North American Fetal Therapy Network
www.naftnet.org

Official Rules and Policies Pertaining to the North American Fetal Therapy Network (NAFTNet)

www.NAFTNet.org

Adopted
April 20, 2012

Amended
October 20, 2012
October 12, 2018
October 28, 2022
January 16, 2025

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I. MISSION

A. The primary mission of the NAFTNet is to:

A.1. Provide a cooperative clinical research network to study the natural history of fetal disease

A.2. Develop and evaluate therapeutic prenatal interventions to improve outcomes

B. The secondary missions of the NAFTNet include:

B.1. Function as an educational resource for patients and healthcare providers

B.2. Train future leaders in clinical and basic science research in the field of fetal intervention

II. ORGANIZATIONAL STRUCTURE

A. BOARD OF DIRECTORS

A.1. Membership

A.1.1. 9 members

A.1.2. Maternal Fetal Medicine and Obstetricians trained and active in fetal intervention

A.1.3. Pediatric medical or surgical subspecialists active in fetal intervention

A.1.4. Officers

A.1.4.1. Chairperson

A.1.4.2. Vice-Chairperson

A.1.4.3. Treasurer

A.1.4.4. Secretary

A.1.5. No more than 2 members may be from the same Center

A.2. Function

A.2.1. Administrative support for Network

A.2.2. Establish guidelines for study submission

A.2.3 Initial screening of study concept proposals

A.2.4. Educational development

A.2.5 Promote the mission through website development

A.2.6. Establish financial support for Network activities from outside resources infrastructure and ensure financial stability of the Network

A.2.7. Oversight of Steering Committee Activities

A.2.8. Set annual membership dues and requirements

A.2.9. Change bylaws as needed by 2/3 majority vote of the Board

A.2.10. Administer disciplinary action

A.2.11. Develop and maintain systems to centralized Network records and data management

A.2.12. Report to Steering Committee administrative activities biannually

B. GENERAL MEMBERSHIP

B.1. Membership:

B.1.1. Member Center eligibility

B.1.1.1 Fetal Diagnosis and Treatment Center with desire for active participation in NAFTNet including international locations. Center definition: Institution with prenatal diagnosis and/or fetal intervention expertise, and the ability to contribute to clinical or

basic science research in prenatal diagnosis or fetal intervention.

B.1.2. Application:

B.1.2.1. Applications are accepted for NAFTNet Membership on a rolling basis

B.1.2.2. Prospective member centers will submit application and application fee to NAFTNet/Membership Committee.

B.1.2.4. Membership applications will be reviewed at the next regularly scheduled Board meeting. Membership is effective Jan 1 with the expectation of the new center attending their first meeting immediately upon Board approval

B.1.2.5. Centers will be added after approval of the Membership Subcommittee as a "Member Center" (as Steering Committee or General status) and the Board votes to provide final recommendation. A simple majority of the Subcommittee and the Board is required. As the Network grows, regional specialization to facilitate study evaluations, interventions, data coordination and collection, and specimen acquisition may be considered. All approvals are based on submission date of a complete application and receipt of application fee, not on date of inquiry.

B.1.3 Membership requirements

B.1.3.1. Annual dues. Deadline: By the Spring NAFTNet Meeting. Annual dues invoice will be sent out to NAFTNet centers on January 1st. If there is no payment from the center by July 1st a letter will be drafted indicating impending termination of membership if payment is not received by August 1st.

B.1.3.2. Annual center clinical data. Submission deadline: March 15

B.1.3.2.1. Annual documentation of antenatal ultrasound volume with diversity of detected fetal structural or physiologic malformations and selective fetal intervention will be provided by all NAFTNet member centers (Appendix 1rev2).

B.1.3.2.2. President of the Board of Directors is the only individual who has access to center data. All other members will only have access to aggregate data posted on web site.

B.1.3.3 Centers who fail to submit annual dues or data by March 15th are not permitted to vote at the Spring (April) Meeting. Centers who fail to submit dues or data by July 1st will not be allowed to retain NAFTNet membership. The application process will be restarted after dues and data are not received by July 1.

B.1.4. General Membership benefits and expectations

B.1.4.1. Benefits: General Member Centers will designate one Primary and one Alternate person to attend biannual meetings –

non-voting member for research proposals, leadership elections

B.1.4.2. Expectations: Participate in research

B.1.4.2.1 Contribute data/participants to study with authorship based on ICMJE guidelines (icmje.org). Scientific Review Subcommitee (SRS, defined in Section II.E.) may apply these guidelines in the setting of conflicts of authorship

B.1.4.2.2. Propose NAFTNet study/PI study

B.1.4.3. Expectation: Subcommittee participation – participate in ongoing NAFTNet subcommittee

B.1.4.4. All active Centers will have password-limited access to a secured section of the NAFTNet website that lists ongoing supported studies, principal investigators, study coordinators, contact information and study protocols.

