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This CanCORPS Consortium Agreement (the "**Agreement**") effective as of the date of the last signature on this Agreement (the "**Effective Date**") is made

BETWEEN:

The Research Institute of the McGill University Health Centre
(hereinafter the "**Consortium Lead**")

AND:
The Governors of the University of Calgary;
AND:
Alberta Health Services;
AND:
The Governors of the University of Alberta

AND:
The University of British Columbia & Provincial Health Services Authority (operating at its BC Children's Hospital site)

AND:
The University of Manitoba

AND:
Shared Health Inc. - Health Sciences Centre

AND:
Memorial University of Newfoundland and Eastern Regional Health Authority

AND:
Izaak Walton Killam Health Centre (IWK)

AND:
Hamilton Health Sciences Corporation on behalf of its McMaster Children's Hospital

AND:
Lawson Health Research Institute, a joint venture of
London Health Sciences Centre Research Inc. and Lawson Research Institute

AND:
Children's Hospital of Eastern Ontario Research Institute Inc.

AND:
The Hospital for Sick Children

AND:
Centre Hospitalier Universitaire Sainte-Justine

AND:
CHU de Québec - Université Laval

AND:
CIUSSS de l'Estrie - Centre hospitalier universitaire de Sherbrooke

AND:
Saskatchewan Health Authority
AND:
University of Saskatchewan

(each a "**Member**" a "**Founding Member**", an "**Institution**" or a "**Party**" with their addresses and the names and coordinates of their investigators listed in Appendix 1, attached to this Agreement, and together, the "**Parties**")

Preamble

WHEREAS the Founding Members of this Agreement decided on July 21/22, 2018 to create a consortium, the Canadian Consortium for Research in Pediatric Surgery ("**CanCORPS**") and desire to detail their understanding in writing;

WHEREAS the mission of CanCORPS is to improve pediatric surgical care through high-quality collaborative research;

WHEREAS CanCORPS' scientific objectives are to: i) provide a platform for the successful conduct of collaborative, multi-institutional research focused on patient-centered outcomes; ii) improve efficiency of scientific and ethical reviews through streamlining of research protocols; iii) maintain the highest degree of scientific and ethical integrity in conducting research initiatives; and iv) promote the dissemination of new knowledge into pediatric surgical practice and health care policy;

WHEREAS CanCORPS' administrative objectives are to: i) simplify and improve the efficiency and speed of study start-ups, including signature of agreements through Implementing Letters; ii) use REDCap for all studies done at the Institutions;

THEREFORE, the Parties have agreed to the following terms and conditions;

1 Definitions

1.1 "Aggregate Results": means multi-member aggregate Data or Results generated in the course of a Study.

1.2 "Agreement": means this Consortium agreement, which includes all Appendices attached hereto.

1.3 "Appendix(ces)": means collectively all the following Appendices attached to this Agreement and individually the following Appendices, such Appendices shall be updated as needed by the Consortium Lead and sent out to the Institutions, subject to compliance with Section 15 hereof, without need for formal amendment to this Agreement. The Parties shall include new revised Appendices as addenda to the Agreement/Appendices with an effective date, as needed:

Appendix 1 - Listing of Member Institutions and their coordinates and notices
Appendix 2 - Rules regarding Membership
Appendix 3 - Form "Joinder Letter Agreement"
Appendix 4 - Letter Agreement Templates
Appendix 5 - Study Proposal Template
Appendix 6 - Study Scoring Template
Appendix 7 - Leadership and Governance Policy
Appendix 8 - Presentation and Publication Policy
Appendix 9 - Intellectual Property Policy
Appendix 10 - Study Selection Policy

1.4 "Applicable Laws": means all applicable federal, provincial and local laws and regulations, including Canada's *Food and Drugs Act* and all regulations made pursuant thereto, Health Canada's Therapeutic Products Directorate Guidelines, the International Conference on Harmonisation (ICH) E6 Guidelines for Good Clinical Practice ("ICH/GCP Guideline"), the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans", the Declaration of Helsinki all applicable federal, provincial and local laws and regulations pertaining to confidentiality and the use and disclosure of PHI and in accordance with generally accepted clinical practices means the applicable privacy legislation and regulations to which all Institutions are bound; including the *Personal Information Protection and Electronic Documents Act* (PIPEDA) and applicable provincial privacy laws and regulations.

1.5 "Board of Directors": has the meaning, composition and responsibilities as described in Appendix 7.

1.6 "Chairperson": has the meaning set forth in Appendix 7.

1.7 "Confidential Information": has the meaning set forth in Article 12.

1.8 "Consortium" or "CanCORPS": means the Canadian Consortium for Research in Pediatric Surgery.

1.9 "Consortium Lead": means The Research Institute of the McGill University Health Centre.

1.10 "Data": means de-identified, anonymized or coded data or information collected from or generated by an Institution under this Agreement. "Data" can include clinical de-identified data, molecular data or data derived from this, as those terms are defined in the Policies, or data and/or information and/or data resulting from the analysis of such clinical data or molecular data. Data shall not include any PHI (as further defined below).

1.11 "Defaulting Institution": has the meaning set forth in Section 16.4 (Material Breach).

1.12 "Effective Date": means the date indicated on top of this Agreement.

1.13 "Founding Members": means the initial fifteen (15) Institutions that signed this Agreement.

1.14 "Implementing Letter": means the letter in substantially the same form as that found in Appendix 4, which will serve as a written record of each Data transfer from an Institution/Provider to another (Lead Institution/Recipient), made pursuant to this Agreement. The Implementing Letter will be considered a record of the agreement between Provider and Recipient in respect of the specific transfer(s) of Data, as applicable. For clarity, the Implementing Letter is replacing the need of data transfer agreements between the Consortium Members, and shall override the terms of this Agreement in the event of any inconsistency.

1.15 "Institution(s)": means the Institutions which have agreed to the Policies and are signatories to this Agreement, and those additional institutions listed on Appendix 1 who have subsequently agreed to become parties to this Agreement by signing the Joinder Letter Agreement at Appendix 3. The term Institution includes the Consortium Lead.

1.16 "Lead Institution": means the Institution that proposed a Study. The Lead Institution will act as the coordinating center for the Study and as the Recipient of Data. The Lead Institution may use Consortium resources in fulfilling its obligations.

1.17 "Liability": has the meaning set forth in Section 17. (Responsibility, Limitation of Liability & Insurance).

1.18 "Member(s)": means all the Institutions that are listed in the recital section of this Agreement, labeled Signatures – Approval of Consortium Agreement with their coordinates indicated in Appendix 1 and the Members that have later joined this Consortium by signing the Joinder Letter Agreement at Appendix 3.

