



CANADIAN NEONATAL NETWORK™

POLICIES AND PROCEDURES

VERSION 6

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Part 1 – CNN Introduction, Mission Statement and Objectives

Introduction - The Canadian Neonatal Network™ (CNN) is a group of multi-disciplinary researchers who collaborate on research issues related to neonatal care. CNN was founded in 1995 by Dr Shoo Lee and includes members from 30 hospitals (see Appendix B) representing 17 universities across Canada. The Network maintains a standardized neonatal intensive care unit (NICU) database and provides a unique opportunity for researchers to participate in collaborative projects on a national and an international scale. Health care professionals, health services researchers and health administrators participate actively in clinical and epidemiological outcomes, health services, health policy and informatics research aimed at improving efficacy and efficiency of neonatal care. Research results are published in Network reports and in peer-reviewed journals.

As a network, CNN is unique because of the multi-disciplinary nature of the collaborations between researchers and professionals working to improve care and quality of care for infants and their families. Each site investigator must operate under a sponsoring institution (e.g. University medical centre) and must adhere to the guidelines and rules of that institution during their collaborations with other CNN site investigators.

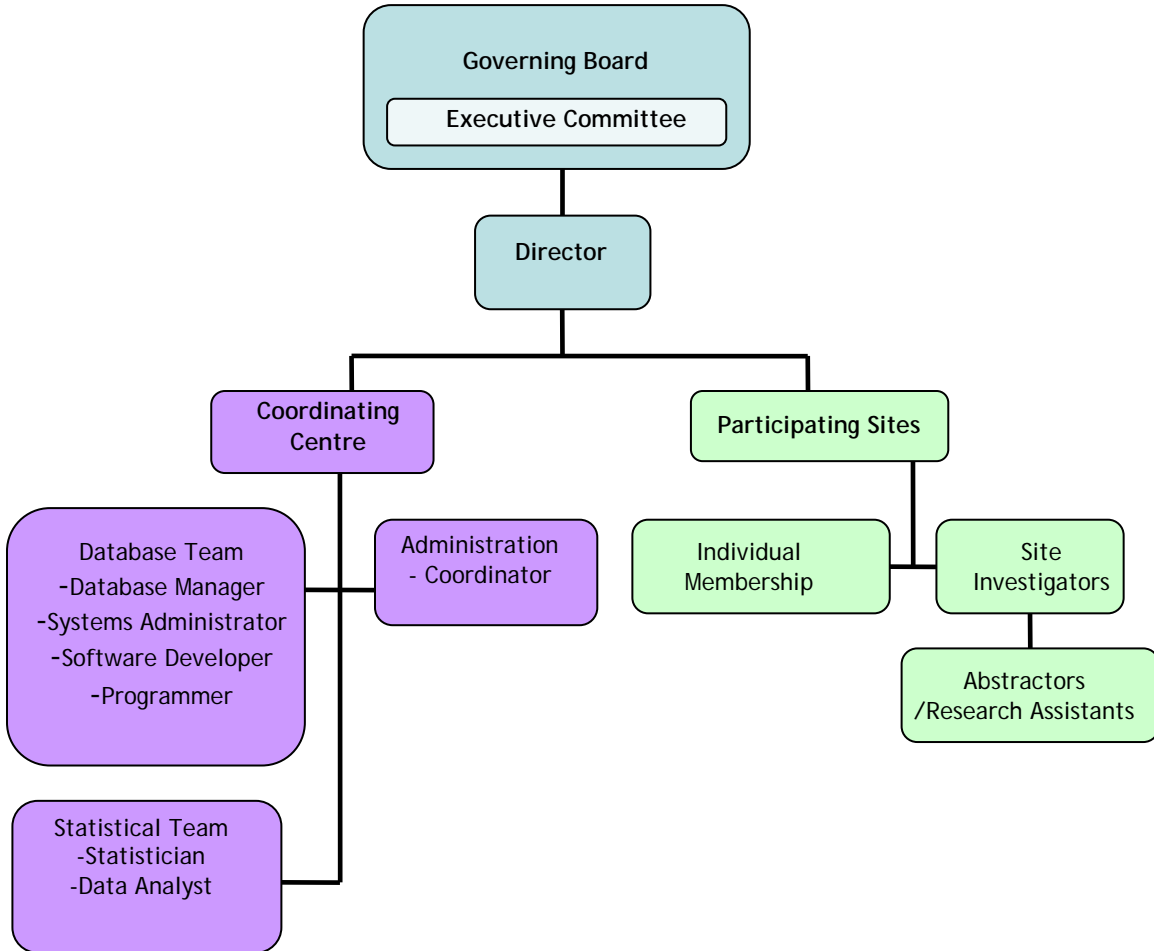
Mission Statement - To be a network of Canadian researchers who conduct leading multi-disciplinary, collaborative research dedicated to the improvement of neonatal-perinatal health and health care internationally.

Objectives - The objectives of CNN are to:

- Establish an international network of multi-disciplinary Canadian researchers interested in neonatal-perinatal research.
- Establish and maintain a truly national neonatal-perinatal database and to provide the infrastructure to facilitate collaborative research.
- Study longitudinal outcomes and variations in medical care incorporating cost-effectiveness of such interventions. This is important because NICU care is one of the largest components of child health care expenditures and exhibits large variations in mortality, morbidity and costs.
- Develop innovative research methods that can result in improvement of health and quality of health care.

Part 2 – Structure

Organizational Structure – The organizational structure of CNN is set forth below.



Governing Board

- The Governing Board sets policies that allow CNN to fulfill its Mission Statement and achieve its objectives.
- The Governing Board has the final decision-making authority on behalf of CNN.
- The Governing Board evaluates the performance of the CNN Director and holds him/her accountable for achieving the established goals and priorities on an annual basis. The Governing Board provides directions to the Director and has the right to appoint or terminate the Director's position at any time.
- The Governing Board meets twice a year. Members should make every effort to participate in the Annual General Meeting (AGM) and at least one (1) teleconference as convened by the Chair.

