ANNEX C: CYP-C DATA ACCESS, USE AND PUBLICATION GUIDELINES

Cancer in Young People in Canada (CYP-C)
Data Access, Use & Publication Guidelines
April 2013

Introduction

The CYP-C program is a collaborative effort between the Public Health Agency of Canada (Agency) and the C^{17} Council, a network of all the seventeen pediatric cancer centers across the country. The project is fully funded by the Agency. The overall purpose of CYP-C is to contribute to the control of cancer in children and adolescents in Canada by collaborating in the collection, analysis, interpretation and dissemination of Canadian population based surveillance data.

The CYP-C Data Access, Use & Publication Guidelines were developed to outline the guidelines and procedures for accessing information contained in the national CYP-C database managed by the Agency. The guidelines have been developed to ensure that the use and disclosure of the CYP-C data complies with all applicable privacy laws including the Privacy Act. In addition, these guidelines ensure that data use is not only appropriate but that its use and results are communicated back to the custodians of the source data, POGO and the five POGO Hospital Partners and the contributing pediatric oncology centers across Canada. Finally, these guidelines ensure that data are managed consistently and are made available to external requestors in a timely manner. This document also outlines data user responsibilities for respecting the confidentiality and integrity of the national CYP-C database. Variables released will be limited to those required and de-identified in a manner that is practicable in order to fulfill the research objectives.

CYP-C Data Custodianship and Individual Patient Level Access

1. Public Health Agency of Canada

The Agency will be the data custodian for the compiled national data. Only a limited number of qualified staff, with an understanding of federal privacy regulations, will have access to the national database for the purposes of national surveillance activities, addressing the study objectives and data quality. Agency researchers wishing to produce research papers for peer-reviewed publication must follow the procedures outlined for external researchers.

2. Pediatric Oncology Centers

Each participating pediatric oncology centre and the Pediatric Oncology Group of Ontario (POGO) and the five POGO Hospital Partners will be custodians of their own data and, within the constraints of their institutional REB, will have unlimited access and use of their own data. Notification of results intended to be published using the institutional CYP-C data should be provided to the CYP-C Data Access, Use & Publications Committee so data use can be acknowledged and credited. Centers wishing to use the national data set must follow the procedures outlined for external researchers.

3. External Researchers

External researchers must submit a request to use and publish data from the CYP-C national database in the form of a research proposal. Currently, only Canadian based researchers can access individual level data. POGO and the five POGO Hospital Partners and all other pediatric oncology centers will be notified in writing of all third party data access requests (when the center's data is included in the request) and will have 15 business days to notify the Agency in writing if they do not permit access to their data by the third party. The CYP-C Data Access, Use & Publications Committee will review all research proposals. If the research proposal is approved by the CYP-C Data Access, Use & Publications Committee, applicants will still need to obtain institutional REB approval and will be required to sign a data confidentiality agreement and follow the publication guidelines outlined by the CYP-C program.

CYP-C Aggregate Level Data Access Requests

Requests for non-identifiable aggregate level (tabular) data from the CYP-C national dataset also require a submission to the CYP-C Data Access, Use & Publications Committee. These requests include those from provincial and/or federal government departments, media, and individuals. No request proposal is required.

Requests should be submitted by one of the following methods:

1. Email to CYP-C Data Access, Use & Publication Committee (CYP-C@phac-aspc.gc.ca);
2. Fax to CYP-C Program Lead at 613-960-0944 (please email notification of fax being sent to email address above); or
3. Mail to Public Health Agency of Canada
   CYP-C Program Lead
   785 Carling Avenue, 7th floor, A.L.6807A
   Ottawa, Ontario, Canada
   K1A 0K9

All requests will be reviewed by the CYP-C Data Access, Use & Publications Committee. Typically, results may be expected within 4 to 5 weeks from request submission date.

CYP-C Individual Patient Level Data Access Requests

External researchers must submit a request to use and publish individual level data from the CYP-C dataset in the form of a research proposal. Applications may be submitted at anytime and will be considered in the order in which they are received. All proposals will be reviewed by the CYP-C Data Access, Use & Publications Committee who will monitor the planning and supervision of analyses and publications using the CYP-C data to ensure adherence to the use and publication guidelines. In addition duplicate research already in progress will be prevented. In addition POGO and the five POGO Hospital Partners and all other pediatric oncology centers will be notified in writing of all third party data access requests (when the center's data is included in the request) and will have 15 business days to notify the Agency in writing if they do not permit access to their data by the third party. All approved researchers must abide by the CYP-C Data Access, Use and Publications Guidelines (herein). Please note that researchers should wait until approval is granted before seeking REB approval, funding, etc.

