

7.1 Preamble

Childhood cancer outcomes have shown truly remarkable improvements in the past three decades. Key to this success has been the large-scale participation in multi-centre clinical trials based on the concept that research is a core component of childhood cancer care.

For patients registered on clinical trials, any therapy or management delivered in any setting is considered part of the clinical trial protocol. Thus, rigorous requirements around assessment of patients, delivery of care, recording of interventions and compliance with regulatory requirements are required in all settings – including POGO Satellite Clinics. To meet these requirements, POGO Satellite Clinics must comply with the regulations of the [National Cancer Institute \(NCI\) Office of Human Research Protections \(OHRP\)](#), [Health Canada](#), the [Children’s Oncology Group \(COG\)](#) and other regulatory bodies.

Failure to comply with the specified regulatory requirements would lead to one of two outcomes: Either the patient would not be enrolled on the relevant clinical trial OR the patient could not receive treatment in the POGO Satellite Clinic.

Ideally, pediatric oncology patients and their families should not be forced to choose between accessing the POGO Satellite Program and enrolling on clinical trials.

This section of the POGO Satellite Manual is intended to define the structure of research participation by POGO Satellite Clinic patients – specifically, in Phase II and III trials conducted by COG and other cooperative groups. The goal of this process is to allow children registered on clinical trials to receive components of care closer to home while still allowing for compliance with all aspects of clinical research within the POGO Satellite Clinic.

In addition to this section, the following are essential elements to the conduct of COG and non-COG trials at POGO Satellite Clinics:

- Master research agreement between each tertiary hospital and its relevant POGO Satellite Clinic community hospital(s)
- Tertiary hospital delegation of Research Ethics Board (REB) oversight to the [Ontario Cancer Research Ethics Board \(OCREB\)](#) for specific pediatric oncology Phase II and III studies
- POGO Satellite Clinic community hospital delegation of REB oversight to OCREB for their role as tertiary hospital affiliates for the conduct of specific pediatric oncology Phase II and III trials
- Per-study addenda to master research agreement implemented by tertiary hospitals in compliance with COG and other cooperative group studies, which extend to the relevant POGO Satellite Clinic community hospital(s)
- Access to the overall study protocol document

Primary author Dr. Paul Gibson, Pediatric Oncology Group of Ontario, Toronto, McMaster Children’s Hospital, Hamilton Health Sciences, Hamilton with input from Dr. Jacqueline Halton, CHEO, Ottawa, Dr. Carol Portwine, McMaster Children’s Hospital, Hamilton Health Sciences, Hamilton, Dr. Mark Greenberg, Pediatric Oncology Group of Ontario, The Hospital for Sick Children, Toronto, Ms. Carla Bennett,

Pediatric Oncology Group of Ontario, Toronto, Dr. Sarah Alexander, The Hospital for Sick Children, Toronto, and Ms. Catherine Deveault, The Hospital for Sick Children, Toronto.

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Record of Updates

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