- Members are expected to attend all Governing Board meetings. Members who are unavoidably absent should provide their written views before the meeting so their views can be made known, recorded and taken account by those present. Proxies are not permitted to attend meetings.
- The Governing Board makes decisions by majority vote.
- The Governing Board shall have a balance of skills and experiences. It is recommended that members of the Governing Board be consisted of both CNN members as well as external members (such as lawyers, bankers, politicians etc). At least one member of the Governing Board must be from Western Canada and at least one member must be able to speak French.
- The Governing Board shall be comprised of six (6) elected members from the CNN membership, no more than six (6) external members, and the Chair.
- Dr. Shoo Lee is the Chair and an ex officio member of the Governing Board.
- The elected CNN members of the Governing Board hold office for a term of three (3) years and are eligible for re-election for one successive term. The terms of office are staggered so that two (2) positions are open for election on an annual basis.
- The Governing Board that is in office appoints the external Governing Board members.

Executive Committee

- The Executive Committee works closely with the Director to provide recommendations on operational and management issues of CNN.
- The Executive Committee works closely with the Director to set the scientific agenda that allows CNN to fulfill its Mission Statement and achieve its objectives.
- The Executive Committee reviews and approves services provided by, and research to be conducted through CNN.
- The Executive Committee sets the eligibility criteria for CNN membership and is responsible for screening membership applications in accordance with the processes and requirements as established by the Executive Committee from time to time.
- There are six Members on the Executive Committee. The Committee Members are elected voting representatives. The two Executive Committee Members who are in their last year of appointment shall co-chair the Executive Committee for one (1) year. The elected Committee Members hold office for a term of three (3) years and are eligible for re-election for successive terms. The terms of office of the elected Committee Members are staggered so that two positions are open for election on an annual basis.
- Individual Members and Site Representatives of Institutional Members are eligible for election as Committee Members. Nominations for the elected Committee Member positions and the process for electing Committee Members from those nominated will take place in accordance with a process established by agreement between the CNN Director and the Executive Committee. Only one of

the Site Investigators or an Institutional Member and any Individual Member associated with that Institutional Member may be a nominee for Committee Member in any year.

- The Executive Committee may establish such rules of procedure relating to the conduct of its business and the calling and holding of meetings as it deems appropriate, provided that all decisions or determinations of the Executive Committee will be made by majority vote of the members entitled to vote on such decision or determination.

CNN Director

- The Director is the scientific and administrative leader of CNN.
- The Director implements the policies as directed by the Governing Board.
- The Director is responsible for the operations and management of CNN, as well as strategic planning of its scientific agenda, while ensuring the Mission Statement and objectives of CNN are fulfilled.
- The Director oversees the functions and supervises the staff of the CNN Coordinating Centre.
- The Director oversees the development and maintenance of the Hosted Database.
- The Director monitors the receipt and expenditure of CNN funds, and is responsible for securing sufficient funds for on-going operations of CNN.
- The Director sets goals and priorities at the beginning of the term, and presents such plan to the Governing Board for approval.
- The Director reports to the Governing Board which reviews his/her performance and achievements on an annual basis.
- The Director prepares the CNN Annual Reports and provides them to the Governing Board for evaluation.
- The Director is accountable to the Governing Board and takes directions from it.
- The Director is appointed by the Governing Board.
- The Director shall serve a term of five (5) years with the possibility of renewal for one (1) successive term.
- The Governing Board has the right to terminate the Director's position at any time.

Project Coordinator - The Project Coordinator is appointed by, and works under the direct supervision of, the Director. The Project Coordinator provides administrative support to CNN and in doing so:

- is responsible for communications between CNN and the Members
- is responsible for monitoring operations at the CNN Coordinating Centre
- is responsible for maintaining the CNN website and the Hosted Databases
- is the central individual at the CNN Coordinating Centre for all data collection and procedural inquiries
- interfaces with the Research Assistants and Site Investigators and

- is responsible for ensuring consistent and accurate data collection at all Institution Member sites

Database Manager and Data Analyst - The Database Manager receives, processes, checks and archives the data sent from each Institutional Member Site. The Data Analyst is responsible for analyzing data at the CNN Coordinating Centre.

Part 3 - CNN Coordinating Centre

Functions of the Centre - The main responsibility of the CNN Coordinating Centre is to provide administrative support for services provided by, and research to be undertaken through, CNN. Services provided by CNN include:

- data cleaning, analysis and archiving;
- technical database troubleshooting and support via phone and/or email;
- database modifications as approved by the membership and Database and Annual Report Committee
- manuscript preparation assistance;
- variable definitions and general data inquiries from Site Investigators or Research Assistants via phone and/or email;
- production of Annual Report which includes those components identified in Appendix C: The CNN Annual Report will be produced each year using the data from the CNN Core Database, with Core and Supplementary Analyses to be defined by the Executive Committee and the Data Analyst.
- coordination of Annual General Meeting: The AGM will be held annually at a location and time to be determined by the Executive Committee. The CNN Annual Report, research project reports and proposals, and budget will be presented at the AGM;
- coordination of teleconferences & meetings: The Executive Committee will meet at the AGM and at teleconferences/videoconferences at the discretion of the Executive Committee;
- maintenance of a CNN Website: CNN will maintain a website to facilitate communications between Members. The Annual Report and abstracts of publications will be available on the website. General and dedicated chat rooms and bulletin boards will be available. These can be requested through the Project Coordinator.
- maintain site anonymity in any of the publications including Annual report. Site codes will only be available to Database and Annual Report Committee Members for the purpose of proper interpretation of Annual report. The members of the committee will destroy any records of site code after annual report is published.
- CNN coordinating center will not release individual patient data to any investigator and all analyses will be conducted at CNN Coordinating Center only except