1.19 "National Coordinator": has the meaning set forth in Appendix 7.

1.20 "PHI": means personal health information, as that term is defined in Ontario's *Personal Health Information Protection Act* and/or the equivalent act in the Province in which the Member operates. PHI shall include any information that could reasonably be expected to identify an individual.

1.21 "Policies": means the current versions of the: Appendix 7 - Leadership and Governance Policy, Appendix 8 – Presentation and Publication Policy, Appendix 9 – Intellectual Property Policy, Appendix 10 - Study Selection Policy, as updated, amended and approved as needed, and such other policies which are created and approved as applicable to the Consortium.

1.22 "Protocol(s)" or "Study(ies)": has the meaning set forth in Appendix 5 of this Agreement.

1.23 "Provider(s)": means an Institution and its Site Principal Investigator providing the Data to the Lead Institution/Recipient for a Study.

1.24 "Provider Researcher": means the Provider researcher/ Site Principal Investigator specified as such in an Implementing Letter as described in Appendix 4.

1.25 "REB": means the applicable research ethics board or similar ethics body.

1.26 "Recipient(s)": means the Lead Institution and its Recipient Researcher/Study Principal Investigator receiving Data for a Study.

1.27 "Recipient Researcher(s)": means the Recipient researcher/Study Principal Investigator specified as such in an Implementing Email as described in Appendix 4.

1.28 "REDCap": means the Research Electronic Data Capture, a secure web application for building and managing online surveys and databases powered by Vanderbilt University and supported in part by the National Institutes of Health.

1.29 "Results": means the results generated in the course of a Consortium Study.

1.30 "Site Associate Director": has the meaning set forth in Appendix 7.

1.31 "Site Director": has the meaning set forth in Appendix 7.

1.32 "Site Principal Investigator": means the Site Principal Investigator is the investigator at a Member who will lead the Study at that Institution.

1.33 "Staff": has the meaning set forth in Section 17. (Responsibility, Limitation of Liability & Insurance).

1.34 "Steering Committee": has the meaning set forth in Appendix 7.

1.35 "Study(ies)" or "Protocol(s)": has the meaning set forth in Appendix 5.

1.36 "Study Co-investigators": All personnel at all sites involved in conducting a Study as set forth in Appendix 10.

1.37 "Study Co-Principal Investigator(s)": means the Study Co-Principal Investigator and includes other investigators from the same Institution or another Institution who will share the responsibilities of the Study Principal Investigator as set forth in Appendix 10.

1.38 "Study Principal Investigator": means the investigator at the Lead Institution who is responsible for formulating the Study, initial submission to the Consortium, obtaining local REB approval, data handling, and spear-heading data analysis and interpretation as set forth in Appendix 10.

1.39 "Term": shall mean an undetermined period of time starting on the Effective Date.

2 Purpose and Scope of the Agreement

2.1 Purpose and Scope

2.1.1 This Agreement applies to: (i) the conduct of research in accordance with the Consortium Studies and Protocols; (ii) all Data submitted by the Providers, or to be submitted by the Providers at some future time, to the Lead Institution/Recipient pursuant to this Agreement and acknowledged by signing the Implementing Letter in Appendix 4; and (iii) the terms and provisions governing the management and control of the transfer of Data to Recipients.

3 Membership

3.1 Members

3.1.1 The Appendix 1 includes the name and coordinates of the Members. The rules regarding membership are indicated in Appendix 2 attached to this Agreement.

3.1.2 By execution of this Agreement, each Institution agrees: (i) to become a member of the Consortium; (ii) to participate in the Consortium activities; iii) to participate in the Consortium Studies, to the best of their ability; iv) to sign the Implementing Letters and send them to the relevant Parties when they participate in a specific Study; and (iii) that the activities described in (i) to (iii) shall be governed by this Agreement including its Appendices.

4 Leadership and Governance

4.1 Leadership and Governance

4.1.1 The Leadership and Governance Policy is detailed in Appendix 7.

5 Funding

5.1 General costs

5.1.1 Each Institution shall bear its own logistics costs associated with Consortium activities, such as travel, lodging, etc.

5.2 Study funding

5.2.1 In the absence of grant support, each Institution will be responsible for its own Study costs. For clarity, in the absence of grant support, there is no obligation to any Institution to participate in a Study.

5.2.2 Grant applications for Study funding may be initiated by the Lead Institution with support from the Members.

5.2.3 Budgeting for grant applications should take into account Study costs at all participating Institutions, including the time of the National Coordinator.

5.2.4 Grant management for each Study will be the responsibility of the Lead Institution and the Study Principal Investigator, with transfers to other Institutions as appropriate, the modalities of such transfers to be determined in separate fund transfer Agreements or in the Implementing Letters.

5.2.5 As applicable, each Institution shall be responsible for ensuring that its respective funding agreements with regards to a Consortium Study do not conflict with any of the rights and/or obligations set forth in this Agreement applicable to the Institutions. Upon request, each Institution shall provide the National Coordinator and the Consortium Lead,

with a copy of its funding agreement(s), unless prohibited by the terms of such agreement.

6 Records and Reports

6.1 Records

6.1.1 Each Party shall maintain complete and accurate records generated in the course of carrying out the Consortium Studies, in accordance with the Applicable Policies and Applicable Laws. To the extent permitted by Applicable Law and applicable institutional policies and upon reasonable advance written notice and scheduling, only during the Institution's regular working hours, the Consortium Lead and Lead Institution with regards to its proposed Study, may examine and inspect the Institution's facilities including all reasonable records, Data and work products to the extent relating to its participation in the Consortium Studies.

6.2 Reporting Obligations

6.2.1 Each Party furthermore agrees to report to the Consortium Lead and to the Steering Committee according to the timelines and requirements as set forth in specific Protocols and the Policies or as otherwise determined by the Steering Committee or the Consortium Lead.

7 Data

7.1 Software

7.1.1 REDCap shall serve as the data storage software for Consortium Studies.

7.1.2 A Provider(s) may provide Data to a Lead Institution/Recipient, provided that all such transfers shall be in accordance with all Applicable Laws, the Policies and the specific Protocol, as applicable. The Provider(s) specifically warrants that transfer Data will be in accordance with applicable REB approval and executed informed consent forms or terms of a REB waiver of consent (or equivalent), as applicable.

7.2 Data ownership

7.2.1 Individual institutional Data and Results generated in the course of a Consortium Study are the property of the Site Principal Investigator(s) and/or Institution(s) that generated the Data, unless specifically provided for otherwise, in separate agreements between Institutions or with external sponsors or counterparties.