The proposal (1-2 pages) should include the following information (see Appendix A for template):

1. Project title
2. Name and affiliation of principal investigator and co-applicants
3. Name and affiliation of others who will have access to the data or results prior to publication
4. Objective(s) and rationale for the analysis
5. Planned method(s)/proposed analysis
6. List of variables requested
7. Time schedule for the proposal
8. Data security measures to be used
9. Publication plan

All requests must include the names and affiliations of all individuals who will have access to the data or be responsible for the analysis and interpretation of the data. If the research conducted will include analyses on a sub-population of the data, this must be explicitly outlined in the submitted data access request.

Requests may be submitted by one of the following methods:

1. Email to CYP-C Data Access, Use & Publication Committee (CYP-C@phac-aspc.gc.ca);
2. Fax to CYP-C Program Lead at 613-960-0944 (please email notification of fax being sent to email address above); or
3. Mail to Public Health Agency of Canada
   CYP-C Program Lead
   785 Carling Avenue, 7th floor, A.L.6807A
   Ottawa, Ontario, Canada
   K1A 0K9

CYP-C aims to acknowledge all applications within one week of receipt of a proposal and a decision from the CYP-C Data Access, Use & Publications Committee can be expected within 4 to 5 weeks after the date of proposal submission.

Data for approved proposals will be sent to the principal investigator by CD which will be password protected and encrypted. The data set will be limited to the variables requested in the proposal. The data must be treated as confidential and only used for statistical purposes. Data released by the CYP-C Data Access, Use & Publications Committee will not include direct identifiers (names, addresses) and will contain only internal study identification numbers. Although the data does not contain direct identifiers, the data must be held securely due to the fact that the file may contain indirect identifiers such as dates or partial dates of birth, diagnosis or death, sex or geographical region. Written assurance that data will be properly stored and protected must be provided in the form of a signed confidentiality agreement (see Appendix B). Once institutional REB approval is obtained, a copy must be sent to the CYP-C Data Access, Use and Publications Committee.

CYP-C Data Use Guidelines

1. All individuals who will have access to the data must sign the confidentiality agreement and abide by the terms outlined in the confidentiality agreement.

2. Institutional REB approval (of the primary investigator) is required and must be renewed on an annual basis until project termination. A copy of the REB approval must be sent to the CYP-C Data Access, Use & Publications Committee.

3. The data must only be used for the purposes stated in the accepted data research proposal submitted to the CYP-C Data Access, Use & Publications Committee.

4. All individuals who are permitted access to the data will not release the data to a third party. The data may not be transferred or accessed by individuals not included in the research proposal.

5. Those using the data will not attempt to link or allow others to link the data with individually identified records in another database without further approval by the Data Access, Use and Publications Committee and the Institutional REB.

6. Anyone with access to the data will not attempt to learn the identity of any individual included in the data file.

7. Contact of data subjects or attempt to contact data subjects will not be made.

8. The data will be protected by appropriate security safeguards against loss or theft, unauthorized access, disclosure, copying, use or modification. Methods of protection must include:
    a. Physical measures such as locked filing cabinets and locked access to offices.
    b. Organizational measures such as security clearances and limiting access on a "need to know" basis.
    c. Electronic copies of the information must be stored in a computer that is not connected to the Internet unless it is appropriately safeguarded (i.e.,

firewalls, etc); access to the records are protected by passwords specific to those records (secured independently from the password required to access the computer).

d. Data will not be transmitted by email or carried on a mobile device such as a USB key unless encrypted.

9. The Agency must be notified immediately if a breach of any agreement provision relating to the security or management of personal information is suspected or has occurred. This should apply to any situation where personal information may have been compromised, including unauthorized access, destruction, use, modification, or disclosure of personal information. The Agency will notify POGO and all centers whose data was implicated in the breach.

CYP-C Data Publication Guidelines

1. Data will not be published or presented in a form that could reasonably enable a person to ascertain the identity of the individual.

2. Only aggregate, non-identifiable data will be publicly released. No descriptive text, tables or numbers with five (5) or less cases will be published or released.

3. Data defining individual institutions and/or provinces shall not be publicly released without the explicit consent of the institution.

4. All researchers must submit a copy of the intended draft paper to the CYP-C Data Access, Use & Publications Committee prior to publication to ensure appropriate use and interpretation of the CYP-C data. The Data Access, Use & Publications Committee will have three weeks to review and provide comments.

5. Any publication arising from the CYP-C data must acknowledge the contributions of study participants, POGO and the five POGO Hospital Partners and other participating pediatric oncology centers and the CYP-C program. The following acknowledgement should be used: "The authors gratefully acknowledge the contributions of study participants, the participating pediatric oncology centres, members of the Cancer in Young People in Canada (CYP-C) Management and Steering Committees, the Pediatric Oncology Group of Ontario (POGO) and the five POGO Hospital Partners. The CYP-C is fully funded by the Public Health Agency of Canada".

