

12-20-2021

## Governance Documents

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### Recommended Citation

Lindberg, D., Wood, J., Campbell, K., Pierce, M. C., Scribano, P., Leventhal, J., Laskey, A., & Runyan, D. (2021). Governance Documents. Retrieved from [https://digitalrepository.chop.edu/capnet\\_files/4](https://digitalrepository.chop.edu/capnet_files/4)

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## **Child Abuse Pediatrics Network (CAPNET) Governance Documents**

### **Mission**

To improve the care of children by child abuse pediatricians, we will conduct multisite, collaborative, patient-oriented research.

### **Vision**

Our collaborative research will prevent child maltreatment and advance the care given to abused children and children evaluated for abuse.

### **Structure**

CAPNET will consist of 2 types of sites:

- Participating sites (“spokes”):
  - Must contribute to core data collection – may join other protocols at their discretion.
  - May propose core or secondary analyses, or grant submissions in partnership with managing site.
  - Have at least one board-certified or fellowship-trained child abuse pediatrician (CAP) and a recognized child protection team.
  - Designate one investigator as the site lead.
  - Identify one managing site with whom to work.
  - Meet all defined regulatory and administrative requirements (Human Subjects training, IRB submission, etc)
- Managing sites (“hubs”):
  - Meet all criteria of a participating site.
  - Have at least 2 board certified or fellowship-trained CAPs.
  - Coordinate with at least 3 participating sites.
    - Review and submit project proposals from participating sites.
    - Ensure ethical and regulatory compliance (IRB submission, data entry, etc).
  - Commit to submitting at least 1 project proposal within 2 years of initiating core data collection.
  - Participate in at least a minimum number of supported studies (to be determined biennially-every 2 years) by the steering committee.
  - Include at least one investigator with current or prior external funding.
  - Demonstrate prior experience coordinating IRB proposals.
  - Demonstrate dedicated research infrastructure resources such as grants administration, administrative support, statistical support.

Designation of Participating and Managing sites will be the responsibility of the transition committee until at least 6 Managing sites have been designated, or until 24 months after approval of the initial managing site, whichever is sooner. After this, the Steering Committee will assume responsibility for ongoing evaluation of Managing sites.

### **Officers:**

- Chair – Convenes and Presides at meetings. Signs letters of support/endorsement. Nominates Committee Members for approval by the Steering Committee. Liaises with potential federal funders and DCC. Represents the network at national and other meetings.
- Vice-Chair – Performs the role of the Chair when Chair unavailable; assists the chair with liaison activities.

*Selection:* Vote of the steering committee.

*Terms:* Officers will serve for no more than 2 terms of 3 years each.

### **Amendments:**

These governance documents may be changed or amended by a 75% vote of the Steering Committee. Such vote may occur no sooner than 2 weeks after proposed changes are publicized to CAPNET member sites, funding agencies and other relevant stakeholders.

### **Steering Committee:**

The Steering Committee will establish its own definition of a quorum and of standards to approve any motion (e.g. majority, super-majority).

#### *Role*

- Determines scope of core data collection
- Ultimately approves any new projects
- Establishes new committees, approves committee chairs and members
- Sets broad direction/scope of the network
- Allocates resources
- Resolves disputes
- Manages managing sites

#### *Membership*

- Elected Officers
- One representative from each managing site.
  - Each managing site determines their representative.
- Up to 3 senior advisors
  - Senior Advisors are voting members of the steering committee.
  - May submit core or secondary analyses and grant proposals.
  - Senior advisors will be nominated and invited by a vote of the Steering Committee.
  - Term: 3 years with possibility to renew once. Terms will be staggered among senior advisors.
  - Senior advisors will be selected based on prior success in Child Abuse Research as demonstrated by a record of funding, scholarly publication and reputation.
- If and when funding of the network is obtained, the Steering Committee will include a non-voting representative of the funding agency.
- If and when a data coordinating center is established, the Steering Committee will include one voting representative of the data coordinating center.