7.2.2 Aggregate Results generated in the course of a Consortium Study shall be the property of the Consortium Members that have generated it as per their contributions and in compliance with their internal policies and procedures.

7.2.3 Additional Studies of Aggregate Results must be submitted to the Consortium's Steering Committee and Board of Directors through the National Coordinator as a Study proposal.

7.2.4 Approval of additional studies of Aggregate Results must be obtained from the Consortium's Board of Directors prior to conduction of such Studies.

7.2.5 The Members participating in a particular Study will mutually agree on the minimum privacy and security controls for Data on a Study by Study basis.

7.2.6 The transfer of Data to Lead Institution/Recipient constitutes a non-exclusive license to: (a) use the Data exclusively for the purposes of the Consortium Study, for which it was generated; and (b) to use the Data in accordance with the terms of this Agreement, the Informed consents and the specific Protocol. The Lead Institution may not use the Aggregate Results for any other purpose. Aggregate Results may be transferred to

another Lead Institution by Provider, if such Institution has approval from the Consortium Board for a new study using the same Aggregate Results and upon signature of a new Implementing Letter. The Parties acknowledge that they may be the subject of patent applications, patents, copyrights, trade secrets or other proprietary rights in one or more countries. Except as provided in this Agreement, no express or implied licenses or other rights are provided to a Lead Institution, Recipient or Recipient Researcher under any patents, patent applications, trade secrets or other proprietary rights of Provider or any third party, including with respect to any altered forms of, or further developments in respect of, made by Provider.

8 Intellectual Property

8.1 Intellectual Property

8.1.1 The Intellectual Property Policy is detailed in Appendix 9.

9 Study Selection

9.1 Study Selection

9.1.1 The Study Selection Policy is detailed in Appendix 10.

10 Presentations and Publications

10.1 Presentation and Publication

10.1.1 The Presentation and Publication (including authorship) shall be done in accordance with the Policy attached as Appendix 8.

10.1.2

11 Potential Research Ethics Board Reliance Agreement

11.1 REB Harmonization

11.1.1 The Consortium will actively seek opportunities for REB harmonization between centers and entry into REB reliance agreements.

12 Confidentiality

12.1 Confidentiality Obligations

12.1.1 Prior to and during the term of this Agreement, Members may disclose to one another Confidential Information.

12.1.1.1 In order to ensure that each Member understands which information is deemed to be confidential, all Confidential Information will be in written form and clearly marked as "Confidential" and if the Confidential Information is initially disclosed in oral or some other non-written form, it will be confirmed and summarized in writing and clearly marked as "Confidential" by the disclosing Institution to the recipient Institution within ten (10) days after disclosure. Notwithstanding the foregoing, a failure to confirm in writing an oral disclosure or failure to mark information as confidential or proprietary shall not mean that information would not be covered under the definition of Confidential Information in accordance with this Agreement, when the confidential nature of the disclosure is reasonably apparent to the receiving Member.

12.1.1.2 Each Member shall treat such Confidential Information in the same manner as it treats its own Confidential Information but not less than with a reasonable degree of care.

12.1.2 The obligation of a Member to maintain confidentiality under this Agreement will survive its expiration or termination and will continue for five (5) years from the date of disclosure unless specifically provided for otherwise, in separate agreements between Institutions or with external sponsors or counterparties.

12.1.3 Confidential Information shall not include information that:

12.1.3.1 is already known, to the receiving Member prior to the disclosure by disclosing Member, as evidenced by the Member's records;

12.1.3.2 becomes publicly known without the wrongful act or breach of this Agreement by the receiving Member;

12.1.3.3 has been or is disclosed to the receiving Member by a third party who is not, under any obligation of confidence or secrecy to the providing Member at the time said third party discloses to the receiving Member, or has a legal right to do so;

12.1.3.4 is developed independently by employees of the receiving Member without reliance upon the Confidential Information, as evidenced by the receiving Member's records;

12.1.3.5 is approved for release by written authorization of the providing Member;

12.1.3.6 is required to be disclosed by law or governmental regulation or to any governmental entity with jurisdiction, provided that the receiving Member promptly notifies the providing Member as soon as reasonably practical or possible of receipt of the request, and takes reasonable and lawful actions to minimize the extent of such disclosure if requested by the providing Member, at the providing Member's sole cost and expense; and

12.1.3.7 is required to be disclosed to regulatory authorities, the REB and/or REBs of Institutions involved in the conduct of a Study.

13 Privacy

13.1 Privacy Laws

13.1.1 The Parties shall each comply with Applicable Laws regarding protection of patient identifying information or PHI**.** The Applicable Laws apply to all personal information of patients, staff, students or volunteers of the Institutions.

13.2 Compliance

13.2.1 Although it is the intention of the Parties that all Data to be transferred under this Agreement shall be in accordance with the Protocol approved by the REB, in the event that PHI is inadvertently disclosed by a Provider to a Lead Institution and/or Recipient, the Lead Institution and/or Recipient agree to immediately upon becoming aware of such disclosure notify the Provider of receipt of such information and to not use or disclose such information.

14 Conflict of Interest

14.1 Conflict of Interest

14.1.1 It is expected that Members shall communicate to the Chairperson by means of a written and signed document, any existing relationships which may have the potential to create a conflict of interest.

15 Amendments

15.1 Amendment to Consortium Agreement

15.1.1 Any Institution may submit an amendment to the Consortium Agreement to the Steering Committee.

15.1.2 A vote on each amendment will be held by the Steering Committee.

15.1.3 If the amendment passes the Steering Committee, a full vote will be held by the Board of Directors.

15.1.4 Amendments are passed by a simple majority of those voting in the Steering Committee and Board of Directors and shall be signed by all the Members.

15.1.5 The Appendices may be replaced with new versions without the need to amend the Agreement in accordance with this Section 15.

16 Terms of Agreement & Termination

16.1 Written Document

16.1.1 All Members may terminate this Agreement by means of a written document signed by all Members.

16.2 Notice

16.2.1 Any Member may elect to withdraw from Consortium at any time with sixty (60) days prior written notice to Chairperson.

16.3 Effect on Rights

16.3.1 Termination of this Agreement by all Members or withdrawal of a Member shall not affect the rights and obligations of the Members that accrued prior to the effective date of the termination or withdrawal. Nevertheless, in case of withdrawal, the Member shall collaborate in order to make sure that its withdrawal of this Agreement allows the Studies to continue with the other Members. The Member withdrawn from Consortium shall have its participation in all ongoing Studies terminated but can continue to participate in CanCORPS studies as a Partner Institution as per definition in Appendix 2. All the Data collected from all the Studies the withdrawn Member is currently participating in shall remain part of the Study documentation and shall be used by the active Members, mentioning the participation of the withdrawn Member in the collection of the Data, as applicable.

