by law.

Section 2. Executive Committee. The Executive Committee shall act between meetings of the Board of Directors with all of the powers of the Board of Directors, except as restricted by the Act. The Executive Committee shall be comprised of the President, Vice President, Secretary, Treasurer and Immediate Past President (after the initial President completes a three (3) year term).

Section 3. Other Committees. Other committees not having and exercising the authority of the Board of Directors in the management of the Corporation may be designated by a resolution adopted by the Executive Committee. Except as otherwise provided in such resolution, members of each committee may be Directors or Active Members, and shall be appointed for at least a (1) one year term. Any member thereof may be removed by the Executive Committee whenever in their judgment the best interests of the Corporation would be served thereby. The Corporation shall have the following committees, as well as those committees designated from time to time in the manner set forth herein and set forth in applicable policies of the Corporation:

- A. **Research Collaborative Committee.** The Research Collaborative Committee shall develop and maintain guidelines for the establishment of the Corporation's research collaborative efforts, which will be reviewed and approved by the Board of Directors. These guidelines shall include the process for project review and acceptance, and data management, storage and sharing. The Research Collaborative Committee shall develop and maintain a mechanism for support of facilitating multicenter collaborative research projects and overseeing approved collaborative research projects. The Chairman of the Research Collaborative Committee is an elected officer and *ex-officio* member of the Board of Directors and serves a three (3) year term, such term, which may be renewable for one (1) additional term, with the option for re-election after three (3) years have elapsed since their last term. The remaining committee members shall consist of an additional member of the Board of Directors, and a minimum of three (3) Active Members who will be recommended by the Research Chair and appointed subject to approval by majority vote of the Board of Directors.
- B. <u>Publication Committee</u>. The Publication Committee shall develop and maintain guidelines for authorship and publication. The Publication Committee will oversee the publication of all works supported by the Corporation. The Chairman of the Publication Committee is an elected officer and *ex-officio* member of the Board of Directors and serves a three (3) year term, such term, which may be renewable for one (1) additional term, with the option for re-election after three (3) years have elapsed since their last term. The remaining committee members shall consist of an additional member of the Board of Directors, and a minimum of three (3) Active Members who will be recommended by the Publication Chair and appointed subject to approval by majority vote of the Board of Directors.
- C. <u>Education Committee</u>. The Education Committee will be responsible for Fetal Heart Society education initiatives including creating and maintaining a curriculum for web

based and written educational materials for providers, nurses, coordinators and parent education. The Chairman of the Education Committee is an elected Officer and *ex officio* Member of the Board of Directors and serves a three (3) year term, such term, which may be renewable for one (1) additional term, with the option for re-election after three (3) years have elapsed since their last term. The remaining committee members shall consist of a minimum of three (3) Active Members who will be recommended by the Education Chair and appointed subject to approval by majority vote of the Board of Directors.

Section 4. Vacancies. Vacancies in the membership of any committee may be filled by appointments made in the same manner as provided in the case of the original appointments.

Section 5. Quorum and Manner of Acting. Unless otherwise provided in the resolution of the Board of Directors or Executive Committee designating a committee, a majority of the whole committee shall constitute a quorum, and the act of a majority of the committee's members present at a meeting at which a quorum is present shall be the act of the committee.

Meeting Procedures. The Committee's Chairman shall notify members of a Section 6. committee of its meeting or meetings. If the Secretary is not available to serve as Secretary of the committee, the committee's chairman shall designate a Secretary. Full minutes of each meeting shall be recorded by the Secretary, containing results of the deliberations of any committee with recommendations, if any, and submitted within thirty (30) days of each committee meeting to the Board of Directors. To the extent permitted by the Act, any person participating in a meeting of any committee may participate by means of conference telephone or by any means of communication by which all persons participating in the meeting are able to hear one another and otherwise fully participate in such meeting. Such participation shall constitute presence in person at such meeting. Any action required to be taken at a meeting of any committee or any action which may be taken at a meeting of any committee may be taken without a meeting if a consent in writing, setting forth the action so taken, shall be signed by all of the committee members entitled to vote with respect to the subject matter thereof. Each committee may adopt rules for its own governance not inconsistent with these Bylaws or with rules adopted by the Board of Directors; provided, however, that all committee meetings shall be conducted in accordance with the latest edition of Robert's Rules of Order.

Section 7. Limitation on Delegated Authority. Actions taken by committees shall in all instances be subject to Article XII (Declaration of Policy) of these Bylaws, relating to limitations of responsibility and authority and restricting commitments on behalf of the Corporation and in matters of policy.

ARTICLE VIII Employees

One (1) or more employees or entities, if such employees or entities are deemed necessary by the Executive Committee, may be hired on a full- or part-time basis, on a temporary or permanent basis, and on an employment or contract basis, by the President.

