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

Introduction

The CYP-C program is a collaborative effort between the Public Health Agency of Canada (PHAC) and the council of Canadian Pediatric Hematology/Oncology Directors (C17 Council), a network of 16 pediatric hematology, oncology, and stem cell transplant programs in Canada. The project is funded by PHAC. The overall purpose of CYP-C is to contribute to the control of cancer in children in Canada by collaborating in the collection, analysis, interpretation, and dissemination of Canadian population-based surveillance data and facilitating research.

The CYP-C Data Access, Use and Publication Guidelines were developed to outline the guidelines and procedures for accessing, using, and publishing data contained in the national CYP-C database managed by PHAC. The guidelines have been developed to ensure that access, use, and disclosure of the CYP-C data are appropriate and comply with all applicable federal and/or provincial privacy laws, including the Privacy Act (Revised Statutes of Canada, 1985, c. P-21). This document outlines data user responsibilities for respecting the confidentiality and integrity of the data released from the national CYP-C database. Additionally, these guidelines aim to ensure that all study results are communicated back to the custodians of the source data, the Pediatric Oncology Group of Ontario (POGO) and all contributing pediatric oncology centres across Canada.

Any use or disclosure of CYP-C data must comply with the principles and procedures set forth in this Policy. Requests for exceptions to this Policy must be submitted in writing to the Data Access, Use and Publications Committee (Management Committee); must specify the CYP-C data requested and its intended use; and provide a justification for why the exception is necessary.

CYP-C Data Custodianship and Individual Patient Level Access

1. Public Health Agency of Canada

PHAC is the custodian of the compiled national CYP-C dataset. Access to the national database is restricted to a small group of qualified PHAC staff who are trained in federal privacy regulations. These staff may access the data for the following purposes:

- Surveillance and research aligned with CYP-C protocol objectives,
- data quality activities
- the creation of analysis files for approved research projects.

PHAC researchers who wish to publish peer-reviewed research must follow the same procedures as external researchers, unless the work is conducted by CYP-C program staff for surveillance purposes or is otherwise approved by the CYP-C Management Committee.

2. Pediatric Oncology Centres

In Ontario, POGO, as a *Prescribed Entity*, is the data custodian for the active, population-based database of all children and adolescents with cancer who are diagnosed and/or treated in a specialized childhood cancer program.

Outside Ontario, each participating pediatric oncology centre is the custodian of its own data. Centres have full access to and use of their own data, subject to their institutional Research Ethics Board (REB) requirements and institutional policies.

Any centre wishing to access data from the national CYP-C database must follow the data access procedures outlined in this document

3. Researchers

Researchers seeking to use and publish results based on CYP-C national data must submit a research proposal. Only researchers based in Canada may access individual-level data.

The CYP-C Management Committee will review all proposals according to the CYP-C Data Access Review Process. Proposals must:

- clearly identify all requested data elements
- justify why the research or statistical objectives cannot be met without access to the specified personal information
- request only the minimum data necessary to achieve the study objectives

If access is approved by the CYP-C Management Committee), researchers must:

1. Obtain institutional (or alternate) REB approval.
2. Submit the REB approval and a completed, signed Data Confidentiality and Publication Agreement to PHAC.

Following Management Committee approval, PHAC will assess whether the proposed use is a consistent use under the *Privacy Act*. This assessment is a privacy compliance requirement only and does not replace, override, or alter the Management Committee's decision regarding access.

- If the use is deemed consistent with the original purpose of collection—pediatric cancer surveillance, research, analysis, interpretation, and dissemination—data may be disclosed under section 8(2)(a) of the *Privacy Act*.
- If the use is not deemed consistent, the researcher must submit an Application for the Disclosure of Personal Information for Research and Statistical Purposes under section 8(2)(j) before any data can be released.

When a request includes POGO data, POGO will be notified in writing/email of the approved access. POGO will have 15 business days to inform PHAC in writing if it does not permit access for the requesting researcher(s). If a researcher is requesting access only to Ontario data, the request must be managed directly through POGO rather than through the national CYP-C data access process.

If a request for data access is denied or if restrictions are placed on the requested data elements, the Management Committee will provide a written explanation outlining the reasons. Researchers may resubmit their application after addressing the Committee's recommendations. The Management Committee will then review the revised submission to determine whether the changes are sufficient or whether further revisions are required.

CYP-C Individual Patient Level Data Access Requests

Researchers must submit a request to use individual level data and publish analytic results from the CYP-C dataset in the form of a research proposal with the components outlined below. Applications may be submitted at any time and will be considered in the order in which they are received. All proposals will be reviewed by the CYP-C Management Committee. If a member of the committee is an investigator or has another conflict of interest, that individual will be recused during the deliberation process. Researchers will be obligated to respond to committee inquiries about knowledge dissemination efforts and research progress.