16.4 Material Breach

16.4.1 In the event of a material breach of any term or condition of this Agreement by any Institution (the "**Defaulting Institution**"), which breach is not remedied within thirty (30) days of notice thereof from the Steering Committee, the Consortium Lead may, at the direction of the Chairperson, terminate continued participation of that Defaulting Institution as an Institution in the Consortium by notice to the Defaulting Institution. Such termination shall be without prejudice to any rights or remedies of the Consortium Lead or any other Institution against the Defaulting Institution whether pursuant to this Agreement or otherwise at law.

16.5 Termination by Steering Committee

16.5.1 This Agreement with an Institution may also be terminated if the Steering Committee deems that an Institution is not fulfilling the criteria for continued membership. The Steering Committee may reassess whether to terminate this Agreement with the Institution, if approved by the Chairperson.

16.6 Site Director

16.6.1 The Site Director may transfer their appointment to a replacement or withdraw from CanCORPS should they no longer be able to fulfill their responsibilities, with the approval of the Steering Committee and Chairperson which approval shall not be unreasonably withheld.

17 Responsibility, Limitation of Liability & Insurance

17.1 Responsibilities of the Parties

17.1.1 Each Institution agrees to be responsible and assume liability for its own negligence or willful misconduct, and those of its officers, directors, trustees, employees and professional staff (but specifically excluding any licensed physicians) (collectively "**Staff**"), arising out of or as a result of, or in connection with the performance of this Agreement (the "**Liability**"), to the full extent required by law.

17.2 Limitation of Liability

17.2.1 The foregoing notwithstanding, an Institution shall not be liable for any lost profits, lost opportunities, or other indirect or consequential damages suffered by another Institution.

17.3 Insurance

17.3.1 Each Institution shall maintain sufficient policies of general liability insurance to cover its obligations herein, for the duration of the Term. To the extent applicable, each Institution shall ensure that its licensed physicians who are involved in the Consortium maintain their membership with the Canadian Medical Protective Association (CMPA) during their involvement with the Consortium.

18 Miscellaneous

18.1 This Agreement Supersedes

18.1.1 This Agreement and the attached Appendices represent the entire understanding between the Parties related to the Agreement and supersedes any previous understandings, commitments or agreements, whether written or oral. If any provision of this Agreement is wholly or partially unenforceable for any reason, all other provisions will continue in full force and effect.

18.2 Applicable Laws and Jurisdiction

18.2.1 This Agreement shall be governed by and construed in accordance with the laws of the home province/state of the Party defendant in the litigation. The Parties further acknowledge that the courts of the home province/state of the Party defendant in the litigation, shall have exclusive jurisdiction to entertain any complaint, demand, claim or cause of action whatsoever arising out of this Agreement and hereby irrevocably submit to the exclusive jurisdiction of said courts.

18.3 Survival

18.3.1 No termination of the Agreement, however effectuated, will release the Parties from their rights and obligations that, by their nature, shall survive the termination of this Agreement.

18.4 Amendment

18.4.1 This Agreement shall not be amended, modified, varied, or supplemented except in writing signed by each of the Parties except for the appendices that may be modified, as

foreseen in Clause 15. Such modified Appendices shall be distributed to the Parties by Consortium Lead.

18.5 Use of Name

18.5.1 No Party shall use, or authorize others to use, the name, symbols, or marks of another Party hereto or its staff for any endorsement purposes without prior written approval from the Party whose name, symbols or marks are to be used.

18.6 No Assignment

18.6.1 No Party may assign any of its rights or obligations under this Agreement without the prior written consent of the other Parties.

18.7 No Partnership

18.7.1 Nothing in this Agreement creates, implies, or evidences any partnership or joint venture between the Parties, or the relationship between them of principal and agent. No Party shall have the authority to act on behalf of any other Party or to bind another Party in any manner.

18.8 Notices

18.8.1 Any notice, direction or instrument required or permitted to be given hereunder to any Institution shall be given in writing and shall be deemed to have been given only if delivered, mailed postage prepaid by registered mail, transmitted by fax to the address or fax number of such Institution. Any such notice, direction and or instrument if delivered, shall be deemed to have been given or made on the day on which it was delivered, if mailed postage prepaid by registered mail shall be deemed to have been made or given on the fifth business day following the day on which it was mailed, or if transmitted email shall be deemed to have been made or given on the day on which the sender receives confirmation of receipt at the faxed number of the fax or upon confirmed receipt of such email if emailed. Notwithstanding the foregoing, in the event of threatened or actual mail strike or slow down, notice shall not be given by mail. The contact information of the Institutions to be used for providing notice is set forth in Appendix 1.

18.9 Electronic Copies of Agreement

18.9.1 Each Party represents that it is permitted to enter into this Agreement; to consent to its conditions and that each has authority to sign this Agreement. This Agreement may be executed in counterparts and may be executed and delivered electronically by PDF and all such counterparts and PDF copies shall together constitute one agreement. The Parties agree that PDF copies of signatures have the same effect as original signatures.

18.10 Language

18.10.1 The Parties declare that they have accepted that this Agreement and all writings relating thereto be drawn in English. *Les parties déclarent avoir accepté que la présente entente et tous écrits s'y rapportant soient rédigés en anglais.*

(Signature page follows)*
**Note - signature pages have been removed from this document.*

Appendix 1 - Listing of Member Institutions and their coordinates and notices

The Montreal Children's Hospital	The Research Institute of the McGill University Health Centre (RI-MUHC)
Alberta Children's Hospital	The Governors of the University of Calgary and Alberta Health Services
Stollery Children's Hospital	The Governors of the University of Alberta
BC Children's Hospital	The University of British Columbia & Provincial Health Services Authority (operating at its BC Children's Hospital site)
Health Sciences Centre - Children's Hospital of Winnipeg	The University of Manitoba and Shared Health Inc. – Health Sciences Centre
Janeway Children's Health and Rehabilitation Centre	Memorial University of Newfoundland and Eastern Regional Health Authority
IWK Health Centre	Izaak Walton Killam Health Centre
McMaster Children's Hospital	Hamilton Health Sciences Corporation on behalf of its McMaster Children's Hospital
Children's Hospital London Health Sciences Centre	Lawson Health Research Institute, a joint venture of London Health Sciences Centre Research Inc. and Lawson Research Institute
CHEO	Children's Hospital of Eastern Ontario Research Institute Inc.
Sick Kids	The Hospital for Sick Children
Centre Hospitalier Universitaire Sainte-Justine	Centre Hospitalier Universitaire Sainte-Justine
CHU- Laval	CHU de Québec - Université Laval
CHU-Sherbrooke	CIUSSS de l'Estrie - Centre hospitalier universitaire de Sherbrooke
Jim Pattison Children's Hospital	Saskatchewan Health Authority and The University of Saskatchewan

**Note - For confidentiality purposes, complete details are not included.*

Appendix 2 - Rules Regarding Membership

The Consortium Members wish to put in place the following rules regarding the Membership of the CanCORPS Consortium. The rules concerning the Membership can be changed, as needed, upon approval by the Board of Directors.