ARTICLE IX Compensation

Officers and Directors as such shall not receive any salary for their services, but by resolution of the Board of Directors, reimbursement to Officers and Directors of expenses of attendance, if any, may be permitted for one (1) or more regular or special meetings per year of the Board of Directors; provided, that nothing herein shall be construed to preclude an Officer or Director from serving the Corporation in any other capacity and receiving reasonable compensation therefor.

ARTICLE X <u>Finances</u>

Section 1. Fiscal Year. The fiscal year of the Corporation shall be July 1 through June 30, or such other period established by the Board of Directors.

Section 2. Operating Budget. An annual operating budget of the Corporation shall be prepared by the Treasurer and approved by the Board of Directors each year prior to the beginning of the Corporation's fiscal year.

Section 3. Contracts. The Board of Directors may authorize any Officer or Officers, or agent or agents of the Corporation, in addition to the Officers so authorized by these Bylaws, to enter into any contract or execute or deliver any instrument in the name of or on behalf of the Corporation. Such authority may be general or confined to specific instances.

Section 4. Checks and Drafts. All checks, drafts or other orders for the payment of money, notes or other evidence of indebtedness issued in the name of the Corporation shall be signed by such Officer or Officers, or agent or agents of the Corporation, and in such manner as shall be determined by resolution of the Board of Directors. In the absence of such determination by the Board of Directors, such instruments shall be signed by the Treasurer of the Corporation.

Section 5. Deposits. All funds of the Corporation shall be deposited to the credit of the Corporation in such banks, trust companies or other depositories as the Board of Directors may select.

Section 6. Internal Controls. The Board of Directors shall ensure that reasonably proper and sufficient controls of the Corporation's finances are established and maintained.

Section 7. Grants. The Board of Directors may authorize from time to time the making of grants to organizations exempt under Section 501(c)(3) of the Internal Revenue Code. Such grants must be restricted such that the amounts of the grant are dedicated solely to activities consistent with the Corporation's exempt purposes.

Section 8. Acceptance of Contributions. The Corporation may accept gifts, legacies, donations, contributions, and/or grant funding, and in any amount and any form from time to time upon such terms and conditions as may be decided from time to time by the Board of Directors.

ARTICLE XI Books and Records

The Corporation shall keep correct and complete books and records of account and shall keep minutes of the proceedings of its Board of Directors, committees having any of the authority of the Board of Directors, and of the Active Members.

ARTICLE XII Waiver of Notice

Whenever any notice is required to be given under the provisions of the Act, the Corporation's Articles of Incorporation, or these Bylaws, a waiver thereof in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice. Attendance at a meeting shall constitute a waiver of notice of such meeting, except where the person attends such meeting for the express purpose of objecting to the transaction of any business because the meeting was not properly called.

ARTICLE XIII Declaration of Policy

Responsibility and authority for any declaration of Corporation policy, and/or endorsement, and/or rejection of any matter on any subject of policy, is reserved to the judgment and discretion of the Board of Directors of the Corporation. Committees members of the Corporation are not authorized directly or indirectly to commit the Corporation in any way or in any manner, financially or otherwise, without the prior approval of the Board of Directors. The Board of Directors, except as otherwise provided herein, shall have control of the affairs of the Corporation, including all matters relating to the acquisition, holding, management, control, investment, and disposition of the funds and other property of the Corporation.

ARTICLE XIV Limitation of Liability and Indemnification

Section 1. Limitation of Liability. The personal liability of the Officers, Directors and employees of the Corporation is hereby eliminated to the fullest extent permitted by the Act and the Code.

Section 2. Indemnification. The Corporation shall, to the fullest extent permitted by the Act and the Code, indemnify and hold harmless its Officers, Directors and employees from and against any and all of the costs and expenses (including reasonable attorneys' fees and expenses), liabilities or other matters of the Corporation. The indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any Bylaw, agreement, vote of disinterested Directors, or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office. Such indemnification shall continue as to a person who has ceased to be an Officer, Director or employee of the Corporation, and shall inure to the benefit of the heirs, executors, administrators, beneficiaries, and other successors in interest or obligation of such person. The Corporation shall be authorized but not required to purchase insurance for the purpose of the indemnification provided for herein; provided, however, that such indemnification shall not be limited by the scope or extent of such insurance.

ARTICLE XV Duration

The duration of the Corporation shall be perpetual, except that it may be dissolved in the manner provided by the Act.

ARTICLE XVI <u>Amendments</u>

Section 1. Amendment Procedure. Amendments to these Bylaws may be made by a proposal by the Board of Directors, which shall be submitted to the Active Membership for approval. A majority of the Active Members voting where a quorum is satisfied, either at a meeting or by ballot, must approve the proposed amendments.