- Individual sites have obtained a separate ethics approval for a site specific data to be assimilated and with specific instruction to CNN coordinating center to provide individual patient data from participating institution to either coordinating investigator or coordinating site
- Individual projects have obtained prior approval from individual REB and CNN Executive Committee that data will be linked with other networks for analyses
- Individual site requests access to their own site data including individual patient data that they submitted to CNN
- Approved by General Membership in special circumstances with as much de-identification as possible is conducted
- In all reports (publications or annual reports) any cell size that contains values less than 5 will be masked and not reported as per Statistics Canada Policy to prevent re-identification.
- Linking CNN data with other databases:
 - CNN coordinating center can host individuals who wish to link CNN data with other dataset.
 - The project has to be approved by CNN Executive Committee
 - An individual investigator can bring their own network or other data to CNN coordinating center where linkage of patient level data can be made.
 - The investigator will be asked to and leave linked files for CNN analysts to perform aggregate analyses
 - Results will be released to investigators in aggregate format ONLY.
- A Data Sharing Agreement (DSA) between CNN Coordinating Centre's Host Institution and individual sites:
 - Data sharing agreement to be developed by the host institution (currently Mount Sinai Hospital) during 2013.
 - The agreement will be sent to individual site investigator for approval and signature from responsible individual within institutions.
 - CNN coordinating center will maintain such agreements as current and in accordance with appropriate regulations in effect at that time in Canada and the province of the coordinating center's host institution.

CNN Coordinating Centre Staff - The CNN Coordinating Centre staff will be located at the CNN Coordinating Centre and will be responsible for the following:

- maintaining all current documents between CNN and Members;
- maintaining CNN membership lists, and preparing and monitoring membership invoices and payments;
- maintaining a copy of the current REB/IRB certificate of approvals for an Institutional Member's participation in CNN ;
- maintaining, and where appropriate providing, all meeting minutes and archives;
- Communicating with abstractors and site investigators regarding database items, modifications and definitions.

CNN Core Database - The CNN Coordinating Centre will maintain or cause to be maintained a CNN Core Database in accordance with any agreement with a Member, local and federal regulations and acts on privacy and confidentiality and the policy requirements concerning content and use of the CNN Core Database as such policies are determined by the Executive Committee. Modifications to the database will be performed as approved by General Membership and/or Database Reporting Committee.

Part 4 –Membership

Categories of Members - There are three types of Members – Institutional Members, Individual Members and Associate Members. Each member will following acceptance as a Member comply with all provisions of these Policies and Procedures applicable to that category of Member.

Institutional Member – A corporation, society or legal entity that operates a hospital with a treatment facility providing care for newborn infants which hospital is located in Canada approved by the Executive Committee may apply to become an Institutional Member.

A corporation, society or other legal entity that does not operate a hospital with a treatment facility providing care for newborn infants but (i) is affiliated or otherwise involved with one or more of those corporations, societies or other legal entities that does or (ii) has a role or interest in neonatal-perinatal medicine that would make its admission as an Institutional Member of benefit to CNN (the “Affiliated Applicant”) may apply to become an Institutional Member.

An application to become an Institutional Member will be reviewed and either approved or rejected in accordance with the processes and requirements established by the Executive Committee from time to time.

An Affiliated Applicant that becomes an Institutional Member will not be required to collect and provide data to CNN to be used in the creation of the CNN Core Database. The Executive Committee may also exempt an Affiliated Applicant that becomes an Institutional Member from compliance with any other provision of these Policies and Procedures that it considers inconsistent with the operations of the Affiliated Applicant. However the Executive Committee may as a condition of its approval of a membership application by an Affiliated Applicant require that Affiliated Applicant to enter into an undertaking to conduct other identified activities or provide other identified support to CNN.

- Application: Application for membership must be submitted to the Chair of the Executive Committee or to the Project Coordinator.
- Membership Fee: There is no membership fee for an Institutional Member.

- **Inter-Institutional Agreement:** Each Institutional Member will concurrently with becoming a Member enter into an Inter-Institutional Agreement with Mount Sinai Hospital substantially in the form attached as Appendix A and any renewal or replacement agreement approved by the Executive Committee for such period of time as it remains a Member (the “Inter-Institutional Agreement”).
 - **Health Information Agreement:** An application for membership shall identify laws in force in the jurisdiction in which the applicant conducts operations which are applicable to the disclosure of data by the applicant in accordance with the Inter-Institutional Agreement and which require the recipient of such data to enter into an agreement respecting the disclosure and use of such data. Where any such requirement is identified the Institutional Member and Mount Sinai Hospital will enter into such an agreement of any renewal of the same concurrently with entering into the Inter-Institutional Agreement.
- Representation: An Institutional Member will in conjunction with submission of its application for membership and as required thereafter designate a neonatologist, or a clinician who cares for infants in an equivalent capacity, at the site of that Institutional Member as its Site Investigator with the rights and responsibilities outlined in these Policies and Procedures.
- Renewal and Termination: Membership of an Institutional Member is on-going until terminated by: (i) the Institutional Member giving written notice to that effect to the Chair of the Executive Committee; (ii) by the Chair of the Executive Committee giving written notice to that effect to the Institutional Member if it fails to comply with any obligation of that Institutional Member pursuant to these Policies and Procedures or pursuant to the Inter-Institutional Agreement..

Site Investigator of Institutional Member - The Site Investigator will serve as the primary representative of the Institutional Member site and will provide leadership and direction for the other staff members at that site. A Site Investigator will:

- attend at least one CNN meeting a year, and make every effort to participate in meetings to represent the Institutional Member’s site regarding policies and decisions;
- hire and supervise one or more Research Assistants at the Institutional Member’s site;
 - ensure data collection required by the Institutional Member under the Inter-Institutional Agreement is maintained and up-to-date and submitted in accordance with the Inter-Institutional Agreement and that the same is in compliance with local regulations governing the Institutional Member;
 - ensure all data collected by the Institutional Member under the Inter-Institutional Agreement is stored and maintained, with back-up in accordance with Institutional Member Information Systems requirements;
- ensure local IRB or Ethics Review Boards have reviewed and approved the participation of the Institutional Member in CNN and that renewals are completed each year with copies of each approval and renewal sent to the CNN Coordinating Centre.

If a Site Investigator fails to comply with the foregoing requirements, the Institutional Member that designated such Site Investigator may if it so determines, and shall upon notice to that effect from the Scientific Director, remove the designated individual as Site Investigator and designate an alternate individual who meets the requirements of these Policies and Procedures.