B.1.5. Membership status review. All member centers will be reviewed for continued General Member status and/or Steering Committee membership at least once every two years (April meeting) by the Membership Committee and will be granted one of the following, subject to Board approval:

a) Continued General Member status

b) Membership in the Steering Committee

c) Movement to General Member status from Steering Committee

d) Loss of Steering Committee or General Member status

C. STEERING COMMITTEE

C.1 Steering committee eligibility

C.1.1 A Fetal Treatment Center meeting the requirements of NAFTNet Membership (B.1) and active clinical program in fetal diagnosis and/or intervention described as:

a) Member center with an established (2 year) history of performance of complex fetal diagnosis and/or therapy

b) Member center with established participation in NAFTNet – defined as active leadership role (committee chair, Board of Directors member), study PI, NAFTNet paper authorship, or contribution to ongoing NAFTNet prospective database (fMMC or Monochorionic Database), and active involvement and enrollment in NAFTNet studies.

C.2. Steering Committee membership benefits and expectations

C.2.1. Benefits: Center vote for NAFTNet supported research, programs, leadership

C.2.2. Benefits: Attend biannual meetings – voting member

C.2.3. Expectations: Participate in research, including ability to utilize SRS for research assistance and eligible for NAFTNet funding support as available

C.2.4. Expectations: Contribute data/participants to study/registry with contribution-based authorship

C.2.5. Expectations: Propose NAFTNet study/PI study

C.2.6. Expectations: Committee participation

C.2.7. Benefit: Eligible for Center's representatives to attain NAFTNet leadership position including committee chair, Board of Directors and Board of Directors leadership positions, and Steering Committee Chair

C.3 Steering Committee Appointment

C.3.1. Steering Committee member centers will designate a principal voting member and an alternate to the Steering Committee

C.3.2. Active participation in NAFTNet activities is responsibility of each Center. Appointment to and continued membership in the Steering Committee requires each Center to have active patient contribution to at least one NAFTNet registry (fMMC and/or Monochorionic Twin Registry) AND have at least two additional active contributions over a biennial time period. Examples of qualifying activities include:

A) Research production – enrollment of patients in active NAFTNet study, PI of a study, or active study proposal. A Center's willingness to participate in studies will be demonstrated by copies of their letters of approval of NAFTNet protocols by their local Investigational Review Board (IRB) that will be available for annual review if requested and evidence of contribution in said study supported by the study PI

B) Faculty participation in NAFTNet sponsored educational activity

C) NAFTNet Committee participation

D) Active leadership position in NAFTNet

E) Ad hoc contribution assigned/sponsored by the Board of Directors (position paper authorship, innovative program leadership)

C.3.3. Membership status review - all members will be reviewed for continued General Membership status and /or Steering Committee Membership based on "Steering Committee Expectations and Active Participation" outlined in Section C.2 and C.3 above at least once every two years (April meeting) and will be granted:

a) Membership to Steering Committee

b) Continued membership in Steering Committee

c) Provisional movement to General Member status with a 1 year 'warning'
d) Movement to General Member status
e) Loss of membership

C.3.4. Board of Director members may attend annual meetings as non-voting members of the Steering Committee unless he/she is the designated member or alternative for that Center at that meeting

C.4 Steering Committee Chairperson

C.4.1. Elected by 2/3 majority of Steering Committee

C.4.2. 3 year appointment

C.4.3. Must be the Member Delegate from a Steering Committee Member Center.

C.5 Steering Committee Ad Hoc Members

C.5.1. Statistical Data Management

C.5.2. Ethics Consultant

C.5.3. Panel of Subspecialists to assist Board in initial study protocol review

C.5.3.1. Pediatrics

C.5.3.2. Cardiology

C.5.3.3. Urology/Nephrology

C.5.3.4. Infant Development

C.5.3.5. Neurology/Neurosurgery

C.5.3.6. Anesthesia

C.5.3.7. Other Subspecialists as needed

C.5.4.1. Pathology, Laboratory Medicine

C.5.4.2. Epidemiology

C.5.4.3. Clinical Genetics

C.6. Steering Committee Function

C.6.1. Review submitted research proposals

C.6.1.1. Members and investigators presenting study proposals are responsible for their own travel and hotel expenses.

