



Scientific Review Subcommittee Terms of Reference Version 5.0

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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 Executive Committee (EC) 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 EC 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 Decisions regarding whether the protocol should progress from the EC to the SRS or should be withdrawn will be made by the EC based on the concept proposal received. If the EC moves the proposal to the SRS, the SRS may, after review of the protocol, recommend to the EC that the protocol: a) be presented to the upcoming SC, b) be withdrawn, c) be postponed, or d) be sent back to the PI for consideration at a later round of review.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 responsible for maintaining adequate subspecialty representation and diversity within the subcommittee together with the EC 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 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.

Process: Research proposal will be presented by the principal investigator (PI) to the Chair of the EC 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 EC moves the proposal forward to the SRS.

If approved by the EC, 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 EC 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 EC Chair by Dec 1 and full study proposals due to the SRS Chair by January 15
- For the October meeting, proposals due to the EC 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 EC Chair, the EC will reject or approve the proposal. The PI will be notified in writing of the EC'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 EC 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 EC in a manner consistent with the timeline presented above. It will also work with the PI



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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 EC Chair.



Timeline for Concept Proposal Review

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