Research Assistant (Database Abstractor) of Institutional Member - A Research Assistant (also called a chart abstractor) is responsible for accurate and efficient data collection and data transmission. A Research Assistant abstracts data directly from patient charts according to strict research protocol, maintains constant communication with the Site Investigator and the Projects Coordinator, and ensures data is transmitted to the CNN Coordinating Centre consistently and promptly. A Research Assistant is responsible for keeping up to date with the most current abstracting protocol and data definitions.

Note: the Research Assistant (RA) is the main cost incurred by hospitals in becoming a member of the CNN. Each individual hospital site is responsible for employing their own Research Assistant and providing them with a computer necessary for data abstraction. Please see Appendix D for detailed information on the computer requirements. The RA could be a nurse, student or part-time employee depending on the hospital site's preference. It is estimated that you will likely need to hire the RA for approximately 3-4 days a week, depending on workload requirements at your site. In addition to the Site Investigator, your site is also free to submit the names of anyone else who may be interested in being involved in the CNN.

Individual Member – An eligible individual may apply to become an Individual Member. An eligible individual is a researcher who is affiliated with an Institutional Member or a researcher falling within such other category established from time to time through a determination of the Executive Committee in accordance with a recommendation of the CNN Scientific Director. An application to become an Individual Member will be reviewed and either approved or rejected in accordance with the processes and requirements established by the Executive Committee from time to time.

- **Application:** Application for membership as an Individual Member (with a current curriculum vitae) must be submitted to the Projects Coordinator and must be endorsed by a current Institutional Member. An applicant for membership as an Individual Member should have expertise and/or experience relevant to CNN research goals and in the absence of evidence of such expertise and/or experience the application for membership may be declined.
- **Applicability:** The individual must have demonstrated teaching, clinical, research or administrative involvement in the field of neonatology or perinatology to the satisfaction of the Executive Committee.
- **Membership Fee:** There is no membership fee for an Individual Member.
- **Obligations:** Members may use CNN infrastructure for research collaboration and cooperation. However, research projects using network data must be approved by the Executive Committee.

- **Renewal and Termination:** Membership of an Individual Member will be terminated by: (i) the Individual Member giving written notice to that effect to the Chair of the Executive Committee; (ii) by the Chair of the Executive Committee giving written notice to that effect to the Individual Member if that Individual Member fails to comply with any obligation of that Individual Member pursuant to these Policies and Procedures; or (iii) if the individual that is that Individual Member ceases to be an eligible individual for the purpose of applying to become an Individual Member.

Associate Member – An eligible individual may apply to become an Associate Member. An eligible individual for Associate Membership is a Neonatal-Perinatal Trainee who is affiliated with an Institutional Member or a trainee falling within such other category established from time to time through a determination of the Executive Committee in accordance with a recommendation of the CNN Scientific Director. An application to become an Associate Member will be reviewed and either approved or rejected in accordance with the processes and requirements established by the Executive Committee from time to time.

- **Application:** Application for membership as an Associate Member (with a current curriculum vitae) must be submitted to the CNN Coordinator and must be endorsed by a current Institutional Member. An applicant for membership as an Associate Member should be pursuing expertise and/or experience relevant to CNN research goals and in the absence of evidence of such expertise and/or experience the application for membership may be declined.
- **Applicability:** The individual must have demonstrated commitment to the field of neonatology or perinatology to the satisfaction of the Executive Committee.
- **Membership Fee:** There is no membership fee for an Associate Member.
- **Obligations:** Members may use CNN infrastructure for research collaboration and cooperation. However, research projects should be discussed with site investigator where an individual is working or with members of CNN Executive Committee. Any request for using network data must be approved by the Executive Committee.
- **Renewal and Termination:** Associate membership is for a maximum period of three years. At the end of the third year an individual who is affiliated to a Canadian Institute will be eligible to apply for Individual Membership. Associate membership will be terminated: (i) at the end of three year period or earlier if an individual ceases to be affiliated to a Canadian Institution; (ii) the Associate Member giving written notice to that effect to the Chair of the Executive Committee; (ii) by the Chair of the Executive Committee giving written notice to that effect to the Associate Member if that Associate Member fails to comply with any obligation of that Associate Member pursuant to these Policies and Procedures; or (iii) if the individual that is that Associate Member ceases to be an eligible individual for the purpose of applying to become an Associate Member; (iv) Associate Member becomes an Individual Member.

Part 5 - Research Projects

Research projects are initiated by groups of researchers, led by a principal investigator. Project applications are submitted in abstract form to the Executive Committee, who will ensure that there are no conflicts with existing studies, and approve projects for discussion by the CNN within three weeks of receipt.

- **Project ownership:** The principal investigator and associated researchers of a project retain ownership of the project and project protocol for the duration of the project. Such ownership lapses if an approved project is not initiated within two years of approval.
- **Publication rights:** Please see the next section 'Publications' for prescribed guidelines.

Part 6 – Publications

The following outlines the policy on publications based on results produced from the CNN Core Database and its related projects and databases:

Authorship

- 1) Any publication from the CNN will be authored using the rules laid out below for CNN members, paid staff members, non-paid contributors and other students.
- 2) The Canadian Neonatal Network™ will be included as the final author in each publication.
- 3) In the case of a working group: Each working group leader will be responsible for allocating lead authorship and writing responsibilities for publications. Lead authorship will be on a rotating basis among members of working groups. In the event of a disagreement, a decision will be made by the Executive Committee.
- 4) **Sunset Clause** – Authors pursuing a topic will have up to two years from the time of assignment to produce a scientific work. Lack of substantial progress within that year (as evidenced by production of an abstract and a significant body of analyses and first draft of manuscript) will relinquish their authorship priority. Extensions can be granted if there are documented problems with data quality, acquisition, etc by written submission to Executive Committee.

For CNN Members:

Their name(s) will be included in the author's list when one of the following conditions is met:

- 1) The member initiated the project resulting in a publication **OR**
- 2) The member is involved in the working group for this project **OR**
- 3) The member is involved in the publication and is put forward by the project initiator to the CNN Executive Committee to be an author.