C.6.2. Advise and serve as a resource and provide guidance to Principal Investigator (PI) for ongoing NAFTNet supported trials

C.6.3. Provide PI with mentoring support for proposal revision and refinement prior to final study presentation and submission

C.6.4. May serve on Study Oversight Committees if funded and requested by PI

C.6.5. Establish and participate in the following subcommittees and others as so designated by the Board, and to be reviewed by the incoming Board Chair at the beginning of their term.

C.6.5.1. Publication/Ancillary Study

C.6.5.2. Education & Website

C.6.5.3. Innovation

C.6.5.4. Membership:

C.6.5.4.1. Subcommittee is charged with establishing qualifications for NAFTNet membership. The subcommittee is charged with reviewing all members every 2 years to determine membership eligibility status as outlined in section B and C and making recommendations to the Board regarding membership status

C.6.5.4.2. Composed of 3 members from the Board of Directors and 3 members from the Steering Committee

C.6.5.5. Scientific Review Subcommittee (SRS): will be charged with the initial review of studies proposed to NAFTNet as well as provide support for study proposals to ensure optimal scientific merit and feasibility. Ad hoc study groups may be created from the SRS to support development of research projects. As available, the SRS will provide input to the Board to determine studies eligible to receive any available NAFTNet funding support. See Section II.E.

C.6.5.7 Board members, Steering Committee Members, and General Members may participate on other subcommittees

C7. A principal voting member delegate or alternate who leaves a Steering Committee Center will no longer be considered a NAFTNet member delegate unless they are joining another existing NAFTNet Center or if they are currently serving on the Board they may maintain status until their service is concluded. Otherwise, a new member center application needs to be submitted for consideration at the individual's new location. Individual alumni delegate status may be considered through Board review and approval.

D. BIANNUAL MEETINGS

D.1. Meetings are limited to the Board of Directors, Alumni Delegates, Steering Committee Member representatives, General Member representatives, invited ad hoc members, and investigators presenting study proposals.

D.1.1. Each Center (Steering Committee/General Member Center) is allotted 4 attendees to include the delegate and alternate representative, research coordinator, and additional Center clinical or research personnel. Additional personnel from a Member or Steering Committee Member Center may attend at additional cost to the Center. The cost will be determined at the time of registration based on current meeting costs.

D.1.2. All Steering/General Committee Members may participate in discussion during the biannual meetings. Based on projected growth, the Steering Committee member representatives may be located in visibly

identified areas of the meeting to be identified for the voting/business contributions of the meeting

D.1.3. Only the Steering Committee member delegate (or alternate) may vote on NAFTNet business or research proposals during the meeting with one vote per Steering Committee Member Center.

D.2. Biannual Meeting Dates

D.2.1. April and October (typically the 3rd Saturday of the month). Refer to Bylaws Article III.3.8.

D.2.2. The Board of Directors Meeting will be held the evening prior to the Steering Committee Business Meeting

D.2.3. The April meeting is typically designated as the Annual Meeting for elections. Refer to Bylaws Article III.3.8.

E. RESEARCH PROPOSAL SUBMISSION

E.1. Study Concept Proposal

E.1.1. Application must be typed in 11point font, single-spaced, with one inch margins. The length of the proposal is not to exceed 2 pages.

E.1.2. Submitted electronically as an attachment to the Board of Directors Chairperson

E.1.3. Deadline for Concept Form Proposal Submission:

E.1.3.1. December 1st for Spring Meeting

E.1.3.2. June 1st for Fall Meeting

E.1.4. The Chairperson will distribute a copy of the proposal to the Board of Directors for review. A simple majority approval moves the study proposal forward to the Scientific Review Subcommittee

E.1.5. Chairperson or designee will notify applicant and SRS Chair of acceptance within 15 days of receiving proposal and invite the applicant to present complete research proposal to the Scientific Review Subcommittee for review and preparation for the Steering Committee presentation. Questions and concerns about the proposal may be included in the notification letter.

E.1.6. Rejection of the initial concept proposal will be sent to the applicant within 30 days of proposal receipt by the Chairperson of the Board. Reasons for rejection will be included.

E.2. Research Proposal

E.2.1 PI of accepted concept proposal will submit a research study proposal

to Scientific Review Subcommittee (SRS) Chairperson who will forward to subcommittee members. Proposal must be received 3 months prior to the next scheduled meeting (January 15th for the spring meeting, July 15th for the fall meeting). (Appendix 3). The Scientific Review Subcommittee will provide feedback within 2 weeks of reception of the proposal and work with the PI to prepare the proposal for presentation to the Steering Committee. This review and preparation process will be completed 30 days prior to the meeting, to allow the PI to prepare for the oral presentation.
E.2.2. Oral proposal presentation will be in PowerPoint and not to exceed 20 minutes followed by open discussion and questions with the SC. Steering Committee will provide guidance and feedback to improve proposals regardless of vote outcome. The SC will then vote via anonymous ballot

E.2.3. The Steering Committee may either 1) **Approve as presented** as a NAFTNet approved study requires 2/3 of votes for approval OR 2) **Support ongoing development** with a working group and review at the next SC meeting requires a simple majority (>50%) of votes for support development or approval the study OR 3) **Reject** the proposal if 50% or less of votes support development or approve the proposal.

