

# PEI RESEARCH ETHICS BOARD

## Investigator's Submission Checklist

<b>Full Study Title:</b>	
<b>Principal Investigator:</b>	
<b>Please consider for:</b>	<b>Expedited Review      OR      Full Board Review</b>
One copy of each item is required ( ✓ )	<b>ITEM (please include version number and dates)</b>
	Completed Submission Checklist
	Table of Contents (please submit one PDF file with continuous page numbers)
	Cover letter
	Recruiting & Consenting Step-By-Step Process
	Research Protocol
	Consent Forms (which comply with PEI REB Consent Form Guidelines)
	Investigator's Brochure and/or Product Monograph, Device Manual (If applicable)
	Safety Updates (If applicable)
	Questionnaires or Measurement Instruments
	Written Information for Participants (Diaries, Brochures, Pamphlets, Leaflets, Kits)
	Telephone Scripts
	Advertisements (for recruitment of participants)
	Budget
	Health Canada Letter of No Objection (if applicable)
	Current Curriculum Vitae & License for Principal Investigator
	Copies of Letters of Agreement/Support from impacted services
	Requisition for Invoice (Contract Studies Only)
	Letters of Approval from other Research Ethics Boards
	Letter to Primary Care Provider Advising Patient is Study Participant (if applicable)
	Confirmation of Supervisor's Review Form (if applicable)
	TCP2 Certificate

**Please answer the following questions:**

- a) How many subjects are expected to be enrolled in this research? \_\_\_\_\_
- b) Is there a Data Safety Monitoring Board?      NA      No      Yes      If yes, is it independent?      No      Yes
- c) In research for new pharmaceutical agents that are not yet commercially available, will participants who respond favorably be able to continue to receive the agent beyond the timeframe of the research?      NA      No      Yes
- d) Does anything in the protocol or the contract unreasonably limit your ability to publish the results? \_\_\_\_\_
- e) Is the study funded?      No      Yes      If yes, please name the contract or grant \_\_\_\_\_
- f) What is the clinical trial registry number? \_\_\_\_\_ Name of Registry: \_\_\_\_\_

\_\_\_\_\_  
Printed Name of Principal Investigator

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Contact Person  
for this Submission

\_\_\_\_\_  
Tel # of Contact Person

\_\_\_\_\_  
Email Address of Contact Person

**Please submit electronic documents to: [reb@ihis.org](mailto:reb@ihis.org) or hard copy to PEI Research Ethics Board,  
16 Garfield Street, Charlottetown, PE C1A 7N8**