Research Ethics and CPSP Studies: Frequently Asked Questions

1. Under what authority can the CPSP collect surveillance data?

The Public Health Agency of Canada (PHAC), as a federal government institution whose purpose is to support health protection and promotion, has the authority to collect health information for public health surveillance purposes under Section 4 of the *Department of Health Act* and Section 3 of the *Public Health Agency of Canada Act*. Through a contract between the Canadian Paediatric Society (CPS) and PHAC, the CPSP collects this information on behalf of PHAC.

All provincial and territorial health acts in Canada provide the authority to health care providers to disclose health-related information to public health agencies at the local, provincial, and federal levels for surveillance purposes, provided that provincial/territorial privacy legislation requirements are met.

While Quebec's distinct health surveillance framework gives health care providers the authority to disclose case notifications (birth year/month, sex) to the CPSP, study investigators must obtain a research ethics board (REB) approval and a data transfer agreement (DTA) from each institution to authorize the collection of more detailed case-level surveillance data.

2. Are CPSP studies approved by a research ethics board (REB)?

The CPSP is a national public health surveillance program that collects paediatric surveillance data on behalf of PHAC. Public health surveillance does not typically require REB approvals, the CPSP requires its study investigators to seek approval from the Health Canada and PHAC REB.

Given specific restrictions in Quebec's provincial privacy legislation, CPSP study investigators must obtain REB approval and a DTA from each participating institution in that province. The four main paediatric tertiary care hospitals in Quebec include the following: Montreal Children's Hospital, Centre hospitalier universitaire (CHU) Sainte-Justine, Centre mère-enfant Soleil—CHU de Québec—Université Laval, and CHU de Sherbrooke. We strongly encourage study teams to engage a co-investigator in each of these four hospitals to facilitate obtaining these REB approvals.

For the collection of CPSP data in Alberta, REB approval is required from either the University of Calgary or the University of Alberta. A DTA with Alberta Health Services must

be obtained once the REB approval is successful. We strongly encourage study teams to engage a co-investigator from Alberta to facilitate obtaining REB approval.

For more details on how to seek REB approvals and DTAs, contact the CPSP office.

3. Does the CPSP require REB approval from each individual institution of the study team members?

REB approval is not required from the institutions of each study team member; however, multi-centre approval is beneficial. Having at least one REB approval from the home institution of one of the principal investigators is encouraged.

4. Is patient consent required?

Under the *Department of Health Act* and the *Public Health Agency of Canada Act,* patient consent for the collection of surveillance data for public health purposes is not required.

In addition, as part of the Health Canada and PHAC REB review, CPSP studies qualify for waivers of explicit consent.

5. Can patients opt out?

Yes, patients can ask their paediatrician not to share their data with the CPSP. Participating paediatricians are invited to display an information poster to inform patients and families/caregivers about the importance of the data collected by the CPSP. The poster explains that patients' information will be included unless they request otherwise from their paediatrician.

6. How does the CPSP protect privacy and confidentiality?

Maintaining patient privacy and confidentiality is essential to the success of the Program. The CPSP assures the privacy and the confidentiality of all information collected by the Program in the following ways:

- All data collected through the Program is handled according to applicable federal and provincial/territorial privacy legislation.
- The data that the CPSP collects contains no names and no direct identifiers such as address or health card number. PHAC, and study investigators receive only de-identified data and the Program does not contact children/youth or their families.
- Strict policies and procedures are followed to keep the data that is collected safe and secure. Because de-identified case-level medical information about paediatric patients

is collected related to rare or emerging conditions, the CPSP is committed to treating data with the highest level of security and sensitivity, according to strict guidelines, procedures, and multiple physical and technical safeguards.

- Only CPSP staff are aware of the name and contact information of the participating paediatrician. This information is not transferred to PHAC or study investigators.
- Should a CPSP study or survey result in publication, data is presented so that patient privacy is protected. Only aggregate data is reported and case counts of fewer than five are suppressed.

7. Will a code linking individuals to laboratory results be created to confirm patient diagnosis?

No codes linking patient data are permitted. Validation of case counts can only be done by contacting regional laboratories across Canada to determine, anonymously, how many tests were performed and positive in the years of the study investigation. This number can then be cross-referenced against the provincial/territorial reporting to CPSP during the same year.

8. Where is the CPSP data stored?

CPSP data is stored on a secure web-based, public health informatics and surveillance platform of PHAC that is hosted by the Canadian Network for Public Health Intelligence (CNPHI). CNPHI serves a large number of federal, provincial, and territorial public health agencies across Canada.

9. How do CPSP investigators access the data?

CPSP investigators must request access to the surveillance data in writing using the *Privacy Act* 8(2)(j) application form which is submitted to the Privacy Management Division of PHAC. The request includes a description of the study, a list of all data elements, an explanation of how the investigator will use the data, and why the project cannot be accomplished without the disclosure of data. The request also includes a description of all the measures the investigator will take to safeguard the requested information, and the terms for data disposal. The data collected by the CPSP can only be used for the purpose described in the study proposal.

10. What are the requirements for disposal of CPSP study data?

CPSP data is retained for a period of seven years after the conclusion of a study. After this time period, the data are destroyed in a secure fashion, such that it is not reasonably

foreseeable that the data may be reconstructed to permit the identification of an individual.

11. How will study results be presented/published to ensure patient anonymity?

The CPSP recognizes that the scientific and public health value of surveillance conducted into rare paediatric medical conditions must be balanced against the need to protect the privacy of patients subject to these conditions. Where there are fewer than five cases reported or confirmed, only aggregate data may be published or presented. Any data element with fewer than five cases will be suppressed.