E.2.4. Fast Track
If an investigator has a completed grant proposal in final format that they wish to submit for funding, but would like to submit to NAFTNet for support, the completed grant proposal may be submitted in place of the research study proposal with a request for "Fast Track" status. If after review, the Steering Committee Chairperson believes the proposal does not require major revisions and should be considered for approval, the Chairperson will distribute the proposal to the Steering Committee members or "Fast Track" review and vote at the next meeting. A "Fast Track" proposal is one that can gain final NAFTNet approval at its initial review by a 2/3rds majority of the Steering Committee in an effort to help the investigator increase their chances of obtaining study funding. If, however, the proposal does not achieve approval, it may be submitted for standard NAFTNet review and approval process as noted above.

E.2.5. Approved Study: If a research proposal has been approved as a NAFTNet protocol, the Board of Directors Chairperson will send a letter of Network's commitment to participate to the PI to accompany any submitted grant applications or requests for funding. Information about participating NAFTNet Centers and NIH Biographical Profiles of the designated primary NAFTNet member from the centers will be available to the study PI to from the NAFTNet Executive Office to accompany their funding application.

E.2.6. Supported Development:
E.2.6.1. For proposal obtaining support to move forward but

requiring further review, the Scientific Review Subcommittee Chairperson will appoint a working group (chaired by one member of the Scientific Review Subcommittee) to support the PI. There will be a conference call between the members of the working group within 30 days of the SC meeting to discuss desired improvements to the study. Ongoing feedback will be given to the PI by the working group following each revision until all issues are resolved and the working group feels it is ready for final presentation, aiming for completion of this process within 30 days of the next SC meeting.

E.2.6.2. The working group chair will provide the Scientific Review Subcommittee Chairperson with a progress report after the Steering Committee meeting, describing progress and challenges. The PI will submit the final edited research proposal within 30 days of the next meeting (March 15, September 15) for distribution and review by the full Steering Committee.

E.2.6.3. The PI will re-present the proposal to the next Steering Committee meeting outlining changes made to address the issues raised at the initial presentation. Following further discussion, the study proposal will be voted on for NAFTNet support. An anonymous vote with a 2/3 majority approving support is required

III. BUSINESS PLAN

A. BUDGET

A.1. NAFTNet will be established as a Non-profit Foundation
- A.1.1. A 513 application will be maintained
- A.1.2. The Foundation funds will managed by the NAFTNet Treasurer
- A.1.3. Article of Organization with an official Tax ID number will be established
- A.1.4. An independent Accounting firm will be hired to audit account annually or as required by law; firm to be announced

A.2. Estimated Operational Expenses
- A.2.1. Meetings ~
  - A.2.1.1. Conference room
  - A.2.1.2. Food/Beverage Refreshments
  - A.2.1.3 Travel and lodging expenses for staff
  - A.2.1.4 A/V, entertainment, etc.
- A.2.2. Website maintenance
- A.2.3. Infrastructure maintenance including accounting, legal, insurance, and other expenses
- A.2.4. Management Company Expenses

B. FUNDING FOR NETWORK DEVELOPMENT

B.1. Annual Commitment:
- B.1.1. Member Center, Steering Committee dues are $3000/Center annually
  - B.1.1.1. In the event a Board Member leaves his/her respective Center after being elected to the Board he/she will be allowed to complete the current term limit.
  - B.1.1.2. Steering Committee Member Center, Board of Director dues covers 4 total Center representatives for each biannual meeting
    - B.1.3.2.1 Additional attendee from a Center cost is $150 per person for Friday and Saturday meetings, or $75 per day of attendance

B.2. Annual dues may be adjusted by the Board based on projected budget, present deficits, and projected revenue generated by external sponsoring agencies or industry, and projected revenue from dues based on the number of NAFTNet participating Centers.

B.3. Funding from non-member agencies or funding sources will receive website acknowledgement and link to their respective commercial or nonprofit website.

Appendix 1: NAFTNet Annual Report Form - Updated 2025

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NAFTNet - Annual Data

Below is the questionnaire about your Fetal Treatment Center's annual data. It is recommended to fill it out first, and to save it as a reference, before entering the data on-line.
On-line submission can only be done once per year, and only by one individual per center. By default, the center's lead representative will have access to the data entry pages. If you wish to transfer this access to someone else at your center, please send an e-mail to info@naftnet.org.

