

Pregnancy Testing Standards

1. Purpose

This document describes the HREB's transition from a mandatory serum pregnancy testing requirement to a risk-based approach. The goal is to align local standards with sponsor protocols, national harmonization efforts, and current evidence-based practices. This shift ensures robust, defensible oversight while removing unnecessary administrative barriers and improving the participant experience.

2. Context for Change

The HREB has historically required serum (blood) testing prior to Investigational Product (IP) administration, often overriding sponsor protocols that specify urine testing. This update addresses three key areas:

- **National Harmonization:** Aligning with multi-center REB reviews across Canada.
- **Participant Experience:** Reducing the burden of invasive blood draws when not clinically superior.
- **Scientific Efficacy:** Recognizing that the analytical sensitivity gap between serum and high-quality urine tests is minimal in a clinical trial context.

3. Evidence-Based Rationale

Data from *Morse et al. (2018)* indicates that while serum testing is more sensitive, the absolute difference is marginal. Global regulatory bodies do not mandate serum-only testing; instead, the testing modality should be dictated by the specific risk profile of the IP and the study population.

4. Revised Policy Framework

The following table outlines the shift from a "one-size-fits-all" mandate to a flexible, risk-based oversight model:

Feature	Current Practice	New Practice
Default Method	Mandatory Serum	Acceptance of Sponsor Protocol (Urine or Serum)
HREB Role	Imposes local requirement	Reviews rationale for testing strategy
High-Risk IP	Serum required regardless	PI/Sponsor must justify method or enhance testing

5. Implementation & Oversight

Under this new framework, the HREB retains the authority to intervene based on the teratogenic potential of the drug or the vulnerability of the study population.

1. **Sponsor Responsibility:** The Primary Investigator (PI) and Sponsor must provide a clear rationale for their chosen testing strategy in the protocol.
2. **Board Intervention:** For high-risk circumstances, the HREB may:
 - Request explicit justification for the sufficiency of the proposed testing.
 - Mandate enhanced testing (e.g., serum or increased frequency) as a specific condition of approval.