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 (Agency), the Canadian Partnership Against Cancer (CPAC) and the C^{17} Council, a network of all the seventeen paediatric cancer centres across the country. The project is funded by the Agency. 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.

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 the Agency. The guidelines have been developed to ensure that data 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 results are communicated back to the custodians of the source data, the Pediatric Oncology Group of Ontario (POGO) and all contributing paediatric 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; 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 (Agency)

The Agency is the data custodian of the compiled national data. Only a limited number of qualified staff, with an understanding of federal privacy regulations, have access to the national database for the purposes of surveillance and research, addressing CYP-C protocol objectives, data quality and creating data analysis files for approved research proposals. Other Agency researchers wishing to produce research papers for peer-reviewed publications must follow the procedures outlined for external researchers except in circumstances where CYP-C program staff are handling the data and the project is for surveillance purposes or otherwise approved by the CYP-C Partners Group or Management Committee.

2. Paediatric Oncology Centres

Outside Ontario, each participating paediatric oncology centre is custodian of their own data. Within the constraints of their institutional Research Ethics Board (REB) and institutional policies, they have unlimited access and use of their own data. Centres wishing to access and use data in the national database set must follow the procedures outlined in this document.

3. Researchers

Researchers must submit a request, in the form of a research proposal, to use and publish results using data from the CYP-C national database. Only Canadian-based researchers can access individual level data. The CYP-C Data Access, Use and Publications Committee will review all research proposals according to the guidelines in the CYP-C Data Access Review Process.

If access is approved by the CYP-C Data Access, Use and Publications Committee, researchers will need to obtain institutional (or alternate) REB approval and provide it to the Agency along with a completed and signed Data Confidentiality and Publication Agreement (Appendix A) and an *Application for the Disclosure of Personal Information For Research and Statistical Purposes* as prescribed by the Privacy and Data Protection Guidelines of Section 8(2)(j) of the *Privacy Act* prior to data release. POGO will be notified in writing/email of all approved data access requests, when POGO data are included in the request, and will have 15 business days to notify the Agency in writing if they do not permit access to the requesting researcher(s).

Where request for access to data is denied, or restrictions are placed on the data elements requested, the CYP-C Data Access, Use and Publications Committee will prepare and deliver a written summary of the reasons for denial or restricted access. Applications may be re-submitted following compliance with the modifications recommended in the summary.

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 Data Access, Use and Publications Committee. In the event that 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

Requests may be submitted by email:

> Email to CYP-C Data Access, Use and Publications Committee (CYP-C@phac-aspc.gc.ca) or to the CYP-C Surveillance Co-ordinator

CYP-C Data Access, Use and Publications 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, he/she should follow-up with CYP-C Data Access, Use and Publications Committee by email or telephone. It is the responsibility of the applicant to ensure the CYP-C Data Access, Use and Publications Committee has received the proposal.

Data for approved proposals will be released in accordance with standard procedures established by the Agency. 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 Agency to work together to redefine certain variables in order to protect patient privacy. Data released will meet or exceed minimum requirements set by the Agency 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.

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

Project title:

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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, loss of collaborative research opportunities, and loss of research access to other federal data sources. 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 Research Ethic Board (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 and Publications Committee. Any changes to the project plan require immediate notification to the CYP-C Data Access, Use and Publications Committee and a revised application including the proposed changes must be re-submitted for approval.
2. Institutional REB approval (at the institution of the Principal Investigator) is required and must be renewed on an annual basis until project termination. A copy of the complete REB approval must be sent to the Agency prior to release of data. All individuals who will have access to the data must sign the Data Confidentiality and Publication Agreement and abide by the terms outlined in the agreement.

3. The data will not be released to a third party. The data may not be transferred or accessed by individuals not included in the Data Confidentiality and Publication Agreement.
4. 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 are supplied in the data file. Contact of subjects or attempt to contact subjects is not permitted.
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 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.
6. Data will not be published or presented in which an individual is potentially identifiable. In addition to small cell sizes, information on any single individual will not be published without the written permission of the Public Health Agency of Canada (Agency). In general, statistics calculated on 1 to 5 cases should not be publicly disclosed (including publications and conference presentations). Age standardized rates must not be calculated on 1 to 5 events (i.e. deaths or cancer cases). Cell sizes of zero are permitted. The risk of residual disclosure must be considered and addressed when disclosing information (including publications and conference presentations). For example, it may be possible to derive cell sizes of 1 to 5 individuals through single tables or through the cross-referencing of two or more tables. One way to prevent residual disclosure is by rounding all numbers to a base of 5 using either random rounding or controlled rounding.
7. Data defining individual institutions and/or provinces should not be publicly released without the explicit consent of the institution. Approval to evaluate data by province will require the approval of all institutions within that province.
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 laptop, smartphone or USB key.

9. Proximal to the anticipated time for project completion, the Principal Investigator will be asked to report on the status of the project and to determine if an extension of time is required. The request for an extension will be reviewed by the CYP-C Data Access, Use and Publications Committee. If the request is not approved, procedures for data destruction must be conducted according to this document.
10. Once the research project is completed, the data and all intermediate products must be destroyed at the end of the project. A notification to the CYP-C Data Access, Use and Publications Committee must be sent when destruction has taken place.
11. Compliance with all applicable Provincial and Federal policies and laws relating to the confidentiality and privacy of personal information must be adhered to.
12. 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.
13. Any publication arising from the use of the CYP-C data should have the following in the title: "A report from CYP-C").
14. Any publication arising from the use of the CYP-C data must acknowledge the study participants, POGO, the participating paediatric oncology centres and the CYP-C program. The following acknowledgement should be used: "The authors gratefully acknowledge the contributions of study participants, participating paediatric 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 federal government of Canada."

15. All researchers must submit a copy of the manuscript prior to journal submission (or other form of publication) to the CYP-C Data Access, Use and Publications Committee to ensure appropriate use and interpretation of the CYP-C data. The manuscript must not become publicly available prior to receipt and addressing of CYP-C concerns (if any).
16. At any time the researcher(s) and their institution(s) may be audited by the Agency to ensure compliance with this agreement.
17. The Principal Investigator takes all responsibility for members of the research team that have access to the data. The Agency reserves the right to terminate this agreement at any time for any reason.

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Principal investigator	Date	Signature

Other persons with access to the CYP-C data:

_____	_____	_____
Name	Date	Signature
_____	_____	_____
Name	Date	Signature
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