Diagnostic Imaging Procedures (Number in/for your Fetal Center patients)	
Complete Anatomic Surveys	
Fetal MRI	
Fetal echocardiography	

Diagnostic Procedures (Numbers performed in Fetal Center)	
Genetic amniocentesis	
Chorionic villus sampling	
Fetal blood sampling	

Available Procedures (Check each that your center offers):	
Vesicoamniotic Shunt	
Thoracoamniotic Shunt (i.e., for lung lesions, pleural fluid)	
Peritoneoamniotic (abdominal) Shunt	
Diagnostic Fetoscopy	
Fetal Cystoscopy	
Fetal Vesicostomy	
Fetal endoscopic tracheal occlusion (FETO)	
Fetoscopic meningomyelocele repair	
Open meningomyelocele repair	
Percutaneous fetal cardiac interventions	
Amniotic Band Resection	
Laser Photocoagulation	
Fetoscopic laser for Vasa Previa	
Radiofrequency Ablation	
Bipolar Umbilical Cord Occlusion	

Umbilical Cord Ligation	
Open fetal surgery for Lung Lesions	
Open fetal surgery for Sacrococcygeal Teratoma	
Open fetal surgery for other (specify)	
EXIT Procedure	
Interstitial laser treatment	
Placental chorangioma treatment	
Anomalies and interventions	
Amniotic band	
# treated w/fetoscopic release	
Fetal neck mass	
# treated w/EXIT procedure	
Structural congenital heart disease (except isolated VSD or ASD)	
# treated with balloon dilation in utero	
# Other interventions (specify)	
Fetal cardiac arrhythmias	
Congenital heart block	
# treated with maternal dexamethasone +/- IVIG	
Supraventricular tachycardia	
# treated with maternal medications	
Chest lesions	
Lung Lesions	
# treated with steroids	
# treated with shunt	
# treated with open fetal surgery	
# EXIT to resection delivery	
Pleural effusions (isolated unilateral or bilateral)	
# treated with thoracocentesis	
# treated with shunt	
# treated with prenatal pleurodesis	
Diaphragmatic hernia	

# diagnosed	
# treated with open fetal surgery	
# treated by fetal tracheal occlusion	
# EXIT to ECMO delivery	

Abdominal wall defects	
Gastroschisis	
# diagnosed	
# treated in-utero (specify)	
Omphalocele	
Total # diagnosed (incl. small ones, with bowel only)	
# giant omphaloceles (containing majority of liver)	
Lower urinary tract obstruction	
# diagnosed	
# treated with shunt	
# treated with fetoscopic ablation of valves (cystoscopy)	
# treated with open vesicostomy	
Meningomyelocele	
# diagnosed	
# treated with fetoscopic surgery	
# treated with open fetal surgery	
Sacrococcygeal teratoma	
# diagnosed	
# treated with open fetal surgery	
# treated with focal thermal or laser vessel ablation	

Number of Intrauterine Transfusions (IUT)	
# Red cell IUT	
# Platelet IUT	
# Stem Cell IUT	
# Exchange Transfusion for TAPS	

Multiple gestation	
Twin-twin transfusion	
# diagnosed	
# treated with only w/amnioreduction	
# treated with only septostomy	
# treated with only laser	
# treated with bipolar coagulation	
# treated with RFA	
# treated with microwave	
# treated with cord ligation	

Discordant anomalies	
# treated with bipolar coagulation	
# treated with RFA	
# treated with microwave	
# treated with cord ligation/transection	
Fetal Growth Restriction (placental insufficiency)	
# treated with bipolar coagulation	
# treated with RFA	
# treated with microwave	
# treated with cord ligation/transection	
TRAP sequence	
# diagnosed	
# treated with bipolar coagulation	
# treated with RFA	
# treated with microwave	
# treated with interstitial laser	
# treated with cord ligation/transection	

Appendix 2: NAFTNet Study Concept Proposal Outline

(Proposal submission format: 11point font, 1.5 line spacing and not to exceed 2 pages)

Primary investigator: Date:

Primary hypothesis and research question:

Secondary hypotheses:

Background and significance of problem to be studied:

Study design

- Study population
- Inclusion criteria
- Exclusion criteria
- Study methodology
- Study methods
- Sample size calculation

Plans for long-term follow-up (methods and length of follow-up)

Please indicate if you are requesting "FAST TRACK" review

Appendix 3: Research Proposal Outline to be presented to NAFTNet Steering Committee