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

FETAL HEART SOCIETY RESEARCH COLLABORATIVE

RESEARCH PROPOSAL AND STUDY IMPLEMENTATION GUIDELINES

I. Research Collaborative Goals

- To foster collaborative multicenter research studies among fetal cardiovascular researchers from any relevant discipline Research studies will include retrospective, prospective, quality assurance/outcomes studies or large case series
- b. To develop and maintain centralized image and clinical data storage repositories for present and future research studies
- c. To facilitate submission and timely peer-review of research proposals from investigators by providing a documentation framework for proposal submission and regular meetings for review of proposals
- d. To share accepted research proposals with other FHS Members and identify investigators interested in participating in that proposal
- e. To facilitate and provide guidance toward publication in quality journals

II. Research Collaborative

- a. Definition: The group of Members that oversee all aspects of research performed under the auspices of the FHS
- b. Members and Defining Roles:
 - i. FHS Research Collaborative Committee: Oversees the research proposal and approval process
 - FHS Publications Committee: Oversee and guide the publication process for presentations, abstracts, and manuscripts generated from FHS research
 - iii. Principal Investigator: Generates the concept and full proposals, develops the core study working group for the full proposal, ensures copies of the full proposal and ethics submission materials are provided to all participating sites/investigators within a timely fashion, ensures that appropriate development of databases and data entry training occurs, ensures entered data is cleaned and analyzed appropriately, provides every 2 month updates to the Research Collaborative and Publication Committee advisors on progress,

coordinates imaging study reviews, is responsible for data analysis and generation of first draft of an abstract(s) and manuscript(s), getting feedback initially from the core study group, Research Collaborative and Publication Committee advisors and sending to remaining investigators with well-defined time line for completion. A Senior Investigator, when present, holds the same responsibilities as the Principal Investigator and both are fully accountable for research completion. The Principal Investigator is also responsible for overseeing the budget and any costs incurred.

- iv. Study Working Group(s): The group of FHS Active or Affiliate Members actively participating in a given study
- Research Study Advisor(s): 1-2 Active Members of the Research v. Collaborative Committee assigned by the Research Chair to oversee a given project after a Concept Research Proposal is approved. The Advisor(s) will provide guidance and support for the Principal Investigator(s) in conducting the research, will ensure adherence to committee guidelines, and will provide progress updates to the Research Collaborative Committee at quarterly meetings. The Research Collaborative Committee Advisor should be invited to Study Working Group meetings, and may choose to meet periodically with the Principal Investigator; at least every 2 months is recommended. The Research Collaborative Committee Advisor will review any abstract and manuscript submissions and must provide approval on behalf of the Research Collaborative Committee before submission. Note: Study Advisor(s) will also include 1-2 Active Members from the Publications Committee known as Publication Committee Advisors (see section on Publication Guidelines)
 - vi. If applicable, a Grant Advisor will also be assigned to the study after the Concept Proposal is approved. This will be applicable in situations when 1) the Research Collaborative Committee recommends funding to support the intended study and/or 2) the investigator has indicated they intend to apply for a grant

III. Research Collaborative Committee

- a. Definition: The group of FHS Active Members that oversee the research proposal and approval process of proposals submitted to the FHS
- b. Composition
 - i. Research Officer (serving as Chair)
 - 1. FHS Active Member
 - 2. Elected by a vote of a plurality of the Active Members and approved by a majority vote of the Board of Directors

- 3. 3 year term with option for re-election for 1 term in succession
- 4. Member of the Board of Directors
- ii. Research Collaborative Committee Members
 - 1. One Member of the Board of Directors (apart from the Chair)
 - 2. A minimum of 3 other Active Members will be recommended by the Research Chair and appointed to the committee subject to approval by majority vote of the Board of Directors
 - 3. Minimum of 1 year appointment
 - 4. May serve on other Committees
 - 5. Additional recommendations for Membership may be made on an ad-hoc basis by the Research Chair and will be appointed subject to approval by majority vote of the Board of Directors
- c. Function
 - i. Provide participants general template documents needed to conduct multisite collaborative research, including
 - 1. FHS Concept and Full Research Proposal Guidelines
 - 2. Documents for use in Internal Review Board submissions
 - 3. Business Associate Agreements and/or Data Use Agreements allowing sharing of clinical research data across all Members of the FHS while allowing for maintenance of autonomy of individual Members within the scope of their individual practices/institutions
 - ii. Review submitted research proposals, provide feedback to Principal Investigators, and present recommendations to the Board of Directors to determine suitability for involvement of the FHS
 - iii. Provide study Principal Investigator with structured mentoring support for proposal revision and refinement prior to final study presentation and submission
 - iv. Oversee centralized image and clinical data storage, including making recommendations to the Board of Directors for funds directed towards data storage and management
 - v. Develop and periodically reassess and revise procedures/protocols for submission, review, and implementation of research proposals

IV. Research Study Proposal and Approval Process

- a. Concept Research Proposal
 - i. Study proposals must be submitted by a FHS Active Member who will be the designated the Principal Investigator
 - ii. The Principal Investigator should submit electronic version of a 1-2 page Concept Research Proposal to the Research Chair
 - iii. Deadline for Concept Research Proposal Submission is 2 weeks prior to quarterly conference calls or in-person meetings of the Research

Collaborative Committee Note: Submissions received after this deadline may be deferred to the following quarterly conference call