Appendix A: CYP-C Research Proposal

1. **Project title.**

2. **Name, address, and affiliation of principal investigator and co-applicants.**

3. **Name, address, and affiliation of others with access to the data.**

4. **Objective(s) and rationale for the analysis.**

5. **Planned method(s)/proposed analysis.**

6. **List of variables requested.**

7. **Time schedule for the proposal.**

8. **Data security measures to be used.**

9. **Publication plan.**

Appendix B: CYP-C Data Confidentiality Agreement

Project title: _____

Contravention of data use guidelines or the conditions of the confidentiality agreement may result in loss of access privileges to the data, termination of receipt of files by CYP-C and loss of collaborative research opportunities. The following recourses may also be taken: legal action; referral of matters to federal or provincial oversight or regulatory bodies for investigation and possible sanctions, and/or a report of the researcher's conduct to the relevant REB and/or federal research sponsor, where relevant and applicable.

I agree to handle the data according to the terms below:

1. The data will only be used for the purpose(s) stated in the accepted data access request submitted to the CYP-C Data Access, Use & Publications Committee. Any changes to the project plan require immediate notification to the CYP-C Data Access, Use & Publications Committee and a new application including the proposed changes must be submitted for approval.

2. REB approval will be sought from the principal investigator's institutional REB and once obtained a copy will be sent to the CYP-C Data Access, Use & Publications Committee. Please note that private REB approval is not acceptable.

3. All individuals who will have access to the data must sign a data confidentiality agreement and abide by the terms outlined in the agreement.

4. The data will not be released to a third party.

5. The privacy of the individual persons included in the data file must be respected. Anyone with access to the data will not attempt to learn the identity of any person or contact any person whose data is supplied in the data file.

6. Those using the data will not attempt to link or combine the data with individually identified records in another database without further approval from the Data Access, Use and

Publications Committee and the institutional REB. The records on the file may be augmented only with non-personal aggregate-level data such as aggregate Census data etc.

7. Data will not be published or presented in which an individual is identifiable. In addition to small cell sizes, information on any single individual will not be published. Data based on counts of five or less are to be combined, suppressed or perturbed. Where denominators of rates are small, consideration must also be given to the difference between the denominator and the numerator, as differences of zero (i.e., rates of 100%) and five or less represent similar potential breaches of confidentiality to the situation where the number of cases is between zero and five. Such data are not to be disseminated, as they are deemed to contain personal information.

8. The data will be protected by appropriate security safeguards against loss or theft, unauthorized access, disclosure, copying, use or modification. Methods of protection must include: (a) physical measures such as locked filing cabinets and locked access to offices; (b) organizational measures such as security clearances and limiting access on a "need to know" basis; (c) electronic copies of the information must be stored in a computer that is not connected to the Internet unless it is appropriately safeguarded (i.e., firewalls, up-to-date anti-virus software, etc.); (d) access to the records are protected by passwords specific to those records (secured independently from the password required to access the computer); (e) data will not be transmitted by email or carried on a mobile device such as a USB key unless encrypted.

9. Once the research project is finalized, the data must be securely returned or destroyed according to the project plan. Data must be returned or destroyed within 4 weeks of the end of the project. A notification to the CYP-C Data Access, Use & Publications Committee must be sent when this takes place.

10. Compliance with all applicable provincial and federal policies and laws relating to the confidentiality and privacy of personal information must be adhered to.

11. The Agency must be notified immediately, in writing, if a breach of any agreement provision relating to the security or management of personal information is suspected or has occurred.

This should apply to any situations where personal information may have been compromised, including unauthorized access, destruction, use, modification, or disclosure of personal information.

12. Any publication arising from the use of the CYP-C data must acknowledge the study participants, POGO and the five POGO Hospital Partners and the other participating pediatric oncology centers and the CYP-C program. The following acknowledgement should be used: "The authors gratefully acknowledge the contributions of study participants, the participating pediatric oncology centres, members of the Cancer in Young People in Canada (CYP-C) Management and Steering Committees, the Pediatric Oncology Group of Ontario (POGO) and the five POGO Hospital Partners. The CYP-C is fully funded by the Public Health Agency of Canada".

13. All researchers must submit a copy of the intended draft paper prior to journal submission (or other form of publication) to the CYP-C Data Access, Use & Publications Committee to ensure appropriate use and interpretation of the CYP-C data. The CYP-C Data Access, Use & Publications Committee must be provided a minimum of four weeks prior to journal submission, to review and provide comments.

Principal investigator	Date	Signature

Other persons with access to the CYP-C data:

Name	Date	Signature
Name	Date	Signature
Name	Date	Signature
Name	Date	Signature