(Proposal submission format: 11 point font, 1.5 line spacing and not to exceed 7 pages unless cleared by Scientific Review Subcommittee.) (Oral powerpoint presentation to the Steering Committee not to exceed 20 minutes)

Primary investigator: Date:

Primary hypothesis and research question:

Secondary hypotheses:

Background and significance of problem to be studied:

Study design:

- Study population
  (Include number of patients, inclusion and exclusion criteria and number of centers that would be involved in enrolling patients)

- Study methodology:
  (Should include type of study. If randomized trial, state method of randomization, whether central or center-specific randomization will be used, stratification or other methods to assure balance, and concealment methods. Define the primary study outcome in sufficient detail to demonstrate that it is clinically relevant, free of bias and measurable in all subjects. State whether interim analyses will be undertaken and for a randomized trial, describe the data and safety-monitoring plan, including formation, location, frequency of review, and criteria that will be used to terminate the study. Are there any special skills or services that will be necessary at centers that enroll patients? How will the PI "certify" centers regarding these skills?).

- Sample size calculation and statistics to be used
  (Include alpha and beta values to be used).

Plans for long-term follow-up:
(Methods and length of follow-up)

Are there any potential maternal or fetal ethical concerns regarding this study? (Outline):

Procedures for informed consent and adverse event reporting:

Proposed time table to complete the study and demonstration of feasibility:

Budget:
(Include detailed, tabular and grant-ready description of time commitment and personnel needs at participating NAFTNet centers, and potential funding mechanisms for this support)

Please indicate if special reviewers should evaluate this proposal:
(Example: pediatric neurology, pediatric cardiology, etc.)

THE NORTH AMERICAN FETAL THERAPY NETWORK
DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

In order for NAFTNet to operate with full credibility in providing a cooperative clinical research network to study the natural history of fetal disease, develop therapeutic prenatal interventions to improve outcomes and function as an educational resource for patients and healthcare providers, it is important that even appearances of conflicts of interest between individual's economic and personal interests and the integrity of NAFTNet activities be avoided. Additionally, conflicts of interest are a potential source of legal liability for NAFTNet.

Conflicts of interest occur when an individual, immediate family member or business associate has a material interest in a company; product or service in which that individual participates is affected by a NAFTNet activity. Conflicts of interest may be real, in that the economic or other interest influences the individual's actions, or may be only perceived, in which case others may believe that the interest precludes unbiased behavior.

NAFTNet, therefore, has established a formal system of disclosure and avoidance of conflicts of interest. This policy applies to Board and Steering Committee and General members.

1. Committee members subject to this policy shall file a statement annually or upon request from NAFTNet Board committee disclosing any material interest in a company, service, product or other concern that might be affected by that individual's NAFTNet, activities. Examples of such interests are: financial interests such as stock ownership (not including "mutual funds" over which the individual has no control); substantial gifts; employment; consultancy arrangements; faculty appointments; arrangements with medical, scientific, or related publishers to write articles or to provide editorial services; pharmaceutical investigation or research support; or honoraria.

2. The disclosure shall include interests of the individual, his or her immediate family (spouse, siblings, parents, and children) and known interests of business associates. In most cases, the interest will be financial, but it may be personal or organizational.

3. The statements shall be files with the Board of Directors Secretary and shall be confidential, except that the Chairpersons of the Board and Steering Committees shall have access to the statements for the purpose of subcommittee member assignment.

4. If any subject is discussed or presented for consideration to the Board or Steering Committee that creates a conflict between any personal or other extra-NAFTNet interests and NAFTNet responsibilities, the individual will agree to disclose the nature of the potential conflict of interest to all present and will agree not to participate in discussion of that subject in any capacity, unless specifically requested to participate by the person responsible for that activity. A determination will be made if the potential conflict is material at the time of the potential conflict disclosure. If the individual is asked to participate in further discussion, the potential conflict will be noted in the minutes. An individual who does not excuse himself / herself from an activity may be asked to do so.

5. Committee members also must strictly adhere to the NAFTNet's confidentiality policy and shall not disseminate information discussed and generated through their NAFTNet activities until a final document or report is issued.

6. The Board of Directors and Steering Committee Chairperson will review and decide any questions of conflicts of interests that arise.

It is important that all persons subject to the conflict of interest policy understand the importance of full cooperation with this policy to assure maximum integrity of NAFTNet actions and minimize NAFTNet's legal liability.

I have read the above statement and agree to disclose any potential conflict of interest with NAFTNet activities.

