Guidelines for Requests for Statistical Analysis and Interpretation of Information from the Canadian Children's IBD Network (CIDsCaNN) Database

Preamble

WHEREAS it is desirable to use the CIDsCaNN database and biospecimens for creation of knowledge to improve the care for children with Inflammatory Bowel Disease (IBD) and to understand the natural history and clinical variations of the IBD in Canada,

THEREFORE, the following set of principles is created:

1. **Advanced Statistical Analysis and Interpretation Requests to the CIDsCaNN Statistician**

1.1: CIDsCaNN members are encouraged to develop research protocols, abstracts and publications utilizing information contained within the CIDsCaNN database.

1.1.1: While trainee members and non-CIDsCaNN members may also access this information, a request under these circumstances must be done in collaboration with at least one (and preferable more than one) CIDsCaNN member in good standing.

1.1.2: A CIDsCaNN member making a request will be considered responsible for the submission and data provided, its use and distribution. The request for data should be considered privileged information from CIDsCaNN and participating contributors. As such, there is an expectation for any communication in the public realm to be inclusive of CIDsCANN source acknowledgement and any abstract/manuscript to be submitted to the Publications Committee for approval with appropriate CIDsCaNN member authorship.

1.1.3: The request must also indicate if and with whom there will be 3rd party sharing of information. Approval for such will be granted through the Committee proposal submitted.

1:2: Any proposed research protocol, abstract or manuscript involving previously collected CIDsCaNN data or data to be collected through the CIDsCaNN should be anticipated to require advanced statistical analysis or interpretation consultation (see Section 2 for preliminary data requests).

1.2.1: An initial proposed research protocol, abstract or manuscript should be submitted to either the Clinical Care & Research Committee (CCRC) or the Basic & Translation Research Committee (BTRC), as appropriate, for preliminary approval to proceed

1.2.2: Following CCRC or BTRC approval of the initial research protocol, abstract or manuscript, the appropriate committee lead will inform primary investigator/author and CIDsCaNN Statistician of such approval.

1.2.3: The primary investigator/author should then arrange a statistical consultation meeting with the CIDsCaNN Statistician. The expectation of this contact will be to determine what data/analysis will be needed and be collected or analyzed (i.e. a statistical plan) and incorporated into the submission of a final proposed research project/abstract/manuscript.

- It should be anticipated that there will be an iterative process and there will be a 2-4 week turn-around time for each iteration.

1.2.3: The final proposed research protocol, abstract or manuscript inclusive of the statistical plan should be re-submitted to appropriate CCRC/BTRC for final approval and then proceed to presentation (see Addendum 1) at a Steering Committee Meeting

1.2.4: The primary investigator should anticipate that further consultation with the Statistician will be required following completion of the data collection phase of the research project for data analysis.

- It should be anticipated that there will be an iterative process and there will be a 2-4 week turn-around time for each iteration.

1.2.5: The Statistician will be available to primary authors of approved protocols for assistance in abstracts or manuscript preparation (e.g., graphs, figures, and statistical methodologies).

- It should be anticipated that there will be an iterative process and there will be a 2-4 week turn-around time for each iteration.

2. Basic Data Requests for the Data Management and Integration Committee

2.1: CIDsCaNN members may want to request preliminary clinical and demographic data available in the CIDsCANN database housed at the Hospital for Sick Children a priori of generation of a research protocol generation (e.g., sufficient sub-group numbers to generate information for initial research protocol submission). The requested data would be expected to only be basic data along with basic statistical details (e.g., median age $\pm$ IQR) that would be sufficient for preliminary data scans or description of the cohort.

2.2: A *Request for Data Form* (available from CIDsCaNN website) should be submitted to the Data Management and Integration Committee (DMIC) lead for DMIC approval. Clarification may be requested by the Committee.

- Approval of such requests is anticipated to be completed within a month of following final submission.

2.3: With notification of DMIC approval, the requestor should contact the Network Management Centre (NMC) Data Manager.

- The NMC Data Manager is anticipated to provide the requested information to Requestor within 2 weeks of being received.

Addendum 1:

The primary investigator/author will deliver a concise presentation on the final proposed research protocol to the steering committee. The presentation will include elements of rationale, study objectives, study design, inclusion and exclusion criteria, primary and secondary outcomes, variable definitions, and statistical analysis plan. The presentation will also include basic data report, as requested by the primary investigator/author from the DMIC/NMC (e.g., number of eligible participants, basic descriptive characteristics of cohort, etc.).

Addendum 2: Flow Diagram for Data Requests