DBPNet Policy & Procedures

Submission and Review of Research Protocols – 10/30/10
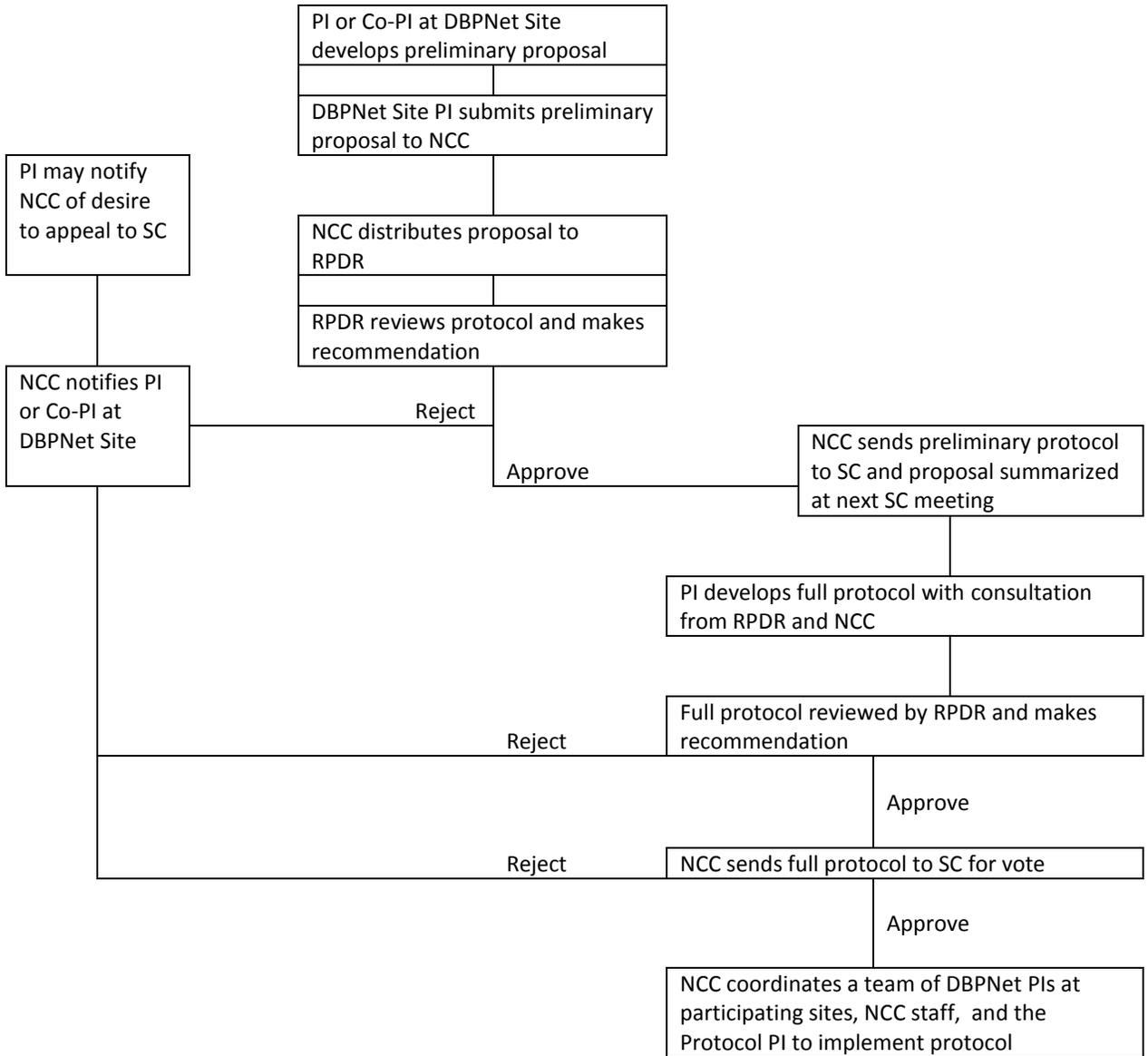
1) A PI at a DBPNet Site interested in proposing a study to be conducted within DBPNet should prepare a brief preliminary proposal (according to current Network guidelines and template; See Appendix B) that outlines the aims and hypotheses, importance of the question, methods proposed, and any potential funding mechanism. This preliminary proposal should be submitted by the DBPNet Steering Committee (SC) member at his/her site to the Network Coordinating Center (NCC). Prospective PI's wishing to consult with the Research Protocol Developmental and Review Subcommittee (RPDR) during the development of this preliminary proposal should send a one paragraph description of the project and the investigators questions to the NCC which will work with the RPDR to appoint an appropriate RPDR or NCC member to answer the investigator's questions.

2) The preliminary proposal will be reviewed by the RPDR 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 and take one of three actions: 1) Approve the proposal for further development and consideration, 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. PIs wishing to appeal a decision to reject a preliminary proposal may appeal the decision to the SC as described under item #5 below.

3) The NCC will send all approved preliminary proposals to all SC members and the chairperson of the RPDR or his/her designee will summarize the proposal at the next scheduled SC meeting or conference call. At the RPDR Chairperson's discretion a member of the RPDR may be assigned to serve as the Subcommittee's contact person for the preliminary proposal's PI.

4) The full protocol should be submitted to the RPDR by the DBPNet Steering Committee member at the proposal PI's DBPNet site. The protocol will be reviewed by the RPDR 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 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) Preliminary or full proposals that are declined by the RPDR 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 RPDR 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.

Appendix A

Flow Chart for Submission of Research Proposals to DBPNet

| PI or Co-PI at DBPNet Site develops preliminary proposal |
| DBPNet Site PI submits preliminary proposal to NCC |

| PI may notify NCC of desire to appeal to SC |

| NCC distributes proposal to RPDR |
| RPDR reviews protocol and makes recommendation |

| NCC notifies PI or Co-PI at DBPNet Site |

Reject

Approve

| NCC sends preliminary protocol to SC and proposal summarized at next SC meeting |

| PI develops full protocol with consultation from RPDR and NCC |

Reject

| Full protocol reviewed by RPDR and makes recommendation |

Approve

Reject

| NCC sends full protocol to SC for vote |

Approve

| NCC coordinates a team of DBPNet PIs at participating sites, NCC staff, and the Protocol PI to implement protocol |

Format for Submitting Preliminary Proposals 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

Pages Two-Three: Structured Scientific Summary
One-two 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.*

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. Indicate the primary outcomes and how they will be measured. Indicate any specimens to be collected, assessment procedures that will be required, and/or interventions that will be performed.*

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.*