_____	_____	_____
Date	**Please PRINT name**	**Signature**

Approved by NAFTNet Board of Directors, 11/29/05

THE NORTH AMERICAN FETAL THERAPY NETWORK

CONFIDENTIALITY POLICY
FOR
BOARD OF DIRECTORS, STEERING COMMITTEE AND GENERAL MEMBERS

Unless specifically stated otherwise, information discussed and generated in the NAFTNet Board and Steering Committee meetings must be kept confidential until a final document or report is issued. Members should not discuss publicly or privately specific details about study proposals or ongoing projects. Confidentiality is necessary to avoid spreading misinformation or release of information that may compromise acceptance from private or public funding agencies for research concepts that have been submitted or are under active review. Until the process of generating a document formulating the NAFTNet position has been completed, the network's stand on a particular research project or question as it pertains to fetal therapy is subject to change. In addition, NAFTNet positions may have commercial impact and premature release of information could be used by third parties, such as friends and associates of Board or Steering Committee or General members for personal benefit.

A related but equally important issue is an action by an Board or Steering Committee or General member on the basis of the NAFTNet's "insider" information, taken before that information is made public. When such action economically or academically benefits the individual, it raises a serious conflict of interest issue.

I agree to adhere to the NAFTNet's confidentiality policy.

_____	_____	_____
Date	**Please PRINT name**	**Signature**

Approved by NAFTNet Board of Directors, 11/29/05

THE NORTH AMERICAN FETAL THERAPY NETWORK
CONFLICT OF INTEREST DISCLOSURE

I,_____**,** as a member of the The North American Fetal Therapy Network (NAFTNet):_____Board of Directors_____Steering Committee---------General Membership to the best of my knowledge, I have no material interest, nor does any business associate or anyone in my immediate family, that poses a potential conflict of interest with my current NAFTNet activities, except as follow:

____**None** **Yes** (please list below)

Commercial Vendor: _____
Medical Director, Advisor to; Other
Specify_____) _____

Journal, Periodical: _____
Editor, Assoc Editor, Owner;
Other (specify_____) _____

Significant Ownership:
(Significant % Position) (___%) _____

If any subject is discussed or presented to me for consideration that creates a conflict between any personal or other extra-NAFTNet interests and my NAFTNet responsibilities, I agree to disclose the nature of any potential conflict of interest to the Board and/or Steering Committee members present. I will not participate in discussion of that subject in any capacity, unless specifically requested to participate by the person responsible for that activity. A determination will be made if the potential conflict is material at the time of my disclosure. If I am asked to participate in further discussion, the potential conflict will be noted in the minutes of the committee meeting.

I understand that a material interest is any financial, personal, professional, or institutional interest that would be judged by the majority of my peers to be more than casual and have impact upon my ability to exercise independent judgment in NAFTNet activities.

I agree to adhere to the NAFTNet's confidentiality policy.

_____ _____ _____
Date **Please PRINT name** **Signature**

RETURN TO THE NAFTNet BOARD SECRETARY

Approved by NAFTNet Board of Directors, effective January 1 2023

Scientific Review Subcommittee Terms of Reference
Version 5.0

Date: December 11, 2024

Authors: Stephen P. Emery MD, Anita Moon-Grady MD, and Alain Gagnon MD

Purpose: The purpose of the Scientific Review Subcommittee (SRS) is to evaluate and improve upon initial research proposals before they are presented to the Steering Committee (SC) at the spring and fall SC meetings. The objectives are to:

1. Improve upon the quality of the research proposals being presented at the SC meeting
2. Streamline the review and approval process
3. Increase protocol participation by member centers
4. Increase the likelihood of individual protocols securing extramural funding

Scope: The SRS is a subcommittee of the Steering Committee (SC). The SRS may not function independently of the Steering Committee. The SRS Chair, however, may communicate directly with the Board of Directors (BOD) Chair and/or the Steering Committee Chair, as required.

Authority: The SRS will report to the Steering Committee Chair. Its decision-making authority will be limited to making recommendations to the PI regarding their study protocol, and to the BOD and SC Chair regarding the proposal's readiness to proceed to the SC. The only exception is studies that include only a survey where the SRS can approve the survey on behalf of the SC. Decisions regarding whether the protocol should progress from the BOD to the SRS or should be withdrawn will be made by the BOD based on the concept proposal received. If the BOD moves the proposal to the SRS, the SRS may, after review of the protocol, recommend to the BOD that the protocol: a) be presented to the upcoming SC, b) be withdrawn, c) be postponed, or d) be sent back to the PI for consideration at a later round of review.

Membership: Membership in the SRS is limited to individuals from member centers and ad-hoc members as needed and as determined solely by the SRS Chair. Individuals from member centers need not be principal or alternate members but must attend a majority of SC meetings. At the discretion of the SRS Chair, for selective protocols, one or more "outside experts" in the field may be invited to participate in the protocol review.

