CANCER IN YOUNG PEOPLE IN CANADA PROGRAM

PROGRAMME CANCER CHEZ LES JEUNES AU CANADA

CYP-C Data Access Request Application Instructions

Table of Contents

A. PATIENT LEVEL DATA ACCESS REQUESTS

Note that applicants are free to append a full protocol/proposal if available.

1. Research Proposal

a. Title of project
Provide the full title of the research proposal being submitted.

b. Principal Investigator and Co-Investigators
Refer to Appendix 1 for definitions of Principal Investigator and Co-Investigator.

Provide the name, address, phone, e-mail address and affiliation (institution) of the ONE Principal Investigator and the Co-Investigators (if applicable). Related qualifications must also be included and should specify degree and field of study. Collaborators can also be specified.

All individuals who will have access to patient-level data must be indicated (tick the appropriate box). Reason for access must be provided. Access to personal health information should be limited to the minimum number of individuals necessary for project completion.

c. Collaborators
Provide the name, address, phone, e-mail address and affiliation (institution) of all other individuals that will have access to the data. Related qualifications must also be included and should specify degree and field of study.

All individuals who will have access to patient-level data must be indicated (tick the appropriate box). Reason for access must be provided. Access to personal health information should be limited to the minimum number of individuals necessary for project completion.

d. Background
Provide a brief summary of current knowledge relative to the proposed research, including any relevant preliminary data, pilot data or exploratory studies and results bearing on the study by other. Describe previously work conducted by the investigators in the area.

e. Objectives and rationale
Provide clear statement of hypothesis or statement of research applicable to the research method and the rationale for the study. Outline the primary, secondary and exploratory objectives.

f. References
Optional area to note literature references for background (or any other section).

g. Methods
Include the following sub-headings:
- Overall design of proposed research
- Cohort to be included with particular attention to inclusion and exclusion criteria. Eligibility criteria must include specific diagnoses and diagnosis time periods.
- Description of control population if applicable
- Endpoints
- Statistical analysis for all objectives
- Sample size justification

h. Data Element Justification

Appendix A and B can be used to reference available data elements and indicate elements requested. Note that not all data elements are available from Ontario centres.

Each element must be justified in relation to the project objectives and associated statistical analysis plan. This section will be reviewed closely prior to release of elements. In the justification table, elements may be grouped together if they fall under the same justification. For example:

Section Number	Justification
1.4, 1.5 & 1.6	Stratification according to sex, age and race during analysis according to objective #x.

****A strong justification is required for release of data elements, especially for personal health information.** All elements of dates (except year), directly related to an individual, are potential identifiers depending on the combination of elements requested. Therefore, applicant must be detailed as to why month and/or day are requested (especially important for date of birth and death). Committee may release year, year & month or full date depending on the request and strength of the justification. Similarly, a stronger justification for full postal code is necessary than if only first 3 digits requested.

i. Publication/KT Plan

Indicate plans for future endeavors and continuations and proposed means of dissemination of knowledge (publications, conference presentations, etc.).

j. Timelines and Data Retention

Complete the proposed timeframe to perform the analysis as well as complete timelines and reasons for maintaining patient level data. Indicate data destruction policies and anticipated destruction date.

2. Funding and ethics approval

a. Check box if funding is available to conduct the proposed work
b. If yes, indicate the funding source for the proposed work.
c. Check box if Research Ethics Board approval has been obtained. If yes, attach submitted proposal and approval letter

3. Review this section to see if your application fulfills the Data Use and Publication Committee expectations.

4. Data Release Checklist

Expectations are outlined and researchers should indicate the methods of protection that will be used by tick box. Receipt of Research Ethics Board approval is highly encouraged at the time of submission to the Data Use and Publication Committee but is not required. A signed Data and Confidentiality Agreement is not required until after the Data Use and Publication Committee has approved the application.

5. **Linkage with Other Datasets**
   This section must be completed if CYP-C data is to be linked with another dataset. Otherwise, skip this section.
   a. Justification for proposed linkage and whether alternatives were considered.
   b. Name and description of dataset(s) to be linked to. Further background as necessary.
   c. Fully describe the linkage process and identified risks.

6. **Complete request date and desired date of data receipt.**
   Requested timelines will be evaluated but timelines for data release cannot be guaranteed related to multiple levels of approval required by the Data Use and Publications Committee and the Public Health Agency of Canada.

APPENDIX A - Data Element Checklist

Indicate diagnoses requested as specific as possible (use ICCC categories or ICDO M-codes if possible).
Indicate diagnoses years requested (2001-2006 currently available for children less than 15 years old).
Indicate geographic regions requested by residence at diagnosis (by province/territory or all of Canada).

Ontario data has been collected in the POGONIS database and merged with CYP-C where possible. Shaded items are only available from CYP-C and therefore all that may be requested. For other elements you may request the merged data or as for CYP-C and POGONIS separately to map yourself.

APPENDIX B - Chemotherapy list

The chemotherapy administered column will return results on whether or not a specific agent was administered during the course of therapy. The cumulative column will return results on total dose administered over the course of treatment.

Indicate requested items on the checklist and shaded areas indicate results not available.

B. AGGREGATE LEVEL DATA ACCESS REQUESTS

1. **Title of Project**
   Provide the full title of the research proposal being submitted.

2. **Applicants**
   Provide the name, address, phone, e-mail address and affiliation (institution) of the applicants. Role of each individual should also be provided (ex statistical analysis, KT plan, interpretation of results, etc).

3. **Description of Data Requested**
   Indicate diagnoses requested as specific as possible (use ICCC categories or ICDO M-codes if possible).
   Indicate diagnoses years requested (2001-2006 currently available for children less than 15 years old).
   Indicate geographic regions requested by residence at diagnosis (by province/territory or all of Canada).
   Discussion with the Data Use and Publication Committee is encouraged to determine availability and appropriateness of aggregate data elements.

4. **Purpose of Data Use**
   Describe stake holders and audience for the data request. Indicate KT plans and acknowledgment of CYP-C data use.

APPENDIX A - Available Data Elements

Reference list of available elements.

APPENDIX 1 - DEFINITIONS

Principal Investigator

a) There is **ONE** Principal Investigator for each application. Additional investigators sharing responsibility for directing the proposed research are termed Co-Investigators.

b) A Principal Investigator is:
   i. Responsible for the direction of the research study; and
   ii. Receives all related correspondence from CYP-C

Co-Investigator

The Co-Investigator shares the responsibility for the direction of the proposed activities. Often the co-Investigator may take the responsibility for particular administrative and/or scientific aspects of the research project.

Collaborator

a) The Collaborator contributes intellectually to the project, but is not responsible for the direction.

b) The Collaborator provides a specific service (e.g. access to equipment, provision of specific reagents, training in a specialized technique, statistical analyses, access to a patient population, etc.).