- iv. The Research Chair will distribute a copy of the proposal for review to the Research Collaborative Committee
- v. Proposals will be approved by the Research Collaborative Committee based on scientific merit, feasibility, and study goals aligned with the mission of the FHS. If project proposals with significant overlap are submitted, the Research Collaborative Committee may suggest merging of proposals and investigator efforts
- vi. If a Principal Investigator is a current Member of the Research Collaborative Committee, he/she should excuse him/herself from voting on the acceptance of his/her research proposal but may participate in discussion at the discretion of the Research Chair
- vii. A majority approval of the Research Collaborative Committee moves the study proposal forward to the Board of Directors for voting. Majority approval from the Board of Directors then moves the study proposal forward
- viii. The Research Chair or designee will notify the Principal Investigator of concept proposal status within 10 days of the Research Collaborative Committee quarterly conference call
- b. Developing the FHS Study Working Group
 - i. The Study Working Group is the group of FHS Active and Affiliate Members actively participating in a given study
 - Once the Concept research proposal is approved, notification of approval will be sent to FHS Active and Affiliate Members, with request for Members seeking to be included in the Study Working Group
 - iii. FHS Active and Affiliate Members interested in joining the Study Working Group will be instructed to contact the Study Principal Investigator
 - iv. Based on responses to the notification, the Principal Investigator will contact interested FHS Active and Affiliate Members to arrange a minimum of one conference call meeting or in-person meeting to further discuss and develop the project
 - v. The aims of the meeting(s) will be to
 - 1. Define who will comprise the Study Working Group (generally those expressing interest and willing to submit cases for the study)
 - 2. Determine study authors and author roles (see Authorship and Publication Guidelines)
 - 3. Further develop the Concept Research Proposal into a Full Research Proposal, including Data Collection instruments
- c. Full Research Proposal (See Table of Recommended Research Proposal Timelines)

- The Full Research Proposal will be submitted by the Study Principal Investigator to the Research Collaborative Chair electronically within 6 months for retrospective studies, 12 months for prospective of acceptance of the Concept Research Proposal and should be submitted no later than 2 weeks prior to the quarterly meeting
- The Full Research Proposal will be reviewed by the Research
 Collaborative Committee at the first available quarterly conference call or
 in-person meeting of the Committee
- iii. The Research Chair will distribute a copy of the proposal for review to the Research Collaborative Committee a minimum of 2 weeks prior to the call
- iv. The Study Principal Investigator will present the proposal to the Research Collaborative Committee at the quarterly conference call or in-person meeting
- v. A vote will be taken by Members of the Research Collaborative Committee to reject, accept as is, accept with minor revisions, or to reconsider after revisions.
 - 1. Proposals will be judged based on the same characteristics described in the Concept Proposal
 - 2. A majority vote from the Research Collaborative Committee is needed for approval
 - 3. If the Primary Investigator sits on the Research Collaborative Committee or the Board of Directors, he/she should excuse him/herself from voting on acceptance of his/her research proposal
- vi. The Research Chair or Research Study Advisor(s) will communicate the decision to the Principal Investigator in writing within 10 days of the Research Collaborative Committee meeting
 - If "accept with minor revisions" is suggested, the Study Principal Investigator and authors should make the suggested changes within 30 days of the response and should return the edited draft to the Research Study Advisor(s) for distribution to the Research Collaborative Committee

The Research Study Advisor(s) will discuss revisions with the Research Collaborative Committee and a final disposition will be determined

2. If "reconsider after revisions" is recommended, the Principal Investigator and Research Study Advisor(s) will work with Members of the Study Working Group to address revisions and will re-submit by the process of original submission Failure to re-submit within one year will constitute withdrawal of the proposal; however, at the discretion of the Research Collaborative Committee, an approved Concept Proposal may be reassigned as a new study

The Principal Investigator would then re-initiate the review process above including a new call for Study Working Group participants

- vii. Once a research proposal has been approved
 - 1. The Research Chair will notify the Board of Directors of the approval
 - 2. The Research Chair will send a letter of the FHS commitment to participate to the Principal Investigator to accompany any submitted grant applications or requests for funding
 - 3. The Research Chair will designate 1-2 Committee Members as the Research Study Advisor(s) to facilitate the rest of the proposal process
- d. Ancillary Studies
 - i. Proposals for Ancillary Studies, defined as studies using data already collected for a prior FHS study, will be submitted directly as a Full Research Proposal (skipping the Concept Proposal step) as above. The Ancillary study Principal Investigator can be any FHS full member, including the original study Principal Investigator, member of the Study Working Group, or a member not involved in the original study. The Ancillary Study Principal Investigator should approach the Co-Investigators from the original study to join the Ancillary Study Working Group as authors or collaborators. If original Co-Investigators have changed institutions and additional data needs to be collected, consideration of identifying Study Working group members that can retrieve these data should be considered.
- e. Surveys or Questionnaire Based Projects
 - Proposals for Surveys/Questionnaires are submitted using the Survey/Questionnaire form. The proposal is reviewed by an assigned subcommittee of the Research Collaborative Committee to determine if the Survey or Questionnaire meets criteria for "research" or not. Proposals deemed to be research are defined as Surveys/Questionnaires designed to answer a question and obtain new knowledge for purposes of dissemination through publication. In this instance, the proposal will be forwarded to the Research Collaborative Committee for review.
 - Proposals submitted to the Research Collaborative Committee in most cases will undergo an expedited initial review as follows: The proposal and Survey or Questionnaire will be sent to the Research Collaborative Committee via email and will reply with one of the following within 7 days: 1) Approve as is, 2) Revise, 3) Move to standard Research Collaborative Committee review, or 4) Reject. If revisions are suggested,

