Guidance on management of incidental findings relating to pregnancy testing in CHEO research

When pregnancy testing is conducted for research purposes, the protocol must include a plan for disclosure and management of related incidental findings (e.g., positive pregnancy result) in accordance with TCPS2 Article 3.4.

Protocol: Incidental Findings management plan

When pregnancy testing is conducted solely for research purposes, the research protocol (or CHEO protocol addendum) must describe the management of related incidental findings (i.e., pregnancy). If a positive result from a research related pregnancy test is identified, the study team should (i) inform the Principal and/or Qualified Investigator and (ii) report the finding to the patient-participant. When deemed appropriate by the Principal and/or Qualified Investigator, consideration should be given to engagement of the Adolescent Medicine and/or the Child and Youth Protection Team (CYPT) who can provide guidance and support with appropriate follow-up and referrals. [See workflow on page 2]

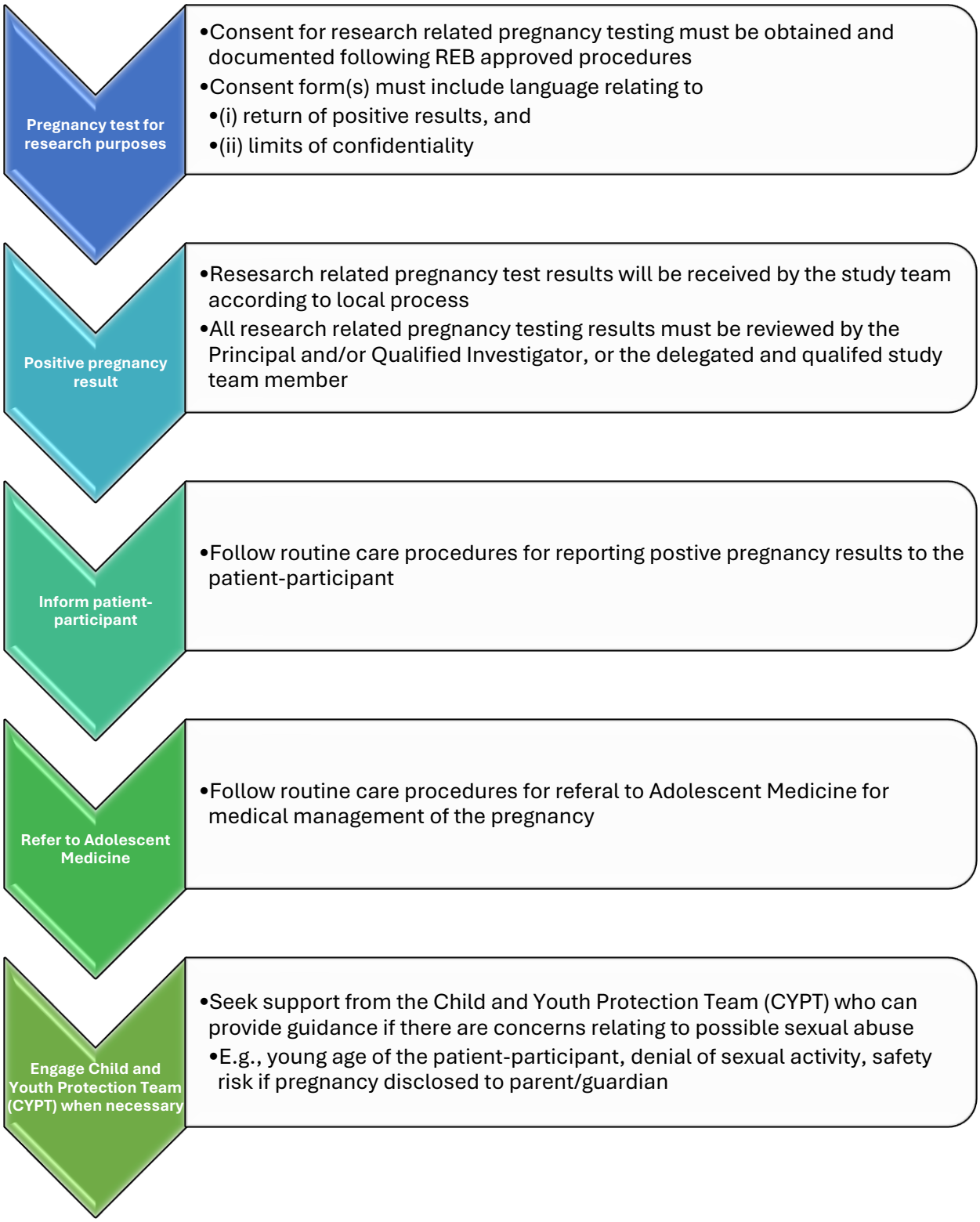
Consent form language

When pregnancy testing is required in a research protocol, the following consent form information must be included in the specified sections of the CTO Consent Template(s):

> HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?
>
> Any information that may indicate that a child is being harmed or at risk of harm would not be kept confidential as required under the law.
>
> WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?
>
> During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may identify that you are pregnant.
>
> If any new clinically important information about your health is obtained as a result of your participation in this study, you will be informed. Referral for medical care related to the pregnancy will be facilitated by the researchers.

November 12, 2025
Developed with input from CHEO Adolescent Medicine and CHEO Child and Youth Protection Team

General workflow for reporting of positive pregnancy results in CHEO research



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