Representation: The SRS will include representation from clinical subspecialties that participate in fetal therapy; namely maternal-fetal medicine, pediatric surgery, pediatric cardiology and other pediatric subspecialties, ultrasound, and neonatology, but also include individuals with knowledge of study design and methodology, bioethics, grant writing, and funding. The Chair of the SC is an ex officio member of the SRS.

Service Term: The SRS will consist of at least nine (9) members, including the Chair and Co-Chair. The SRS Chair is appointed by the Board of Directors, and is responsible for maintaining adequate subspecialty representation and

diversity within the subcommittee together with the BOD Chair. The Co-Chair is responsible for assisting the Chair in duties and responsibilities, and for filling in for the Chair if unable to participate, thereby avoiding delays in the review process. A two-year committee member commitment will be requested with the hopes that most members will serve for a minimum of three years or beyond at the discretion of the Chair. The SRS Chair appointment will be a minimum of three years, and no more than six consecutive years.

Process: Research proposal will be presented by the principal investigator (PI) to the Chair of the BOD in writing using the Study Concept Proposal format and timeline posted on the NAFTNet website as outlined in the NAFTNet Policies and Procedures. The concept proposal will be circulated to EC members. A majority vote within the BOD moves the proposal forward to the SRS.

If approved by the BOD, a full proposal will be forwarded by the PI to the NAFTNet Executive Director, who will distribute it to the SRS subcommittee. After individual member review and comment collation, the SRS will convene by teleconference or videoconference to discuss the proposal and finalize the comments for the PI. Thereafter, one to three meetings between the SRS and the PI (+/- members of their research team) will be held to answer questions and review iterations of the proposal based on comments and finalize the research proposal. The SRS Chair or Co-Chair will provide written feedback to the PI after completion of the SRS review, and will continue to work with the PI until the protocol is ready for presentation to the SC.

Once the study is approved by the SC, the SRS will remain available to the PI and will assist in seeing the protocol through to execution (such as grant application review) either directly or by appointing a research support team from the SC membership.

At the request of the PI, the SRS Chair may ask the SC Chair to appoint SC members to create a research support team to assist the PI in refining the research project such as developing data collection tools, defining specific outcomes of interest, and potentially becoming a member of the research study team. The membership of this group should include at least one member of the SRS for continuity.

The SRS will limit reviews to no more than three (3) proposals per 6-month cycle (excluding surveys). The SRS Chair has the liberty to prioritize studies under review or add additional studies in consultation with the BOD Chair and the SC Chair. Although optimal and probable, the SRS is under no obligation to complete the review process of a proposal in a single review cycle.

Timeline: A minimum of three months will be required for the above process in order to have protocols final prior to the April or October meeting.

- For the April meeting: Study Concept Proposals due to the BOD Chair by Dec 1 and full study proposals due to the SRS Chair by January 15
- For the October meeting, proposals due to the BOD Chair by Jun 1 and full study proposals due to the SRS Chair by July 15.

Once the initial Study Concept Proposal is submitted to the BOD Chair, the BOD will reject or approve the proposal. The PI will be notified in writing of the BOD's decision within 2 weeks of submission. Proposals/reviews that do not meet these timelines may roll over to the following SC meeting timeline.

Resources and Budget: The SRS may, from time to time, request resources from the BOD such as the use of the virtual meeting application or a meeting room during the SC meeting. The SRS will be supported by the NAFTNet administrative office. The SRS will not have a budget.

Deliverables: The SRS will report its recommendations to the PI and the BOD in a manner consistent with the timeline presented above. It will also work with the PI and the Publications Subcommittee to proactively address issues including but not limited to authorship, author ranking, and NAFTNet representation.

Review: The SRS will report on its progress to the SC during the Subcommittee Reports section of the twice-yearly SC meeting. The Chair of the SRS will report any significant developments when necessary to the BOD Chair.

Timeline for Concept Proposal Review

4 mo. before SC	3 mo. before SC	2-1 mo. before SC	SC
Study Concept Proposal to BOD Chair	Full Proposal to SRS Chair	SRS Chair convenes teleconference with SRS and PI to finalize proposal	Research Proposal presented to SC
BOD Chair distributes (anonymous) to Board members	SRS Chair distributes to SRS, collates feedback	SRS Chair makes final recommendations on proposal readiness to SC Chair and BOD Chair	SC majority vote for approval
BOD majority vote for approval	SRS Chair convenes teleconferences		Research Proposal becomes Active Protocol
Study Concept Proposal to SRS Chair	SRS Chair gives written feedback to PI		

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