### **Research Development Committee:**

#### *Role*

- Initial evaluation of research proposals involving CAPNET – review for importance, methodology, feasibility, fundability

#### *Membership*

- One representative from each managing site – nominated by the managing site
- At least one member of the steering committee
- Chair cannot be member of steering committee

### **Writing & Publication:**

#### *Role*

- Foster the highest quality and quantity of scholarship produced by the network
- Approve requests for data to be used in secondary analyses
- Prevent duplication of analyses
- Determine/manage expectations/timelines for authorship

#### *Membership*

- One representative from each managing site (managing site lead may designate a participating investigator to serve)
- At least one member of the steering committee
- Chair cannot be member of steering committee

### **Grant Management/Regulatory/Quality Assurance (QA):**

#### *Role*

- Foster the submission of competitive grants for federal funding
- Ensure that the network is able to meet commitments defined by grant applications
- Work with network investigators to allocate appropriate funds for approved projects in grant applications
- Recommend approval of all grant submissions (ultimately reviewed by the steering committee)
- Work with each project PI to ensure regulatory compliance with funders
- Develop guidelines and checklists of requirements for QA procedures
- Develop and implement QA policy standards for all network research
- Review all protocols for QA compliance
- Assist lead investigators in meeting QA/regulatory requirements
- Establish protocol and network report cards for QA/regulatory compliance
- Work with the steering committee to ensure that all relevant QA issues are addressed
- Advise lead investigators during protocol development

#### *Membership*

- One representative from each managing site (managing site lead may designate a participating site investigator to serve)
- At least one member of the steering committee
- Chair cannot be member of steering committee

### **Transition Committee:**

#### *Role*

- Oversee the initial start-up phase of the network.
- Certify new Managing and Participating Sites

#### *Membership*

- Phil Scribano
- Kristine Campbell

- Joanne Wood
- John Leventhal
- Mary Clyde Pierce
- Antoinette Laskey
- Des Runyan
- Dan Lindberg
- One representative from each newly certified managing site

*Term*

- The transition committee will oversee the network until 6 Managing Sites have been certified or until 24 months after certification of the first managing site, whichever is sooner.
- At the point that a site is certified as a managing site, any members named above associated with that site will step down from the transition committee unless they are designated as their site's representative.

**Project Selection Process:**

**Principles:**

- Our goal is to be as responsive as possible to submitting investigators, while assuring network members that they will be participating in sound, feasible and impactful research that expands our understanding of the prevention, response and outcomes of child maltreatment.
- Each site will ultimately determine whether they will participate in any given project/module/data collection.
- The Steering Committee (SC) will periodically publish priorities, scope and capacity for the network's near future so that investigators who submit proposals will know which are likely to be funded.
- The Research Development Committee (RDC) will develop and will periodically publish the criteria they will use to evaluate submissions.
- The SC and RDC will develop a process to handle conflicts of interest in the evaluation of all submissions.

**Structure:**

- Anyone can submit a proposal to the RDC. Managing sites should collaborate and facilitate project submissions. All submissions should be reviewed by the lead investigator of the relevant managing site, or his/her designee.
  - This process will be reviewed after 2 years or 10 proposal submissions, whichever comes first.
- Each submission will be reviewed for scientific merit, feasibility, fundability and priority by the RDC. The SC will provide final approval or deferment for studies approved by the RDC based on network capacity and priorities. Each participating site will ultimately determine which projects they participate in.
- The RDC will determine format and content for all submissions. Submissions will need to include enough detail that the RDC can determine whether the project is

methodologically sound, that it could feasibly be completed and to estimate likelihood of funding.

- The RDC will determine ranking criteria and review process. This process will be consistent with and responsive to SC priorities.