For paid staff members:

Their name(s) will be included in the author's list when one of the following conditions is met:

- 1) The staff member initiated the project resulting in a publication and it was decided upon up front by those involved that they would have their name within the author's list **OR**
- 2) The staff member was involved in the project at a later date, they have contributed to the writing of the publication and the first author has received approval from the CNN Executive Committee to include their name.

For non-paid contributors (Post-doctoral Fellows, Medical Trainees, Graduate Students):

Their name(s) will be included in the author's list when one of the following conditions is met:

- 1) The student initiated the project resulting in a publication and it was decided upon up front by those involved that they would have their name within the author's list **OR**
- 2) The project is part of the student's Ph.D or MSc. dissertation **OR**
- 3) The student made an active intellectual contribution.

For other students (Medical, Co-op, Undergraduate):

Please see the above policy for non-paid contributors.

Publications/Manuscripts/Abstracts

- 1) Manuscripts and abstracts resulting from CNN and site data must be reviewed by the Executive Committee prior to submission for publication.
- 2) Papers published by local sites or by other parties using either local and/or CNN data must acknowledge the Canadian Neonatal Network™.
- 3) A copy of manuscripts resulting from local and/or CNN Core Database must be forwarded to the CNN Coordinating Centre.

International Comparisons

Studies on international comparisons will be authored by the principal investigators from each of the Networks together with the names of the Networks. Members of the Networks will be named as part of their respective Networks.

Contact:

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Part 7 - Changes to Policies and Procedures

These Policies and Procedures may be altered from time to time through a determination of the Executive Committee consented to by the CNN Scientific Director. Any such alteration must be posted on the CNN website and is not effective as an alteration to these Policies and Procedures until thirty (30) days following such posting.

APPENDIX A

INTER-INSTITUTIONAL AGREEMENT

THIS AGREEMENT made as of the (the “Effective Date”).

BETWEEN:

(the “Applicant”)

OF THE FIRST PART

- and -

Mount Sinai Hospital,

having a principal place of business at 600 University Avenue, Toronto, Ontario, Canada
M5G 1X5

(“MSH”)

(each a Party, and collectively, the “Parties”)

OF THE SECOND PART

WHEREAS:

- A. The Canadian Neonatal Network (“CNN”) is a network of Members including health care providers, which are Institutional Members, and researchers, who are Individual Members, as defined and provided in the Policies and Procedures attached hereto as Schedule A (such Policies and Procedures as varied, from time to time, in accordance with their terms being the “CNN Policies and Procedures”);
- B. The mission of CNN is to facilitate the conduct of, and to support the researchers who conduct, leading multi-disciplinary, collaborative research dedicated to the improvement of neonatal-perinatal health and health care internationally;
- C. CNN undertakes its operations in accordance with, and the rights and obligation of each Member in relation to CNN are set forth in, the CNN Policies and Procedures;
- D. The Applicant is either an Institutional Member of CNN, or is, concurrently with the delivery of this Agreement, delivering to CNN through MSH, a membership agreement (the “Membership Agreement”) pursuant to which the Applicant shall become an Institutional Member;
- E. The CNN Scientific Director is Dr. Prakeshkumar Shah. He holds an appointment as Staff Neonatologist at Mount Sinai Hospital, as well as being an Associate Professor of Pediatrics, University of Toronto.
- F. The CNN Scientific Director has requested that MSH provide support services to the CNN Coordinating Centre as described in the CNN Policies and Procedures, including the operation of a data acquisition system and the hosting of the Core Database and the Member Database as each is described in the CNN Policies and Procedures;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of MSH and the Applicant agrees with the other as follows:

- 1.0 **Hosting Services** - MSH shall, throughout the Term (as defined in Section 9), provide the following database hosting services (the "Hosting Services") to the Applicant:
 - 1.1 maintenance and operation, to the standard provided in relation to the maintenance and operation of other MSH comparable hardware and software systems, of the necessary hardware and software system, at premises of MSH, to receive, store, retrieve, transfer, return and otherwise manage the Member Database and CNN Core Database (collectively the "Hosted Databases") as required or permitted pursuant to this Agreement;
 - 1.2 receive, store, retrieve, transfer, return and otherwise manage the Applicant's Member Data, as required or permitted pursuant to this Agreement;
 - 1.3 create from the CNN Core Database and provide to the Members the annual reports (the "Reports") described in Appendix E hereto as varied in accordance with the provisions of this Agreement.

- 2.0 **Collection and Transmission of Member Data** - The Applicant shall, from time to time, collect and transmit to MSH De-Identified Data consisting of health information on neonatal-perinatal clinical treatment delivered by or through the Applicant as otherwise required or permitted pursuant to the CNN Policies and Procedures (the "Member Data") for inclusion in the Member Database and the CNN Core Database, such information to be transmitted by the Applicant in a secure manner and in accordance with such process as reasonably required by Program Coordinator of CNN who will be in direct communication with individual sites and outline requirements . If the Applicant transfers Member Data that is not De-Identified Data, it shall be deemed a breach of terms and conditions of this Agreement, and it shall be solely responsible for the consequences of such transfer. For the purposes of this Agreement, "De-Identified Data" means data which has been removed of any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual. Notwithstanding the foregoing, the Parties acknowledge and agree that for the purposes of this Agreement, the Member Data shall be treated as Confidential Information as defined below.

- 3.0 **Application of Laws** –The Parties acknowledge and agree that this Agreement is subject to Ontario's *Personal Health Information Protection Act, 2004* (PHIPA), and that in the course of performing their responsibilities hereunder, the Parties may have access to or otherwise view or obtain personal health information, as defined under s.4 of PHIPA. The Parties represent and warrant that all employees, students and agents will at all times comply with all applicable federal, provincial and local laws and regulations including, but not limited to PHIPA as it pertains to confidentiality, use and disclosure of personal health information ("Applicable Laws").