19 Initial and Future Membership

19.1 Opportunity for membership is restricted to Institutions with pediatric surgical practices residing within the territorial boundaries of Canada.

19.2 The fifteen (15) Institutions that originally signed the Agreement shall be named as Founding Members of the Consortium upon endorsement of this document.

19.3 Non-member institutions may apply for membership at any time.

19.4 On a going forward basis and upon approval by the Board of Directors, additional institution(s) may agree to be bound by the terms and provisions of the Agreement as evidenced by execution of the Joinder Letter Agreement (attached to the Agreement as Appendix 3). Upon execution of said Joinder Letter Agreement by the Consortium Chairperson and Consortium Lead (on behalf of the Parties) and an institution, said institution shall be deemed to be an Institution under this Agreement. Executed Joinder Letter Agreement(s) shall be incorporated into this Agreement in the form of updates to Appendix 1 with notification to, but no further action required of, existing Institution(s). The Consortium Lead shall be responsible for the notification to existing Institution(s) pursuant to this Appendix 1 and shall further provide copies of all executed Joinder Letter Agreement(s) to said existing Institution(s). No preference under this Agreement will be granted to an Institution over another Institution based on the temporal order in which, and/or mechanism under which, an Institution has executed this Agreement.

19.5 Each Member Institution shall internally appoint a Site Director and, if desired, a Site Associate Director.

19.6 The Site Director and Site Associate Director will represent the Institution in all affairs related to the Consortium.

19.7 Each Member Institution shall exert one (1) vote in study selection and one (1) vote in all voting procedures related to Consortium affairs. Voting will be provided by the Site Director of each Institution.

20 Criteria for continued membership

20.1 Continued membership in the consortium will be contingent upon the following:

20.1.1 Active participation in conference calls and face-to-face meetings held by the Consortium.

20.1.2 Demonstration of the highest standards of research stewardship as it pertains to the Consortium Studies and membership.

21 Partner institutions

21.1 Partner institutions (non-Canadian institutions or Canadian institutions without dedicated pediatric surgical practices) may participate in specific Studies with the sponsorship of a Member. The Site Director of the sponsoring institution will act as Study Co-Principal Investigator for the partner institution. A majority of Members have to agree to such participation.

Appendix 3 - Form "Joinder Letter Agreement"

INSERT DATE

INSERT INSTITUTIONAL NAME AND ADDRESS

RE: Inclusion as an Institution(s)/Party/Member onto the Consortium Agreement for the "Canadian Consortium for Research in Pediatric Surgery" (CanCORPS) originally executed INSERT CONSORTIUM AGREEMENT DATE; and as may have been further amended.

The Research Institute of the McGill University Health Centre ("**RI-MUHC**" or "**Consortium Lead**") and a number of research institutions are Parties to the CanCORPS Consortium Agreement originally dated [INSERT CONSORTIUM AGREEMENT DATE] (the "**Consortium Agreement**").

This Letter Agreement dated and effective as of the date first written above is between the above noted institution and the Consortium Lead (on behalf of itself and all other signatories to the above noted Consortium Agreement, hereinafter collectively referred to as the "**Institutions**").

INSERT INSTITUTIONAL NAME desires to participate in respect of the activities encompassed by the Consortium Agreement. INSERT INSTITUTIONAL NAME represents that it has received and reviewed the Consortium Agreement and agrees to be bound by its terms and conditions as of the date first written above. As such, the Institutions (through their representative and agent in this matter – the Consortium Lead) agree to this participation by INSERT INSTITUTIONAL NAME and its inclusion as a party to the above noted Consortium Agreement.

*(*Signature page follows)*
**Note - signature pages have been removed from this document.*

Appendix 4 - Letter Agreement Templates Implementing Letter

The purpose of this Implementing Letter is to provide a record of all Data transfers occurring pursuant to the Agreement and to provide the specific information regarding each transfer, namely, as applicable: Recipient and Recipient Researcher, Data being transferred, including details of how the Data will be used (needed for the Lead Institution's/Recipient reports to the REB responsible to approve the Study for its Institution and to the Providers' REBs or the REB responsible to approve the Study for Provider), and to confirm that the Recipient Researcher/Study Principal Investigator will submit to the Consortium Lead and Recipient results and unpublished data of the experiments conducted using the Data on a timely basis. The Recipient Researcher/Study Principal Investigator may also request that such results and data be kept confidential for up to twelve (12) months after the date of submission to the Consortium Lead/Recipient, which can be further extended on approval of the Board of Directors.

The Data shall not contain any PHI nor any information at an individual level in a form which could reasonably be expected to identify an individual.

Each completed Implementing Letter forms a part of the Consortium Agreement and is binding on the Parties to the transfer and to all terms and conditions of the Consortium Agreement regarding such transfer. The Implementing Letter will be considered a record of the agreement between Provider(s) and Recipient(s)/Lead Institution, as applicable, in respect of a specific transfer of Data from the Provider to the Recipient/Lead Institution under the Agreement. No Data transfers will be made under the Agreement without a corresponding completed Implementing Letter.

The Institution representatives of the Recipient/Lead Institution and the Recipient Researcher/Study Principal Investigator receiving an Implementing Letter pursuant to this Agreement shall retain a copy of each completed Implementing Letter for the Parties' files.

The Consortium Lead and the National Coordinator will retain a copy of each Implementing Letter sent to the Recipient/Lead Institution for their files.

