

Policy & Procedures

Submission and Review of Research Protocols – August 18, 2021

- 1) A PI at a DBPNet Site interested in proposing a study to be conducted within DBPNet should prepare a brief Letter of Inquiry/Intent (LOII) (according to current Network guidelines and template) which outlines the aims and hypotheses, importance of the question, methods proposed, and any potential funding mechanism. This LOII should be submitted by the DBPNet Steering Committee (SC) member at his/her site to the Network Coordinating Center (NCC). Prospective PIs wishing to consult with the Research Protocol Review Subcommittee (RPR) during the development of an LOII should send a one paragraph description of the project and the investigators questions to the NCC, which will work with the RPR to appoint an appropriate DBPNet Consultant to answer the investigator's questions. In doing so, the submitting investigator may recommend a network member he/she might be interested in working with.
- 2) The LOII for the proposal will be reviewed by the RPR Subcommittee which will consider **network priorities**, importance of the research question, likely feasibility of the study, any human subjects' concerns, competing protocols, and other relevant issues. At the time of submission, 2 supporting DBPNet Consultants appointed by the RPR will be assigned to work with the submitting investigator to ensure that the conceptual framework aligns with the network vision and answer any questions. The consultants will have the authority to act on behalf of the committee and take one of three actions: 1) Approve the proposal ideas for further development (into a full protocol) and consideration at a full committee meeting, 2) decide that the proposal is not appropriate for further consideration as a Network study at this time, or 3) request further information from the investigator before making a decision. Investigators wishing to appeal a decision to reject a LOII may appeal the decision to the SC as described under item #5 below. If the supporting DBPNet consultants disagree with one another in this process, the decision will defer to the chair of the RPR Committee or the chair of the Steering Committee (in the event that the RPR Chair is one of the assigned representatives reviewing). In the event of restrictive timelines (for grant submissions, etc.) the assigned supporting DBPNet consultants may also act on behalf of the committee and approve a LOII without the full protocol going to full committee review.
- 3) The NCC will send all approved LOIIs to all SC members and the chairperson of the RPR or his/her designee will summarize the proposal at the next scheduled SC meeting or conference call.

- 4) The full protocol should be submitted to the RPR by the DBPNet Steering Committee member at the proposal PI's DBPNet site. The protocol will be reviewed by the RPR Subcommittee which will consider the importance of the research question, likely feasibility of the study, any human subjects' concerns, potential for funding, and other relevant issues (including data management) and send protocols recommended for approval to the NCC and SC for consideration. Comments regarding the protocol from SC members or the NCC will be sent to the SC Chairperson who may either schedule an electronic vote to approve or reject the protocol or schedule the protocol for discussion at the next SC meeting or conference call. At the time of the discussion the SC should approve a motion to take one of the following 4 actions: 1) approve the protocol; 2) approve the protocol pending resolution of specific SC stipulations by the PI and Executive Committee; 3) defer the protocol and request clarifications or modifications from the protocol PI; 4) Reject the protocol. A PI may appeal the decision to reject a protocol as described in #5 below.
- 5) LOIIs or full proposals that are declined by the RPR will not be forwarded to the SC for further consideration; notification and the explanation of the reason the proposal was declined will be sent to the PI via the NCC. The decisions of the RPR or the decision of the SC to reject a proposal can be appealed by the PI to the SC Chairperson via a written communication with the NCC; information on the appeal process will accompany the notice that the proposal has been declined.
- 6) Trainees who are conducting their training within a program affiliated with a DBPNet site may serve as a Co-PI for proposals and will require a Co-PI who is a faculty member of a DBPNet site.
- 7) Study proposals initially considered by investigators who are not affiliated with a DBPNet site must first involve a DBPNet member as PI or Co-PI who assumes the responsibility for the proposal and ultimately the project if approved for implementation. The process for submission of the summary proposal proceeds as noted above and is submitted via the Steering Committee member of the DBPNet Site for the PI or Co-PI.
- 8) Confidentiality of DBPNet Protocols: Protocols under review or development by DBPNet are to be considered confidential. DBPNet members agree not to use the information to benefit themselves or others (such as through publication of information drawn from the proposal or to develop alternative proposals for the same or similar studies) and shall not quote or share information from the proposal to others outside the network or those within the network who are not participating in the review or development process. Members of DBPNet should refrain from independently negotiating to participate as an independent research site, collaborator, or consultant during the time a proposal is under consideration or if approved as a Network project.

Format for Submitting a Letter of Inquiry/Intent (LOII) for a Proposal to DBPNet

Page One: Administrative Information

- 1) Title of the Study
- 2) Principal Investigator and Co-Investigators
(Please provide contact information for the PI including mailing address, email address, telephone number, and fax number. If the PI is not at a DBPNet site please also provide contact information for the Co-PI at a DBPNet site)
- 3) Institution of PI
- 4) Length of Study
- 5) List any DBPNet Sites that collaborated in developing this proposal
- 6) Funded? Yes/No, Potential funding sources, estimated budget (if known). Indicate if you are responding to a specific request for proposals. Indicate anticipated budgetary support for collaborating DBPNet sites (with understanding that this may require further discussion).

Pages Two-Four: Structured Scientific Summary

One-three pages with one-inch margins all around. The following information should be incorporated in the scientific summary:

- 1) Background (limited to 2-5 sentences): *Describe the significance of the problem under study to Developmental Behavioral Pediatrics. Describe what is not known about the problem that the proposal intends to address. Describe how DBPNet can best support this proposal and potentially who might best serve as a network consultant to support this work.*
- 2) Preliminary data: *Provide any data that have been collected in support of the application.*
- 3) Objective(s) and Hypothesis(es): *Describe the precise objective(s) of the proposed research. State the specific hypothesis(es) to be tested.*
- 4) Design: *Describe the basic design of the study. Outline inclusion and exclusion criteria and sample size estimates. If feasible, include the number of DBPNet sites you intend to involve or geography/demographics of participants you intend to recruit, so that the network could suggest sites that might fit best. Indicate any specimens to be collected, assessment procedures that will be required, and/or interventions that will be performed. Indicate the primary outcomes and how they will be measured. Indicate your data management plan and what support might be needed from the network.*
- 5) Potential Impact (limit to 1-2 sentences): *Discuss where the research is leading and in what ways and how the findings might potentially influence the prevention, diagnosis and/or treatment of developmental or behavioral problems or disorders in children.*

Please email the completed [submission form](#) to Jaclyn Cacia at caciaj@chop.edu. Investigators may also submit outside of this form as long as all applicable sections are included.

Appendix A

Flow Chart for Submission of Research Proposals to DBPNet