### **Timeline Specifics:**

- The RDC will evaluate proposals on a rolling basis once submitted by a managing site (anyone can submit proposals, but these should be vetted by their managing site). Projects will be submitted to the RDC chair who will then distribute the proposal to all RDC members. The RDC chair will recruit a primary and secondary reviewer from the RDC. Primary and secondary reviewers will submit detailed reviews to other committee members by email within 1 month of initial project submission. RDC members will vote (go/no-go) on the project's suitability within 1 week of receiving detailed reviews from primary and secondary reviewers.
- Projects that receive <25% approval from RDC members will be rejected with comments. Projects receiving 25-74% approval will be returned for revision. Projects receiving >75% approval will be forwarded to the SC.
- The SC will review and have a final vote within 1 month of receiving an approved protocol.
- These timelines will be re-evaluated after 2 years or 10 submitted proposals (whichever is earlier) to determine whether they are feasible.

### **Resource Sharing Plan:**

#### **Principles:**

- Authorship should follow effort.
- All authors need to fulfill a journal's requirements for authorship.
- Effort that serves to build and maintain the network infrastructure should be acknowledged along with work on a particular project.
- Authorship, data and funding should incentivize investigators to create viable research protocols, secure external funding, or identify novel analyses.
- Prospectively designed studies and analyses are much better for the network as a whole than retrospective, secondary analyses and authorship should incentivize prospectively designed work.
- Each site will always have access to data from their own site.

#### **Prospectively Proposed Protocols:**

- Investigators that generate prospective protocols for the network are core to the network's success and deserve wide latitude in assigning authorship for core analyses.
- Protocols submitted for consideration of the wider network should include an authorship plan outlining how authorship will be shared.
- Prospectively planned secondary papers should be listed in the protocol submission along with an authorship plan for each secondary paper.
- The Principal Investigator of each prospectively planned protocol should work with participating investigators to fairly distribute other chances for academic credit (i.e. presentations at scientific meetings or in other forums).

### **Secondary Analyses Planned after Data Collection has Begun:**

- Proposals for secondary analyses will include an authorship plan. Additional authors will be determined by the primary author.
- For at least 1 year from data lock, proposals for secondary data analysis of data from protocols in which data collection has begun must include at least one investigator from a participating site for that study.
- After 1 year from data lock, network investigators from sites that do not contribute data to a given study may submit proposals for secondary analyses.
- 2 years after data lock (unless subject to more stringent requirements from an external funder) data will be made available to investigators outside the network.
- The Writing & Publication Committee will review submissions for secondary analyses to determine:
  - Whether another proposal has already been approved to examine the same data or perform the same analyses;
  - Whether the proposal is scientifically valid;
  - Whether the proposal meets ethical, regulatory and data management requirements.
- In cases where 2 investigators propose similar analyses, both of which are methodologically sound, the Writing & Publication Committee may encourage collaboration, or may assign authorship privileges to the first viable submission received.
- The Writing & Publication Committee will establish procedures to eliminate conflict of interest from its decisions.
- All studies that use network data should acknowledge the network as a whole and at least one investigator from all sites that contribute data (e.g. “John Doe, Jane Smith and A.B. Jones for the CAPNET investigators”)
- In cases where requirements of external funding sources conflict with network policy, (e.g. a requirement to make available a public dataset) the requirements of the external funder prevail.
- For protocols submitted after the establishment of the data coordinating center, all analyses must be reviewed by the data coordinating center to ensure internal consistency prior to submission for publication.
- An initial draft manuscript, suitable for submission, should be available to the Writing & Publication Committee within 6 months of the release of data to the authors. If no draft is produced, authorship may be made available to other interested investigators. The initial authors may maintain secondary authorship if they are able to contribute to the manuscript that is ultimately produced.
- Participating sites will retain access to data from their own site at all times, and for all reasons.

### **Pilot Data:**

- Pilot data – where there is no plan for publication, but which is used to support future research – may be released to any participating investigator.
- The chair of the Writing & Publication Committee will review all requests for Pilot Data which should list the specific data requested and the purpose for which it is requested.
- No patient identifiers will be released as pilot data.