The research proposal should include the following information:

1. Project title
2. Name, address and affiliation of Principal Investigator and co-applicants
3. Name, address and affiliation of other individuals who will have access to the data
4. If applicable, all sources of funding and in-kind support for the project
5. Objective(s) and rationale for the analysis
6. Planned method(s)/proposed analysis including all sub-group analyses planned
7. List of variables requested and rationale for requesting each variable

8. Publication and dissemination plan

9. Time schedule for the proposal including anticipated date of completion

10. Plan for data destruction at the end of the project

For applications involving machine learning techniques, the research proposal should include a detailed assessment of the machine learning tool, outlining its capabilities, data retention characteristics, potential for re-identification, limitations on use, and any requirements for data linkage or cross-border access. This assessment will enable CYP-C to understand how the tool functions both during and after the research and to determine whether the benefits of the research outweigh the associated privacy risks

Requests may be submitted through an online application (https://c17.ca/committees/CYP-C/Research).

CYP-C Management Committee aims to acknowledge all applications within one week of receipt of the proposal and the Committee's goal will be to render a decision within 4 to 6 weeks after the date of proposal submission. If the applicant does not receive a confirmatory email of receipt, they should follow-up with CYP-C Management Committee by email or telephone. It is the responsibility of the applicant to ensure the CYP-C Management Committee has received the proposal. Data for approved proposals will be released in accordance with standard procedures established by PHAC. The data will be limited to a minimum number of variables requested and approved in the proposal, and it may be necessary for the Principal Investigator and PHAC to work together to redefine certain variables in order to protect patient privacy. Data released will meet or exceed minimum requirements set by PHAC to protect privacy and confidentiality.

Conclusion

These CYP-C Data Access, Use and Publication Guidelines were developed on the basis of federal legislation as well as data sharing agreements and REB decisions that allow the CYP-C program to operate and release data for the purpose of research.

Cancer in Young People in Canada Surveillance Program (CYP-C) Data Confidentiality and Publication Agreement

Project title:

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

1. The CYP-C Data will only be used for the purpose(s) stated in the accepted data access request submitted to the *CYP-C Management Committee*. Any changes to the project plan require immediate notification to the *CYP-C Management Committe*e and a revised application including the proposed changes must be re-submitted for approval.

2. The Principal Investigator must obtain research ethics board (REB) approval from its institution and such approval must be renewed on an annual basis until project termination. A copy of the complete REB approval must be sent to Public Health Agency of Canada (PHAC) prior to release of data.

3. All individuals who require access to the CYP-C Data (hereinafter "Data User") must sign the *Data Confidentiality and Publication Agreement* and abide by the terms outlined in the agreement. Researchers, research assistants, and all individuals approved as part of this study, along with any members added to the research team in the future will be informed of these requirements and will comply with the privacy obligations agreed to in this application.

4. The Data User may not transfer, access or release the CYP-C Data to a third-party or any individuals not identified in the *Data Confidentiality and Publication Agreement*. Any use of personal information for secondary purposes is not permitted without prior consultation with PHAC.

5. The privacy and confidentiality of the personal information included in the CYP-C Data is of paramount importance, and must be respected. Data User shall not attempt to learn the identity of any person or contact any person whose data are supplied in the CYP-C Data. No subsequent disclosure of the information in a form that could reasonably be expected to identify the individual to whom it relates will be made.

6. The Data User shall not link or match the CYP-C Data with records in any other database without obtaining approval from the *Management Committee* and their institution's REB. The records in the CYP-C Data may only be supplemented with de-identified, aggregate-level information such as Census data.

7. The CYP-C Data may not be published or presented in a manner where an individual is potentially identifiable. In addition to small cell sizes, information on any single individual may not be published without the written permission of PHAC. As a guideline, when preparing publications and conference presentations, the Data User must ensure that:

- statistics calculated on 1 to 5 cases are not publicly disclosed
- age standardized rates are not calculated on 1 to 5 events (i.e. deaths or cancer cases).
- cell sizes of zero are permitted.
- risks of residual disclosure are considered and addressed when disclosing information (i.e. use of random or controlled rounding)

8. CYP-C Data elements defining individual institutions, provinces or territories should not be publicly released without the explicit consent of the institution(s). Data User must seek approval from institutions to evaluate data at the provincial level.

9. Personal information will be safeguarded against unauthorized access, copying, use, disclosure, and retention by ensuring that administrative, physical, and technical safeguards are commensurate with the sensitivity of the personal information. The Data User must ensure to protect the CYP-C Data by:

(a) Ensuring presence of physical measures such as locked filing cabinets and locked access to offices.