- 4.0 **Creation of CNN Core Database** - MSH is hereby authorized by the Applicant to extract from the Applicant's Member Database, any data required to create and populate the CNN Core Database. The CNN Core Database is a cumulative database of data extracted from the Applicant's Member Database and Member Databases of each other Member. The CNN Core Database has been established and is subject to alteration in accordance with the provisions of this Agreement or the CNN Policies and Procedures. Notwithstanding the inclusion of the Applicant's Member Data in the CNN Core Database, the Applicant's Member Database shall be maintained as a standalone database as one of the Hosted Databases and shall be used or disclosed only in accordance with the following:

- 4.1 The Applicant's Member Database shall be password protected by MSH and that password disclosed by MSH only to the Applicant.
 - 4.2 Where the Applicant's Member Data in its Member Database relates to a single patient treatment file, that Member Data (which by definition is De-Identified Data in accordance with Section 2.0) shall be provided to MSH with a coded identifier capable of permitting the Applicant, but not MSH or any other person having access to such Member Data pursuant to this Agreement, to match that Member Data to the patient who was the subject of that treatment.
 - 4.3 Upon Applicant request, in accordance with the notice provisions in Section 16, MSH shall provide to the Applicant:
 - 4.3.1 Access to the Applicant's Member Database; or
 - 4.3.2 In conjunction with the Applicant ceasing to be a Member, return **or destroy** all of the Applicant's Member Data included in the Member Database **except that which has formed part of the CNN Core Database**.
 - 4.4 Member Data extracted from the Applicant's Member Database for inclusion in the CNN Core Database may be used by MSH for the creation of the Reports. A Report may identify the Members of CNN for the purpose of indicating the Member Database from which the Member Data was extracted but must not include any other information about the Applicant.
 - 4.5 Member Data must not be re-identified by MSH nor used by MSH for any purpose other than as set forth in this Agreement without the consent in writing of the Applicant.
 - 4.6 MSH shall have no further obligations whatsoever for the Member Data or Hosted Databases other than those described in this Agreement or the Membership Agreement.
- 5.0 **Representations of Applicant** - The Applicant represents and warrants to MSH that:
- 5.1 It has the legal authority, and has received all applicable approvals, required for the Applicant to transfer the Member Data to MSH pursuant to, and for the purposes of, this Agreement.
 - 5.2 It has in place effective administrative, technological and physical safeguards to stop theft, loss and unauthorized access, copying, modification, use, disclosure or disposal of Confidential Information and these safeguards are consistent with prudent practice in compliance with Applicable Laws.
- 6.0 **Representations of MSH** – MSH represents and warrant to the Applicant that:
- 6.1 It has the legal authority, and has received all applicable approvals, required for MSH to provide Hosting Services pursuant to, and for the purposes of, this Agreement.
 - 6.2 Its provision of Hosting Services for the purposes of this Agreement complies with, and is in accordance with, Applicable Laws.

7.0 **Term and Termination** – The term of this Agreement commences as of the Effective Date of this Agreement and continues until the earlier of:

16.1 the expiration of five (5) years from the Effective Date of this Agreement;

16.2 Upon mutual agreement of the Parties.

16.3 the Applicant ceasing, as provided pursuant to the CNN Policies and Procedures, to be a Member;

16.4 a date specified in a notice by MSH to the Applicant to that effect provided such date is not less than sixty (60) days following the date of which such notice is given to the Applicant by MSH; or

16.5 the date specified by one Party in a notice to the other Party provided that other has failed to remedy any breach or default on its part pursuant to this Agreement within thirty (30) days of earlier notice from the first party to that effect.

The termination of this Agreement by a Party pursuant to Section 8.5 is without prejudice of any rights of either Party that have accrued to the date of such termination.

8.0 **Exclusion of Representations, Warranties and Conditions** - Except to the extent otherwise specifically provided in this Agreement, neither Party makes any representations or warranties, either express or implied, as to any matter pursuant to or arising from this Agreement, the merchantability or fitness for any particular purpose of any service provided by one to the other, and all representations, warranties and conditions, expressed or implied, statutory or otherwise, are hereby disclaimed. In addition, each of the Parties expressly disclaims and does not warrant that the data in the Hosted Databases are accurate or that Hosted Databases shall not infringe on any patent, copyright, trademark or other rights of third parties.

9.0 **Indemnification** - Subject to any exception or limitation contained in Section 9.0, Section 11.0 and Section 15.0 or in any other provision of this Agreement, each party shall be responsible for its own acts and omissions.

10.0 **Exclusion of Liability** - Notwithstanding any other provisions of this Agreement, including Section 10.0 and whether such liability would otherwise arise in contract or in tort, including where the same is based on the negligence or willful misconduct of a Party or its officer's directors, employees, students or agents:

10.1 shall either Party be liable to the other for special, indirect, incidental, consequential or punitive damages of the other howsoever caused;

10.2 shall MSH be liable to the Applicant for any inability to, or interruption of, access to the Member Data or Member Database by the Applicant, whether scheduled or unscheduled and howsoever caused;

10.3 shall MSH be liable to the Applicant for any loss of, or damage to, all or any part of the Applicant's Member Data or Member Database.

11.0 **Insurance** - Each of MSH and the Applicant shall insure its operations under a contract of Comprehensive General Liability insurance in an amount not less than Five Million Dollars (\$5,000,000) per occurrence insuring against bodily injury, personal injury and property damage. Such insurance shall include blanket contractual liability.

12.0 **Confidential Information** – For purposes of this Agreement, "Confidential Information" means all records, data and other information whatsoever, in any form or medium (including without limitation, Member Data, financial information, books and records,

policies and procedures, copyright and any other intellectual property rights, and other data relating to the operations of a Party (the "Disclosing Party"), which is made known to another Party or its authorized representative (the "Receiving Party") as a result of the relationship of the Parties under this Agreement, but does not include any information or documents or other items in tangible form which at the time in question:

- a) have become generally available to the public other than as a result of an unauthorized disclosure by the Receiving Party;
- b) were available to the Receiving Party on a non-confidential basis prior to disclosure to the Receiving Party; or
- c) are required by Applicable Laws to be disclosed.