The content of each Implementing Letter will include the following information:

Date:

XXX ("Provider")	
With an address at:	
Contact information: *[address]* *[Contact Person]*	

and

YYY ("Recipient")	
With an address at:	
Contact information: *[address]* *[Contact Person]*	

(each of Provider and Recipient is a "Party", collectively the "Parties") as those terms are used in Consortium's Agreement,

"Data" have the same meaning as set out in the Consortium's Agreement. In this Implementing Letter the following Data shall be transferred:

The Data will be provided by:

XXX [PI] ("Provider Investigator")	
With an address at: *Contact informaion:*	

The Data will be received by:

YYY [PI] ("Recipient Investigator")	
With an address at: *Contact information:*	

INSERT ADDITIONAL INFORMATION

Title of Project Approved by the Board of Directors (that will use Data):

[Please enclose a copy of the protocol to the email]

If applicable, Funder of Project:
If applicable, Amount of Funding:

PURPOSE (attach REB approved Protocol as part of Schedule "A" if applicable)

PUBLICATION arising out of this Study (please send .pdf copy & include acknowledgment):

The data used for this Study were made available by the CanCORPS Consortium and through funds from *[insert funder information, as applicable]*

As a condition of transfer of the Data, Recipient/Lead Institution, Recipient Investigator/Study Principal Investigator, Provider and Provider Investigator/Site Principal Investigator confirm the following:

I have read and received a copy of the CanCORPS Agreement and I agree with its terms and conditions. I understand that this implementing letter is part of Appendix 4 of the Consortium Agreement.

IN WITNESS WHEREOF, THE PARTIES HAVE CAUSED THEIR DULY AUTHORIZED REPRESENTATIVES TO EXECUTE THIS AGREEMENT AS OF THE PLACE(S) AND DATE(S) SET FORTH BELOW.

Provider Institution *Date : _____* *By : _____* *Name* *Title*	*Recipient Lead Institution* *Date : _____* *By : _____* *Name* *Title*
Provider Investigator *Date : _____* *By : _____*	*Recipient Investigator* *Date : _____* *By : _____*

On behalf of the CanCORPS Chairperson for CanCORPS

Date : _____

By : _____
Name

Appendix 5 - Study Proposal Template

The following will be provided in a separate Word document.

Once this Study Proposal Template is completed and approved by the Board of Directors and the relevant REBs, it shall be referred to as a "**Study**" or as a "**Protocol**" of the Consortium.

In a maximum of 2 pages, provide the following information:

1. Study Title: Click here to enter text.
2. Lead Institution: Click here to enter text.
3. Principal Investigator: Click here to enter text.
4. Co-principal Investigator: Click here to enter text.
5. Study Objectives: Click here to enter text.
6. Study Type: Click here to enter text.
7. Study description:
   - 7.1. Background Information (e.g., literature review). Click here to enter text.
   - 7.2. Study hypothesis. Click here to enter text.
   - 7.3. Brief overview of the study design, methodology, and analysis plans. Click here to enter text.
   - 7.4. Dissemination ideas/knowledge translation strategy. Click here to enter text.
8. Level of Evidence: Click here to enter text.
9. Expected progress of the proposed research study
   - 9.1. Brief Summary: Click here to enter text.
   - 9.2. Anticipated start date: Click here to enter a date.
   - 9.3. Milestones included in Gantt chart format: ☐
   - 9.4. Specify the status, if any, of the program's ethics application at the time of study proposal submission: Click here to enter text.
10. Contact information (not counted in page limit)
    - 10.1. Principal Investigator
      - 10.1.1. Name.Click here to enter text.
      - 10.1.2. Title: Click here to enter text.
      - 10.1.3. Institution name: Click here to enter text.
      - 10.1.4. Department name: Click here to enter text.
      - 10.1.5. Full mailing address: Click here to enter text.
      - 10.1.6. Phone number:Click here to enter text.
      - 10.1.7. E-mail address: Click here to enter text.
    - 10.2. Co-Principal Investigator 10.2.1. Name.Click here to enter text.
      - 10.2.2. Title: Click here to enter text.
      - 10.2.3. Institution name: Click here to enter text.
      - 10.2.4. Department name: Click here to enter text.
      - 10.2.5. Full mailing address: Click here to enter text.
      - 10.2.6. Phone number:Click here to enter text.
      - 10.2.7. E-mail address: Click here to enter text.
    - 10.3. Program Research Assistants/Coordinators (if applicable).
      - 10.3.1. Name.Click here to enter text.
      - 10.3.2. Title: Click here to enter text.
      - 10.3.3. Institution name: Click here to enter text.
      - 10.3.4. Department name: Click here to enter text.
      - 10.3.5. Full mailing address: Click here to enter text.
      - 10.3.6. Phone number:Click here to enter text.

10.3.7. E-mail address: Click here to enter text.

11. References (not counted in page limit)

Date of Submission: Click here to enter a date.

Upon completion, please e-mail the CanCORPS National Coordinator

Appendix 6 - Study Scoring Template

See separate sheet.

Appendix 7 - Leadership and Governance Policy

22 Consortium governance

22.1 Consortium governance shall consist of a Board of Directors, a Steering Committee, and a Chairperson.

23 Board of Directors

23.1 Selection of the Board

23.1.1 The Consortium Board of Directors shall consist of the Site Directors and Site Associate Directors for each Institution with active membership. They will be internally appointed by each Institution and shall represent the Institution in all affairs related to the Consortium.

23.1.2 The Steering Committee Chairperson shall serve as Chairperson of the Board.

23.1.3 Each Member shall be entitled to one vote on the Board of Directors.

23.1.3.1 Board membership will have no term limits. Each Member is responsible for designating the Site Director, and if desired a site Associate Director, to represent them on the Board.

23.1.4 Board responsibility and voting procedures

23.1.4.1 The Board will review and approve Studies to be conducted by CanCORPS.

23.1.4.2 The Board will **review study** results and conclusions prior to presentation and publication.

23.1.4.3 The Board will approve new Consortium resolutions and any amendments to the Consortium Agreement.

23.1.4.4 The approvals shall be made by a simple majority; (50% +1 vote) of the votes (directly or remotely) will be required for approvals. Remote votes may be submitted to the National Coordinator or Chairperson.

23.1.4.5 The Chairperson will vote as a representative of his/her Institution if he/she is also the Site Director for that Institution**.**

23.1.5 Board Meeting Frequency

23.1.5.1 At least three (3) times per calendar year.

23.1.5.2 At least one of the three (3) meetings shall be a face-to-face meeting.

23.2 Steering Committee

23.2.1 The Consortium Steering Committee shall consist of a Chairperson and four (4) Board of Director members.

23.2.2 Selection and Terms of the Steering Committee

23.2.2.1 The term for each Steering Committee member will consist of three (3) years with an option to renew once.

23.2.2.2 Two of the inaugural Steering Committee members will serve for a single term of five (5) years to allow for staggered turnaround and continuity within the Steering Committee.