the comments to the authors will be included, and upon return of the proposal, the Research Collaborative Committee will commit to review the revision within 7 days with the same options. Once approved through the expedited pathway, the proposal will be forwarded to the Board of Directors for approval and once approved, a member of the Research Collaborative Committee will be assigned to oversee and advise the investigators as the FHS representative. At times, the Research Collaborative Committee may choose to move the Survey or Questionnaire proposal to standard Research Collaborative Committee review. Once approved by the Board of Directors, the investigators will be instructed to open their study for other collaborators at other FHS sites to include as Study Group members and authors that will assist in survey design, dissemination, analysis and interpretation and reporting of results. In this case, a full Research Collaborative Committee Full Research Proposal should be submitted including input from the entire Study Group.

- iii. Proposals not determined to qualify as research, will be forwarded to the Board of Directors by email for approval. In this instance, a member of the Website Committee will work with the Investigator(s) to post the Survey/Questionnaire on the FHS website and if deemed appropriate, will work with the Secretary to share the Survey/Questionnaire with the membership by email or newsletter.
- iv. All Surveys/Questionnaires that result in a manuscript will be forwarded to the Publications Committee prior to submission for review and to determine wording of FHS support (endorse vs. support vs. sponsored).
- v. The Research Collaborative Committee will keep track of the number of surveys and will ensure a limited number of surveys per year so that the FHS membership is not over-burdened.

V. Study Implementation (See Table of Recommended Research Proposal Timelines)

- a. Once a Full Proposal is approved, the approved proposal will be distributed to the FHS Membership by e-mail and/or posting on the FHS website as an "approved study"
- b. The Principal Investigator and authors will take charge of the study but can elicit help as needed from the Research or Publication Study Advisor(s) and from the Study Working Group
- c. FHS Active and Affiliate Members may choose at this time to join the Study Working Group if they will contribute cases, although additional authors will not be added at this time unless approved by the Study Principal Investigator and Research Collaborative Committee
- d. Institutional Review Board process

i. All FHS Active and Affiliate Members will be encouraged to maintain blanket Institutional Review Board approval at their institution for conduct of retrospective studies without subject contact in collaboration with the FHS

The Research Collaborative Committee will make available standard template Institutional Review Board documents for use

- If a new Institutional Review Board proposal is needed or a specific modification to an existing Institutional Review Board proposal is needed for the study, the Study Principal Investigators and authors will draft a proposal to share with other Members of the Study Working Group
- iii. Obtaining Institutional Review Board or equivalent approval will be the responsibility of the individual FHS Active or Affiliate Member
- iv. All Study Working Group Members will ensure that their participation is in compliance with local regulations regarding conduct of research involving human subjects
- v. Costs associated with Internal Review Board application will be the responsibility of the individual FHS Active and Affiliate Members, not the FHS
- e. The Research and Publication Study Advisor(s) will monitor study progress and adherence to proposed timelines
- f. The Research Chair or Research Study Advisor(s) will update the Board of Directors of the Study status at least twice per year
- g. A current Study Working Group list for each project will be published on Website with other Study Materials
- h. If there are changes to the Study Working group or the planned authors, including author order, addition, or removal of authors from the study, a notification must be submitted to the Publications Committee Conflicts may be reviewed and adjudicated by the Board of Directors
- i. Questions of research compliance should be directed to the Research Collaborative Committee, which will inform the Board of Directors, who will determine if a plan of action is necessary
- j. For research endeavors that fail or are likely to fail to meet deadlines, the Principal Investigator or Senior Investigator must provide justification for the delay to the Research Collaborative Publication Committee in writing with a new acceptable timeline if delay is deemed unavoidable. Recurrent delays may result in the need to identify another Principal Investigator who will take the project forward. The latter decision will be made by the Research Collaborative Committee with approval by the Board of Directors.