12.1 The Receiving Party shall:

- a) hold in strict confidence all Confidential Information of a Disclosing Party using at least the same means that it uses, or would reasonably be expected to use, to protect the Receiving Party's own confidential and proprietary information of a similar nature as the Disclosing Party's Confidential Information;
- b) not disclose or use or allow to be disclosed or used in any manner whatsoever, other than as expressly contemplated by this Agreement or as may be required to carry out the terms of this Agreement or as may be required for MSH to perform the Hosting Services, as the case may be, and then only on a need-to-know basis, any Confidential Information of a Disclosing Party, either during the Term of this Agreement or at any time thereafter, except with the prior written consent of such Disclosing Party;
- c) ensure that all personnel of the Receiving Party that have access to Confidential Information of the Disclosing Party are informed of the confidential nature of the Disclosing Party's Confidential Information in order for such personnel to know to keep such information confidential and not use it for any purpose except as permitted pursuant to this Agreement; and
- d) notify the Disclosing Party promptly in writing in the event of any loss, theft or unauthorized access, use or disclosure of the Disclosing Party's Confidential Information.

12.2 Following any expiration or earlier termination of this Agreement, the Receiving Party shall forthwith upon demand by a Disclosing Party, forward to such Disclosing Party all copies of any tangible items, which are or which contain Confidential Information of such Disclosing Party or, if directed by the Disclosing Party, securely destroy such tangible items.

13.0 **Data Breach** – If a Party becomes aware that there has been a breach or suspected breach of this Agreement, or that a persona has obtained unauthorized access to Confidential information, including but not limited to Member Data, or has used, copied, disclosed or disposed of Confidential Information other than as contemplated in this Agreement, that Party shall, at the first reasonable opportunity, notify the affected Party by telephone followed by written notice. The Parties shall take steps that are reasonable in the circumstances to contain the data breach and prevent reoccurrence.

14.0 **Access to Information Held by Public Bodies** – The Parties shall comply with all Applicable Laws which create a right of access to records under the custody and control of public bodies subject to specific, limited exceptions. Except as required by law or as otherwise permitted pursuant to the terms of this Agreement, neither MSH nor the Applicant shall disclose the contents of this Agreement or the foregoing records other than for the purpose of implementation or enforcement of the same or for a general statement on the Parties to the Agreement, the amount being paid for the Hosting Services and the general nature of the Hosting Services, either Party being entitled to publish that information.

- 15.0 **Notices** - All notices, requests, directions or other communications required or permitted herein shall be in writing and shall be delivered to the parties hereto respectively as follows:

The Applicant:

Attention:

Email:

For MSH:

Dr. Prakeshkumar Shah
Mount Sinai Hospital
600 University Avenue, Room 19-231F
Toronto, ON M5G 1X5
Phone: 416-586-4800 ext. 4761
Fax: 416-586-8745

In order for any notices, requests, directions, or other communications to be effective, the same shall either be delivered in person or, sent by registered mail or facsimile addressed to the party for whom it is intended at the above-mentioned address or fax number and shall be deemed to have been received, if sent by registered mail, when the postal receipt is acknowledged by the other party and, if sent by facsimile, when transmitted. The address or fax number of either party may be changed by notice in the manner set out in this Section.

- 16.0 **Governing Law** - This Agreement shall be governed by and interpreted in accordance with the laws in force in the Province of Ontario and the Parties expressly attorn to the exclusive jurisdiction of the courts of Ontario for enforcement thereof.

- 17.0 **General** – The following general provisions apply to this Agreement:

- 17.1 Nothing contained in this Agreement creates or shall be deemed or construed to create between the parties a partnership or joint venture.
- 17.2 Neither party shall assign its rights or obligations pursuant to this Agreement but subject to the foregoing, this Agreement operates for the benefit of and is binding on the parties and their respective successors and permitted assigns.
- 17.3 No condoning, excusing or overlooking by either Party of any default, breach or non-observance by any other operates as a waiver of that Party's rights under this Agreement except to the extent so provided in writing signed by the party entitled to the benefit of that term or right.
- 17.4 No exercise of a specific right or remedy by any Party precludes it from, or prejudices it in exercising, another right or pursuing another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.
- 17.5 All terms which require performance by the Parties after the expiry or termination of this Agreement, shall remain in force despite the Agreement's expiry or termination for any reason.
- 17.6 This Agreement, together with any agreement made pursuant hereto, contains the whole agreement between the Parties in relation to this matter and no changes are binding, unless signed in writing by the parties to this Agreement.
- 17.7 Unless the contrary intention appears, the singular includes the plural, and vice versa, and words importing a gender include all genders.

IN WITNESS WHEREOF the duly authorized officers of the parties have executed this Agreement on the date first above written.

The Applicant

Per: _____
Signature

Name (print): _____
Title (print): _____
Date: _____

Per: _____
Signature

Name (print): _____
Title (print): _____
Date: _____

Mount Sinai Hospital

Per: Executive VP, Corporate & CFO

Signature
Name (print): Joan Sproul
Date: _____

Per: Principal Investigator

Signature
Name (print): _____
Date: _____

Appendix B

Components of Annual Report

Results in the report will comprise of the following categories:

- i. Population demographics;
- ii. Population incidence of common neonatal complications; and
- iii. Descriptive and risk adjusted analyses of survival and outcomes by site

The following outlines the Core Analyses and Supplementary Core Analyses:

- i. Core Analyses

Methods		
Validation		Obstetric Info
SNAP II		SNAP vs. CRIB
Transport Score		Congenital Anomalies
Outcomes		
Mortality		PDA
BPD		Air-Leak
IVH		Seizures
Infection		Surgery
NEC		Bili
ROP		HIE/Asphyxia
Follow-up		Discharge/Post-transfer
Technology		
Transfusions		Monitoring
Ventilation		Procedures
Parenteral nutrition		Pressors
Catheter use		ECMO/N ₂ O
Steroid use		Tracheostomy
Medications		
Resource		
Resource availability		New technology adoption
<i>Technology utilization</i>	<i>Resource utilization</i>	<i>Intensity of care</i>
CT	RN	NTISS
ECMO	MD	DOV
Vent	Beds	DOPK
Referral	Budget	Pain management
Surgery		# of transfers

- ii. Supplementary Core Analyses – those subsequently determined by the group to be part of the core analyses

For confidentiality reasons, all analyses of core data (Core Analyses, Supplemental Core Analyses) will remain within the Coordinating Centre. Specifically, there will be no release of multi-site raw data.