(b) Implementing organizational measures such as security clearances, ensuring all staff undergo training on the proper handling and protection of patients' confidential information, limiting access on a "need to know" basis and creating unique user credentials and, where available, multi-factor authentication.

(c) Ensuring that electronic copies of the CYP-C Data are stored and accessed only through secure electronic systems, whether on-premises or cloud-based, that implement administrative, technical, and physical safeguards. These safeguards include encryption of data both in transit (i.e. LiquidFiles) and at rest, role-based access controls, and strong user authentication mechanisms.

(d) Ensuring access to the CYP-C Data is protected by a unique user credentials, separate from device-level access, and authenticated through secure access controls.

(e) Ensuring that safeguards are in place to prevent unauthorized transmission, downloading, or local storage of the data on unmanaged (i.e. USB key) or personal devices (i.e. laptop, phone), except where appropriately secured and authorized.

(f) Where CYP-C Data is stored or processed using cloud-based or externally hosted systems, the Data User must ensure such systems comply with applicable Canadian privacy and health information legislation, store and process data within Canada, and are administered by authorized personnel using appropriate administrative, technical, and access controls consistent with regulatory, ethical, and institutional requirements.

10. The Principal Investigator, when approaching the project deadline, will be asked to provide PHAC with the status of the project and determine if an extension of time is required. Any request for an extension will be reviewed by the *CYP-C Management Committee*. If the request is not approved, procedures for data destruction must be initiated, in accordance with Section 11 of this Agreement.

11. The personal information obtained from PHAC will be retained only as long as necessary to fulfill the original research objectives, and may be retained for secondary purposes, such as tracing, validation, or auditing of research results, when required by regulators, study sponsors, or publishers, or to comply with applicable regulatory or statutory requirements, including relevant federal or provincial privacy legislation.

At the end of the agreed-upon retention period, all data (including all copies made from the data) must be disposed of in accordance with Government of Canada–approved disposal methods. A written confirmation of destruction must be sent by the lead researcher to PHAC. This confirmation must include the date of destruction.

12. The Principal Investigator and Data User must comply with all applicable Provincial and Federal policies and laws relating to the confidentiality and privacy of personal information.

13. In the event of a privacy breach, defined as the improper or unauthorized collection, use, disclosure, retention, loss, or disposal of personal information, the incident will be contained, documented, and reported to PHAC. PHAC is responsible for reporting the breach to Privacy Management Division through its breach portal as soon as possible.

14. Any publication arising from the use of the CYP-C Data should have the following in the title: "A report from CYP-C".

15. Any publication arising from the use of the CYP-C Data must acknowledge the study participants, Pediatric Oncology Group of Ontario (POGO), the participating pediatric oncology centres, and the CYP-C program. The following acknowledgements should be used:

"The authors gratefully acknowledge the contributions of study participants, participating pediatric oncology centres, members of the *Cancer in Young People in Canada (CYP-C) Management* and Advisory Committees, and the *Pediatric Oncology Group of Ontario (POGO)*. The CYP-C is funded by the Public Health Agency of Canada".

In addition, the following disclosure statement is required:

"Data used in this publication are from the Cancer in Young People in Canada Surveillance Program and are used with the permission of the Public Health Agency of Canada. The analyses and interpretation presented in this work do not necessarily reflect the opinions of the Government of Canada."

16. The Principal Investigator and/or Data User must submit a copy of their manuscript to the CYP-C Research Manager prior to submitting to any scholarly, academic (i.e. journals) or other publications, to ensure appropriate use and interpretation of the CYP-C Data. The manuscript must not become publicly available prior to issues being addressed.

17. PHAC may audit, at any time, the Principal Investigator, the Data User or their respective institution(s) to ensure compliance with this agreement.

18. The Principal Investigator takes all responsibility for members of their research team, including Data Users. PHAC reserves the right to terminate this agreement at any time for any reason.

19. Failure of the Principal Investigator or the Data User to follow the data use guidelines or the conditions of the confidentiality agreement may result in loss of access privileges to the CYP-C Data, loss of collaborative research opportunities, and loss of research access to other federal data sources. The Principal Investigator and/or the Data User may also face legal action, including 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. In addition, if the data are mismanaged, the privileges granted to the Data User may be withdrawn, and the Data User may be required to immediately destroy or return the data to PHAC. Future requests to access

personal information under the research and statistical purposes of provision in paragraph 8(2)(j) of the *Privacy Act* may also be refused.

Principal Investigator	Date	Signature

Other persons with access to the data:

Name	Date	Signature
Name	Date	Signature