23.2.2.3 Terms will run from July 1 to June 30.

23.2.2.4 Election of Steering Committee members:

23.2.2.4.1 Upon vacancy of a Steering Committee position, a call for nominations from the Board shall be issued to the Board of Directors by the Chairperson.

23.2.2.4.2 Should the number of nominations equal the number of positions available, election to the Steering Committee will be by acclamation.

23.2.2.4.3 Should the number of nominations be greater than the number of positions available, a silent vote by the Board of Directors, excluding the Chairperson, will be conducted by the National Coordinator (one vote per site). Should a tie occur, it will be broken by a final vote from the Chairperson.

23.2.2.5 Role of the Steering Committee

23.2.2.5.1 To initially assess studies submitted by Members for consideration of execution by CanCORPS for methodology, quality, and integrity. The Steering Committee will work with the submitting investigators to ensure a complete proposal package is available for consideration by the Board. The Steering Committee may present a recommendation to the Board on the feasibility and appropriateness of the Study for CanCORPS, but the ultimate decision will be made by the Board.

23.2.2.5.2 To assess results and conclusions included in abstracts and manuscripts resulting from CanCORPS Studies. After vetting, they will be presented to the entire Board, with a recommendation by the Steering Committee.

23.2.2.5.3 To oversee financial issues as they arise.

23.2.2.5.4 To coordinate/resolve authorship issues.

23.2.2.5.5 To act as a forum for initial discussion of amendments, resolutions and initiatives of the Consortium, developing recommendations for the Board.

23.2.2.5.6 To hold Study Principal Investigator and Site Principal Investigators accountable for Study progress.

23.2.2.5.7 To create an annual report of Consortium activities on June 30 of each calendar year.

23.2.2.5.8 Each member of the Steering Committee will be entitled to one (1) vote.

23.2.2.5.9 The Chairperson will not vote except in cases of a tie vote by the Steering Committee. In the case of a tie, the Chairperson will make the deciding vote.

23.2.3 Steering Committee Meeting Frequency

23.2.3.1 At least quarterly.

23.2.3.2 The Chairperson may call more meetings at his/her discretion.

23.3 2.3 Chairperson

23.3.1 The Chairperson shall act as the Chair of the Steering Committee and the Board of Directors.

23.3.2 2.3.2 Selection of the Chairperson

23.3.2.1 The term for the Chairperson will be five (5) years, non-renewable.

23.3.2.2 Terms will run from July 1 to June 30.

23.3.2.3 Election of the Chair:

23.3.2.3.1 Upon anticipating vacancy of the Chair, he or she will call for nominations for his/her successor.

23.3.2.3.2 Should only one nominee come forward, they will be elected to Chair by acclamation.

23.3.2.3.3 Should the number of nominations be greater than one, a silent vote (conducted by the National Coordinator) will be performed (one vote per site). Should a tie occur, the decision will be made by the outgoing Chair.

23.3.2.3.4 Should no nominee come forward, the current Chair will be asked to stay in place until a nominee from the Board presents themselves.

23.3.3 Role of the Chairperson

23.3.3.1 The primary role of the Chairperson is to lead the Steering Committee and the Board of Directors through setting meetings, setting agendas, budgeting, and working with the National Coordinator.

23.3.3.2 The Chairperson or his/her designate will represent CanCORPS in public forums, and contact with other organizations and agencies.

23.3.3.3 The Chairperson will review and approve the annual CanCORPS report.

23.4 Local Hosts

23.4.1 The program Chair or co-Chairs will be the site Director (and site Associate Director if applicable) hosting an annual face to face meeting.

23.4.2 The Board will select future meeting sites at each face to face meeting.

23.4.3 The term of the program Chair or co-Chairs will end at the end of the meeting.

23.4.4 Roles and responsibilities

23.4.4.1 Arrange for meeting facilities, accommodations/local travel.

23.4.4.2 Assist the Chair, as needed, to create a meeting agenda Chairperson.

23.5 Additional leadership positions

Additional positions such as secretary or treasurer and additional committees may be created after a recommendation by the Steering Committee and approval by the Board.

23.6 National Coordinator

23.6.1 Roles and responsibilities

23.6.1.1 The primary role of the National Coordinator is to enable and assist the Members to continuously move forward by monitoring and facilitating progress of active or planned projects.

23.6.1.2 The National Coordinator will act as the liaison for all site research coordinators allocated to CanCORPS Studies.

23.6.1.3 The National Coordinator will assist with the REB approvals as needed, maintain a dashboard of projects and facilitate project management and communication between members.

23.6.1.4 When voting is required, the National Coordinator will develop a silent vote and disseminate the results.

23.6.1.5 The National Coordinator will identify potential grants relative to Consortium Studies and organize submission of such grants, working closely with study Principal Investigators.

23.6.1.6 The National Coordinator will manage the Implementing Letters as better explained in Appendix 4 of the Agreement and keep copies of those for future reference.

Appendix 8 - Presentation and Publication Publicity

24 Decision regarding presentation venues

24.1 The Board of Directors will encourage presentation of Study Results at international surgical and pediatric surgical meetings.

24.2 Decisions on presentation venues will be suggested by the Steering Committee.

24.3 The decision on presentation venues of a specific Study will be made by the Study Principal Investigator in collaboration with all co-investigators.

25 Decisions regarding manuscript submissions

25.1 The Board of Directors will encourage publication of Study manuscripts in high impact surgical and pediatric surgical journals.

25.2 Decisions regarding journal submissions will be suggested by the Steering Committee.

25.3 The decision on manuscript submissions of a specific Study will be made by the Study Principal Investigator in collaboration with all Co-Investigators.

26 Authorship

26.1 To better reflect their effort in project conception and overall project management, the Study Principal Investigator and/or Co- Principal Investigator of a specific Study will be listed as the first and last authors as determined by the Study Principal Investigator of the Study. This will be clearly delineated at the beginning of the Study.

26.2 All Co-Investigators/site leads may be included as co-authors based on their contribution to a specific Study as determined by the Study Principal Investigator and shall comply with the International Committee of Medical Journal Editors (ICMJE)[1] authorship criteria.

26.3 Acknowledgements

26.3.1 Site Principal Investigators who contributed to the Study at any Institution but did not achieve author status may be listed in an acknowledgement section at the end of a manuscript.

26.4 Authorship requirements

26.4.1 Obtaining REB approval at author's Institution or from the REB provincially designated to approve for author's Institution and at least one of the following:

26.4.1.1 Engagement in Study development/management.

26.4.1.2 Enrollment of patients or subjects in Study.

26.4.1.3 Critical review of the manuscript.

26.4.1.4 Individual authors may include a trainee or another individual at their Institution as an author.

26.4.2 Authorship order

26.4.2.1 The Study Principal Investigator (and/or Study Co-Principal Investigator as indicated) will be listed as the first and/or last/corresponding author as determined by the Study Principal Investigator of the specific Study.