VI. Data Sharing/Ownership and Publications

a. As appropriate, Business Associate Agreements and/or Data Use Agreements

should be submitted and maintained by Study Working Group Members as appropriate within the scope of their individual practices/institutions

- b. Data collected, including images, as part of an approved Full Research Proposal Study, will remain under the control of the FHS unless a request to withdraw individual records is made in writing to the Research Collaborative Committee by the submitting Member or their agent
- c. Research and publication of aggregate information from the FHS datasets is prohibited except in the context of FHS business or approved studies; however participation in FHS sponsored studies does not preclude individual publication or presentation of individual or institutional results Members may present or publish their own data, but if the institutional study has similar aims to the FHS study, presenting single center data is strongly discouraged

VII. FHS Research Announcements

- a. All approved FHS research projects will be listed on the FHS website
- b. IRB-approved fetal cardiovascular research projects external to the FHS may be submitted for posting on the FHS website after approval by the Research Collaborative and Board of Directors

Study Type	Concept Proposal Acceptance to Full Proposal Submissions (2 wks before RCC meets)	RCC Full Proposal Approval to PI site IRB Approval & Database Opening*	Time from IRB and Database Finalization at Primary Site(s) to ALL Site IRB Completion	RCC Full Proposal Approval to Data Entry Completed	Data Entry Completion to Data Cleaning & Analysis ^{**}	Data Entry Completion to Manuscript Submission to Pub Committee	Total from RCC Full Proposal Approval to Manuscript Submission
Retrospective Chart Review	3-6 mos	3 mos	3-6 mos	6-12 mos	3 mos	6-9 mos	12-21 mos
Retrospective Chart and Central Image Review	3-6 mos	3 mos	3-6 mos	6-18 mos Timeline based on complexity & patient numbers	3 mos	6-9 mos	36 mos maximum Timeline based on complexity & patient numbers
Prospective	6-12 mos	6 mos	6 mos	3 mos from last patient data end point	6 mos	9-12 mos	Timeline based on complexity & patient numbers
Survey-based study	4 mos 3 mos		105	3 mos	6-8 mos	14-16 mos	

Recommended FHS Research Proposal Timelines

These are meant to be guidelines for research proposal timelines. In developing a proposal, changes from the above should be justified based on complexity of the study, retrospective vs. prospective, and case volumes for any given institution. Volumes and complexity of echo analyses will also need to be considered. <u>Ancillary study timelines</u> should follow original retrospective chart +/- central image review timelines. *PI should start the IRB and database process when the concept proposal is accepted. **Would expect abstract development and submission immediately after data analysis.



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

FETAL HEART SOCIETY PUBLICATION COMMITTEE AUTHORSHIP AND PUBLICATION GUIDELINES

I. Publication Committee Goals

- a. Foster multi-center collaboration with the final goal of presentation and publication of high quality scientific manuscripts
- b. Encourage timely preparation of high quality presentations and publications from FHS Research Collaborative
- c. Provide pre-publication oversight and final approval for presentations and publications involving FHS Research Collaborative studies

II. Publications Committee

- a. Definition: The group of FHS Active Members that oversee and guide the publication process for presentations, abstracts, and manuscripts generated from FHS research
- b. Members and Defining Roles
 - i. Publications Officer (serving as Chair)
 - 1. FHS Active Member
 - 2. Elected by a vote of a plurality of the Active Members and approved by majority vote of the Board of Directors
 - 3. 3 year term with option for re-election for 1 term in succession
 - 4. Member of the Board of Directors
 - ii. Publication Committee Members
 - 1. One Member of the Board of Directors (apart from the Chair)
 - 2. A minimum of 3 other Active Members will be recommended by the Publications Chair and appointed to the committee subject to approval by majority vote of the Board of Directors
 - 3. Minimum of 1 year appointment
 - 4. May serve on other Committees
 - iii. Publications Committee Study Advisors: 1-2 Active Members of the Publication Committee assigned by the Publications Chair to oversee a given project after a Concept Research Proposal is approved. The Publications Committee Advisor will meet with the Principal Investigator(s) and Senior Investigators (when present) within 2 weeks of abstract submission and/or data analysis completion to discuss plans

(approach and timeline) for manuscript completion. After abstract submission, they will meet monthly with the Principal Investigator(s) and Senior investigator until the manuscript is submitted to the Publications Committee.

- c. Function of the Publication Committee
 - i. Provide general oversight of the presentation, writing, and publication process in order to ensure presentation to the scientific community is publication quality research and aligned with the FHS mission and interests Ensure wide representation of Active and Affiliate Members of the FHS and its affiliates
 - ii. Allow for reasonable, maximum citation either through authorship or acknowledgement, both of which would be searchable
 - iii. Ensure that all publications be "for The Fetal Heart Society Research Collaborative"
 - iv. Assist with identification of target journal for publication

III. Authors

- a. Definition: The group of FHS Active and Affiliate Members drawn from the Study Working Group who participate in writing and editing of the manuscript
- b. Composition
 - i. First author
 - ii. Last/Senior author
 - iii. Other authors
- c. Expectations
 - i. Active or Affiliate Members wishing to be authors must
 - 1. Participate in study conference calls or in-person meetings
 - 2. Delineate their anticipated roles during development of the full research proposal in manuscript preparation including as appropriate
 - a. Study design
 - b. Data analysis
 - c. Drafting and writing the manuscript
 - d. Reviewing, and/or editing
 - ii. 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
- ii. Note: Submission of case materials alone does not satisfy the ICMJE authorship requirement