Note: Data from all sites who have provided complete data will be used in the analyses, but only aggregated data will be reported; sites will be identified by a randomly assigned number code. Wherever a small cell size (≤ 5) is observed in the data output, every effort will be made to group the data to maintain anonymity.

Appendix C

Computer Requirements for the CNN/EPIQ/INC Database Systems

November 2009

The followings are the minimum requirements of a computer (desktop or laptop) which is used to run the CNN/EPIQ/INC database systems. The requirements are listed in 3 sections below:

- 1) The hardware requirements,
- 2) The software requirements, and
- 3) The Internet access requirements.

Please note: A computer is required to meet ALL the requirements in ALL 3 sections in order to run the CNN/EPIQ/INC database systems.

Section (1): Hardware requirements:

The computer must have the following hardware components:

- 1) CPU speed of 2.0 Ghz or higher (Pentium 4, Core2Duo or AMD similar class CPU)
- 2) 512 MB Memory (1GB recommended)
- 3) Internet connection hardware (e.g. Ethernet adapter card)
- 4) Screen Resolution of 1024 x 768

Section (2): Software requirements:

The computer must have the following software installed:

- 1) Windows XP SP2 or later,
- 2) Microsoft Access 2000 / 2003 or higher,
- 3) .NET framework 3.5,
- 5) Regional Settings/Date Format being set to "yyyy-MM-dd"
- 6) Anti-virus software with up-to-date virus definitions

Microsoft Access 2000 / 2003 or higher is part of Microsoft Office Professional or can be purchased separately. The .NET Framework 3.5 can be downloaded from the Internet for free.

For instructions of how to download the .NET Framework, please refer to Appendix A of this document.

Please note: If you are on a hospital network, you may require your administrator's permission to install the .NET framework. Please let your Computer Services know that you have downloaded these programs and they will then provide access for you.

Section (3): Internet access requirements:

Users of the CNN/EPIQ/INC database systems will frequently call the "Update" or "Upload" functions, in order to bring the database systems up-to-date or to submit data to the coordinating centre respectively. When these "Update" or "Upload" functions are called, the CNN/EPIQ/INC database systems will initiate Internet connections (in particular HTTPS connections) to contact the web servers at the data coordinating centre to carry out the corresponding operations.

Whether Internet connections can be made successfully will also depend on the network settings of your local network (e.g. your hospital network). Firewalls, proxy servers, etc., on your local network, which sits between the CNN/EPIQ/INC database systems and the web servers at the data coordinating centre, may be pre-configured to not to allow your CNN/EPIQ/INC database systems to make such Internet connections.

We recommend that you inform your Computer Services department of the CNN/EPIQ/INC database systems, as well as the Internet connections required, and they will then provide access on the firewalls (or proxy servers, etc.) for the CNN/EPIQ/INC database systems.

Please refer to Appendix B for more technical information about the Internet connections that the CNN/EPIQ/INC database systems require.

Downloading .NET Framework:

To download .NET Framework:

- 1) Please go to www.microsoft.com
- 2) Type in ".NET Framework" in the search field in the upper right hand corner of the Microsoft Home page and click "Search".
- 3) Click on ".NET Framework 3.5 in Related Downloads section on the right hand side.
- 4) Under "Instructions", click on the link that allows you to download the Full Redistributable Package.
- 5) When asked if you would like to open the file or save it to your computer, please click "Save"
- 6) Save the file to a folder where you will keep your CNN/EPIQ/INC Databases
- 7) Once you have saved the file, click "Open" and your computer will do the rest!

Inter-Machine Connections of the CNN/EPIQ/INC Database Systems

The CNN/EPIQ/INC database systems (a.k.a. CNN/EPIQ/INC systems) will only make 3 different kinds of inter-machine connections:

1) HTTP(S) connection for downloading:

When users call the "Update" function, the CNN/EPIQ/INC systems will initiate HTTPS connections to one of the web servers at the data coordinating centre to download a series of files. After finishing these downloading, all connections to the web server will be closed. The files downloaded will then serve as new components of the CNN/EPIQ/INC systems.

2) HTTPS connection for file uploading:

When users call the "Upload" function, the CNN/EPIQ/INC systems will create a temporary file which contains a copy of all the local data EXCLUDING any patient identifiers. Then, the CNN/EPIQ/INC systems will initiate a HTTP connection to one of the web servers at the data coordinating centre to upload this temporary file to the web server. After the uploading, the connection to the web server will be closed.

3) Windows network drive connection:

The CNN/EPIQ/INC systems allow users to have the flexibility to store their local data anywhere on either the local hard disks or the network drives. If the local data are stored on a network drive connecting to a remote machine, while the user is using the CNN/EPIQ/INC systems, the CNN/EPIQ/INC systems will make frequent ADO or DAO connections to the local data (which is stored as a Microsoft Access 2000 / 2003 or higher .mdb file).

Making connection type 1 and 2 above are standard and required operations of the CNN/EPIQ/INC systems when users call the "Update" or "Upload" functions. Connections of type 3 above may be avoided depending on how users set up their own copy of the CNN/EPIQ/INC systems.

Firewalls, proxy servers, etc., sitting between the CNN/EPIQ/INC systems and the web servers at the data coordinating centre may not allow the successful connections of type 1 or type 2 to be made. In such a case, additional configurations may be needed at the firewalls (or proxy servers, etc.) in order for the users to carry out the "Update" and the "Upload" functions. Please consult with administrators of these firewall (or proxy servers, etc.) to verify if these connections are allowed on your computer network.

Please note that the CNN/EPIQ/INC systems is a standalone network application which will initiate HTTPS connections (type 1 and 2 above) directly to pre-designated web servers on the Internet. The CNN/EPIQ/INC systems DO NOT initiate these HTTPS connections by calling local web browsers on the users' computers.