26.4.2.2 The remaining co-authors will be listed in alphabetical order.

26.4.2.3 All manuscripts will list **The Canadian Consortium for Research in Pediatric Surgery (CanCORPS)** at the end of the author line.

[1] http://www.icmje.org/recommendations/

Appendix 9 - Intellectual Property Policy

27 Intellectual property (IP), unless specifically provided for otherwise, in separate agreements between Institutions or with external sponsors or counterparties, shall mean any form of intellectual property recognized worldwide as well as all moral and other rights and interest related thereto, including but without limitation: any invention, improvement, idea, process, formula, algorithm, advanced technology, prototype, results, industrial design, compilation of data, technical information, specification, technology, machine, system, reactive, chemical and derived compound, procedure and method for the synthesis of a compound or derivative, software (source code, code object and documentation), firmware and hardware, model, prototype, specification, method, configuration, genetic and biological material, patentable (or not) copyrightable (or not) by copyright or any other right, including: (i) any patent, patent application, continuation, partial continuation, additional request (divisional application), reissue and review; (ii) any copyright, work or other subject matter, and any application for registration, registration, substituted right and extension; (iii) any industrial design, registration application and registration; (iv) any trade name, brand certification, trademark and trade name, as well as any application for registration and registration relating thereto; (v) any trade secret and know-how; and (vi) any other type of intellectual property right and interest in such right;

28 Background IP includes any form of Intellectual Property or any other outcome or information owned, controlled or made available by an Institution/Study Principal Investigator/Site Principal Investigator in connection with a specific Study, but which does not result from the realization of the specific Study.

29 Foreground IP means any form of Intellectual Property produced, created, designed, discovered, invented, otherwise reduced to practice during the performance of a specific Study;

30 The Members agree unless contrary to the provisions in a specific separate agreement and in accordance with their internal procedures and policies that:

30.1 All Background IP will remain the exclusive property of the Party which has designed, developed, acquired or otherwise obtained it, and the other Parties shall not confer any right, title or interest on such Background IP. In the event Background IP is required for the practice of Foreground IP, rights to such Background IP will be negotiated in good faith; however, no party shall be obligated to grant such rights.

30.2 If the Foreground IP results from the contribution of one Party, any right, title or interest will remain the exclusive property of such Party. If the Foreground IP results from the contribution of more than one Party ("Joint Foreground IP"), any right, title or interest will be shared according to the contribution of each Party's inventor and their internal policies, if applicable.

31 The Parties shall negotiate in good faith an agreement to regulate all the aspects related to the protection, use and exploitation of the Joint Foreground IP. One Party is not allowed to exploit nor to grant licenses with regards the Joint Foreground IP without the other Party(ies)'s consent, which shall not be unreasonably withheld. The Parties grant each other a non-exclusive, perpetual, royalty-free license to use the Foreground IP free of charge and without temporal and geographic limits for research, clinical and education purposes, but not for commercial purposes unless a separate agreement is signed for the use of the Foreground IP for commercial purposes.

Appendix 10 - Study Selection Policy

32 Study submissions

32.1 All Studies must be submitted to the National Coordinator using the template in Appendix 5. Use of a Gantt chart is highly encouraged.

32.2 Studies can be submitted to the National Coordinator for consideration at any time.

32.3 The National Coordinator will work with the Study Principal Investigator to confirm completeness of the application, and forward the Study to the Steering Committee.

32.4 Any Member/Institution may submit a Study to the Consortium and act as the Study Principal Investigator.

32.5 The Site Director(s) of a Lead Institution must act as a Study Co-Principal Investigator(s), if they are not the Study Principal Investigator(s).

33 Study Scoring

33.1 Studies will be initially submitted to the Steering Committee for initial review. The Steering Committee will be responsible for ensuring if the Study is appropriate for wider dissemination to the Board of Directors.

33.2 Once deemed appropriate, the Study will then be circulated for assessment by the Board of Directors using the form in Appendix 5.

33.3 Each Institution will assign the Study a score.

33.4 Sites represented by a Site Director and Site Associate Director will only submit one score, representing an average of both.

33.5 An aggregate score of the Board members will be calculated.

34 Study Selection

34.1 Studies will be discussed and evaluated at either a face-to-face meeting or teleconference of Members.

34.2 In the event of an impasse – further discussion and open voting may be undertaken should Members agree.

34.3 Potential Studies will be judged based on scientific merit, projected impact, and feasibility. Early Consortium Studies will prioritize feasibility.

34.4 A "Consortium Study" shall denote a proposal that achieves majority vote during voting procedures by the Members. A Study may then be considered appropriate to begin or set aside for future launching.

34.5 The number of contemporaneous Studies supported by the Consortium will be dependent on the anticipated capacity of participating Institutions and will be revisited annually by the Steering Committee and Board of Directors.

34.6 The Study Principal Investigator of each Study will be required to provide the Chairperson and Steering Committee a semi-annual progress report, emphasizing adherence to timelines.

34.7 All ongoing Studies will be reviewed annually by the Steering Committee and Board of Directors.

35 Study Roles

35.1 Lead Institution

35.1.1 The Lead Institution is the Institution that proposed the Study. This Institution will act as the coordinating center for the Study, but may use Consortium resources in fulfilling their obligations.

35.2 Study Principal Investigator

35.2.1 The Study Principal Investigator is the investigator at the Lead Institution who is responsible for formulating the Study, initial submission to the Consortium, obtaining local REB approval, data handling, and spear-heading data analysis and interpretation. The Study Principal Investigator will work closely with all Site Principal Investigator's and the Chairperson to ensure Study progress, conducting conference calls as necessary. First and/or corresponding authorship is expected.

35.3 Study Co-Principal Investigator(s)

35.3.1 The Study Co-Principal Investigator includes other investigators from the same Institution or another Institution who will share the responsibilities of the Principal Investigator.

35.3.2 If the Consortium Site Director or Site Associate Director is not the Study Principal Investigator, he or she must serve as a Study Co-Principal Investigator.

35.4 Site Principal Investigator

35.4.1 The site Principal Investigator is the investigator at a participating Consortium Institution who will lead the Study at that Institution.

35.4.2 If the Consortium Site Director or Site Associate Director is not the Site Principal Investigator, he or she must serve as a Site Co-Principal Investigator.

35.5 Study Co-Investigators

35.5.1 All personnel at all sites involved in conduct of the Study