

## REB Questions and Answers

**Q1. Multicentre research** – Does the CPSP have an agreement requiring (or not) REB approval from each individual institution of research team members?

A Canadian research ethics board (REB) must approve a new study before its addition to the program. Ethical approval is required from only one institution; however, multi-centre approval is encouraged. So far, CPSP studies have been approved by REBs from the following universities and hospitals: University of British Columbia, University of Calgary, University of Manitoba, McGill University, McMaster University, Memorial University, Children’s Hospital of Eastern Ontario, Hamilton Health Sciences Corporation, Hôpital Sainte-Justine, The Hospital for Sick Children, IWK Health Centre, The Ottawa Hospital, North York General Hospital, and Health Canada’s REB.

**Q2. Waiver of consent** – Can you include consent documents or make a valid exemption argument for a waiver of consent?

Even though the reporting paediatrician does not have to inform the family or obtain consent because no identifying information is ever revealed or collected, he or she may wish to introduce the CPSP and the importance of its research to families who would welcome additional insight into these rare conditions.

**Q3. External validation** – Will a code linking individuals to laboratory results be created to confirm patient diagnosis?

No, validation of cases can 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.

**Q4. Data disposal** – Describe the plan to destroy the data collected during the study.

As outlined in the CPSP Principal Investigators Agreement, it is the principal investigator’s responsibility to protect data confidentiality by securely storing study information for the period of time that complies with the legislation for the province/territory in which the researcher works.

The principal investigator will retain the data only as long as is necessary to fulfill the purposes of the study and then will ensure all copies of the data (hard copy and electronic) are destroyed in a secure fashion, such that it is not reasonably foreseeable in the circumstances that the data may be reconstructed so as to permit the identification of an individual.

The CPSP treats all data collected with sensitivity, according to strict guidelines, procedures and multiple physical and technical safeguards. A list of safeguards can be accessed at [www.cpsp.cps.ca/about-apos/propos/policies-and-procedures](http://www.cpsp.cps.ca/about-apos/propos/policies-and-procedures).

**Q5. Rare disorder data reporting** – Given that this is a rare disorder, what is the size of the reporting areas and how will the publication of details on this rare disorder be presented to ensure patient anonymity?

Where there are five or fewer cases reported or confirmed in any jurisdiction, only aggregate data may be published or presented.