IV. Collaborators

- a. Definition: Any FHS Active or Affiliate Member actively contributing in any way to a FHS study who does not meet authorship criteria
- b. Composition: Members of a Study Working Group who are not authors will be listed in the abstract and manuscript under "Fetal Heart Society Research Collaborative," with names in manuscript searchable in PubMed, but not listed as authors on manuscript
- c. Definition from Medline: <u>Collaborator Names (defined as non-author FHS Study</u> <u>Working Group Members)</u>

"When a group name for a specific consortium, committee, study group, or the like appears in an article byline, the personal names of the Members of that group may be published in the article text. Such names are entered as collaborator names (also called investigator names) for the MEDLINE citation. Collaborator names are entered exactly as they are published in the article, and in the order in which they are published in the article... If a personal name is entered in a PubMed search without a search tag, all citations will be retrieved for which the name is an author or collaborator."

V. Procedures for Abstract/Presentation and Manuscript Preparation and Review

- a. General
 - i. Upon time of completion of data entry, author meetings should be set up to re-state or plan roles and timing of data analysis, as well as anticipated timing of abstract and manuscript completion
 - ii. Changes in Authors: Proposed changes in designated author roles should be submitted by the Principal Investigator to the Publication Study Advisor(s) immediately in writing
 - iii. Author order: The Principal Investigator will determine author order
 - iv. The Publication Committee and Publication Study Advisor(s) will be available to consult and adjudicate regarding disputes in authorship (inclusion, order)Recommendations will be made to the Board by the PublicationCommittee. Decisions regarding disputes will be made by majority vote of the Board of Directors
- b. Abstracts and Presentations
 - i. The Principal Investigator will lead the authors in drafting an abstract

- ii. All authors will be expected to review and edit the abstract
- iii. The expected final draft of the abstract and abstract presentations (oral or poster) should be submitted to the Study Working Group and the Research Collaborative Committee and the Publications Committee Advisors at least 5 days before deadline
- iv. A presenter must be designated by the Principal Investigator and be one of the authors
- v. Presentation material should display the FHS logo
- vi. The author and collaborator lists will always include "Fetal Heart Society Research Collaborative"
- c. Manuscripts
 - i. Journal is selected by Principal Investigator
 - The Publication Study Advisor(s) together with the Research Collaborative Committee Advisor may make suggestions regarding appropriateness of target journal choice and provide guidance regarding audience, mentorship, and preparation to maximize impact of publication
 - iii. The Principal Investigator will notify the Publication Committee Chair and Study Advisor(s) when data collection or patient enrollment as is appropriate for study design is complete
 - iv. The authors will draft a manuscript within one year of completion of the data collection. 6-9 months for retrospective studies and 1 year for prospective studies of data completion
 - v. All abstracts should be converted to manuscript within 6 months of presentation at any national or international meeting
 - vi. Failure to meet the manuscript timeline may result in action by the Publications Committee including but not limited to suggesting alternate authorship or other action as deemed necessary by the Board of Directors
 - vii. The submission ready manuscript will be submitted by the Principal Investigator to the Study Working Group, the Research Collaborative Committee, the Publications Committee, and the Board of Directors for final approval
 - viii. It is expected that the review of the manuscript will be brief (on the order of 2-4 weeks) and that after a majority vote of the Research Collaborative Committee and the Publication Committee, and final approval from the Board of Directors, the manuscript may be submitted by the Principal Investigator or his/her delegate
 - ix. Response to reviews and revisions should be created by the Primary Investigator. The review should be discussed with the Publication Advisor to determine whether the responses and edits to the

manuscript are straightforward or extensive. Responses designated as "straightforward" will be reviewed and approved by the Study Working Group, the Study Advisors and the Publications Committee, and then may be submitted by the Principal Investigator or his/her delegate. Responses designated as "extensive" will be reviewed and finalized by the Study Working Group, and then upon completion submitted to the Research Collaborative Committee, the Publications Committee, and the Board of Directors. It is expected that the review will be brief (on the order of 2 weeks) and that after a majority vote of the Research Collaborative Committee and the Publication Committee, and final approval from the Board of Directors, the revised manuscript may be submitted by the Principal Investigator or his/her delegate.

- x. Each manuscript must provide appropriate recognition of participating authors, institutions, and the FHS
- xi. If the Principal Investigator declines to pursue publication of research then he/she must notify the Publication Committee and Study Advisor(s) as soon as possible though within one year of completion of data collection or patient enrollment (or within 2 years of an approved Study Concept Proposal)

Lead authorship will then be offered to another investigator on the study

xii. Competitors for lead authorship will be ranked on level of contribution to the study and adjudicated by majority vote of the Publications Committee

Any conflicts will be resolved by the Board of Directors

xiii. The Publication Committee Chair will notify the Primary Investigator (or alternate lead author) if timelines noted above are not met No further research proposals will be accepted from Principal Investigator (or alternate lead author) until the manuscript is submitted



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)

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 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)



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 <u>novel</u> 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

- 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
 - ii. 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.
 - 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, <u>publications@fetalheartsociety.org</u>.

