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 and function as an educational resource for patients and healthcare providers, it is important that even the appearance of a conflict of interest between an individual's economic and personal interests and the integrity of NAFTNet activities be avoided. Additionally, conflict of interest is a potential source of legal liability for NAFTNet.

Conflict of interest occurs when an individual, immediate family member or business associate has a material interest in a company; product or service which might be affected by a NAFTNet activity. Conflict 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 for the avoidance of conflict of interest. This policy applies to Executive and Steering Committee members.

- 1. Committee members subject to this policy shall file a statement annually or upon request from NAFTNet Executive 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 filed with the Executive Committee Secretary and shall be confidential, except that the Chairpersons of the Executive 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 Executive 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. The Executive Committee and Steering Committee Chairperson will review and decide any questions of conflict 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

NAFTNet/AJ: 12/11/08

THE NORTH AMERICAN FETAL THERAPY NETWORK

CONFIDENTIALITY POLICY FOR EXECUTIVE AND STEERING COMMITTEE MEMBERS

Unless specifically stated otherwise, information discussed at NAFTNet executive and steering committee meetings must remain confidential until a final document or report is issued. Committee members shall not disclose any matters discussed at these proceedings unless such disclosure is deemed appropriate to support NAFTNet research endeavors. NAFTNet recognizes that it may, on occasion, be necessary to discuss certain aspects of a proposed trial at potential participating sites, in order to determine its feasibility. Any such disclosure <u>must</u> first be approved by the respective NAFTNet committee chairperson.

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 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 Executive or Steering Committee members for personal benefit.

A related but equally important issue is an action by an Executive or Steering committee member on the basis of the NAFTNet's "insider" information, taken before that information has been 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

NAFTNet/AJ:12/11/08

THE NORTH AMERICAN FETAL THERAPY NETWORK CONFLICT OF INTEREST DISCLOSURE

I, _____, am a member of the North American Fetal Therapy Network (NAFTNet): ____Executive Committee ____Steering Committee.

To the best of my knowledge, neither I, nor any immediate family member or business associate, have any material interest that might pose a potential conflict of interest with my current NAFTNet activities, except as follows:

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) (<u>%</u>)	

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 Executive 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 could 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 EXECUTIVE COMMITTEE SECRETARY