<u>Project Name/Working title:</u> <u>Version of this form:</u> <u>Date submitted to Publications Committee:</u> <u>Date approved:</u>

<u>I. Current paper proposed listings, in order:</u> <u>AUTHORS with institution (meets ICMJE criteria)</u> 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: Name	RoleAuthor=ACollabor-ator=CNone=N	Project title:						
		Concept/ Design	IRB/ database	Recruit- ment	Data acquire/ entry/ Upload	Data analysis	Primary manuscript drafting	Manuscript editing/ revision

(Attach additional pages as necessary)



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

FETAL HEART SOCIETY SURVEY/QUESTIONNAIRE PROPOSAL

Deadline: Rolling

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

Date:

Study Title:

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

Intended Use of Survey: Please delineate whether the results of this survey will be used for the purposes of answering a question and obtaining new knowledge for purposes of dissemination through publication vs. a survey intended to assess best practices or for quality purposes that will not be submitted for publication. If this is intended as a research product, please address A. – C. below:

A. Specific Aims: Please delineate specific research questions and hypotheses that the survey aims to study.

B. Significance/Background: Please provide background that justifies why this survey based study is important

C. Brief Approach:

- 1. Survey design (i.e. validation process or previously validated)
- 2. Study population (who will the survey be distributed to)
- 3. Independent variables: List variables to be studied (What are the primary predictors of the survey)
- 4. Outcomes/Dependent variables: List primary and secondary outcomes.
- 5. Timeline
- 6. Budget details. May be non-applicable for survey based studies unless assistance is requested from the DCC for distribution of survey and/or analysis of survey results.

Please attach a copy of the survey to your submission.



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

MEMBERSHIP DUES:

Membership dues as approved on July 1, 2015 shall be as follows:

Full Membership: \$200 Affiliate Membership: \$50

INSTITUTIONAL and CORPORATE SPONSORSHIP:

Institutions and other organizations will have the opportunity act as sponsors of the FHS at a minimum amount of \$5,000 per year (gold sponsorship) or a minimum amount of \$7,500 per year (platinum sponsorship).

Institutional Sponsors shall receive the following:

- Recognition on the Fetal Heart Society website Sponsorship page, including the institution's name and logo, and a list of all Fetal Heart Society members from the institution;
- Recognition on electronic and print communications of the Fetal Heart Society, and acknowledgement in all abstract presentations and publications for each year of sponsorship, which recognition shall include the institution's name and logo;
- Waiver of individual membership fees for up to 5 FHS Active Memberships and 5 FHS Affiliate Memberships (gold sponsorship) or unlimited Memberships (platinum sponsorship). Such memberships may only be provided to employees or representatives of the institution or organization that otherwise meet all requirements for the respective class of FHS membership. Such memberships shall be valid for each year of sponsorship by the institution.

Companies and Corporations will have the opportunity to sponsor the FHS, subject to approval from the majority of the FHS Board of Directors. Corporate sponsors shall receive the following:

• Recognition of the company or corporation on the Fetal Heart Society website Sponsorship page, including the company's name and logo.

All institutional and corporate sponsors must enter into written sponsorship agreement with FHS, which agreement will set forth the purpose and amount of the sponsorship, as well as the form of acknowledgment and any other sponsorship benefits that will be provided to the sponsor. The sponsorship agreement shall be in a form approved by the FHS Board of Directors.



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

COMMITTEES as of 7/1/2015 Website Committee Membership Committee Steering Committee

COMMITTEES ADDED as of 4/5/2016 Finance Committee, under the direction of the Treasurer Correspondence Committee, under the direction of the Secretary Conference Committee, under the direction of the President

COMMITTEES ELIMINATED as of 4/5/2016 Steering Committee

COMMITTEES ADDED as of 4/11/2016 Education Committee

COMMITTEES ADDED as of 7/10/19 DCC Committee

COMMITTEES ADDED as of 11/01/2019 Nursing Committee Social Media Committee

COMMITTEES ADDED as of 1/1/2021 Mentorship Committee Sonographer Committee



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

Recommended Level of Experience for Governing Board Positions:

- President and Vice President- service on the Board for at least three years (one term)
- Secretary, Treasurer, Member at Large- service on a committee for at least three years
- Research Officer and Publications Officer- service on the Research Collaborative Committee for at least three years
- Education Officer-service on the Education Committee or Conference Committee for at least three years

Alternatively, for any Board positions, recommended experience may be waived if there is an invitation approved by a majority vote of the Board.



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

Cyber Address & Mailing Address

The email address for Fetal Heart Society's administrator is:

• <u>admin@fetalheartsociety.org</u>

Fetal Heart Society's mailing address for correspondence is:

14750 Sweitzer Lane, Suite 100 Laurel, Maryland 20707