



**Study Application Addendum  
For Collaborative Review of  
Canadian Sites with Institutional  
Review Board Services (IRBS)**



**Blank & incomplete answers will result in delayed reviews!**

**STUDY # AND TITLE:**

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**STUDY INFORMATION**

<b>1</b>	<b>Classification:</b> <input type="checkbox"/> Clinical Trial <input type="checkbox"/> Observational Study <input type="checkbox"/> Non-interventional study <input type="checkbox"/> Registry <input type="checkbox"/> Other (specify): _____		
<b>2</b>	<b>Design of Study:</b> <input type="checkbox"/> Randomized <input type="checkbox"/> Open-Label <input type="checkbox"/> Blinded <input type="checkbox"/> Other (specify): _____ <b>If Phase I, specify:</b> <input type="checkbox"/> First in man <input type="checkbox"/> Bioavailability		
<b>3</b>	<b>Test Article:</b> <input type="checkbox"/> Drug/Biologic <input type="checkbox"/> Device <input type="checkbox"/> Natural Health Product <input type="checkbox"/> Cosmetic <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> N/A		
<b>4</b>	<b>Comparator or Reference Product:</b> <input type="checkbox"/> Placebo <input type="checkbox"/> Active Comparator/Reference (specify name): _____ <b><i>If placebo controlled:</i></b> Please provide justification and any provisions to reduce risks to subjects who receive placebo: _____		
<b>5</b>	<b>Anticipated # of qualified investigators (QIs) for Canada:</b> _____ Anticipated # of subjects to be enrolled per site in Canada: _____		
<b>6</b>	<table style="width:100%; border:none;"> <tr> <td style="width:50%; border:none;"><b>Month when QIs will begin to be submitted to IRB Services:</b></td> <td style="width:50%; border:none;"><b>Total duration of study:</b> _____ (months)</td> </tr> </table>	<b>Month when QIs will begin to be submitted to IRB Services:</b>	<b>Total duration of study:</b> _____ (months)
<b>Month when QIs will begin to be submitted to IRB Services:</b>	<b>Total duration of study:</b> _____ (months)		
<b>7</b>	<b>What is the source of funding for the study (check all that apply):</b> <input type="checkbox"/> Industry <input type="checkbox"/> United States federal grant (e.g. NIH, NSABP, NCI, etc.) <input type="checkbox"/> Canadian federal grant (e.g. CIHR, NSERC, SSHRC) <input type="checkbox"/> Other (specify): _____		
<b>8</b>	<b>Does this study require prior Health Canada authorization?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b><i>If yes, the Health Canada No Objection Letter (for drugs or biologics), authorization (for medical devices) or notice of authorization (for natural health products):</i></b>  <b>Check one:</b> <input type="checkbox"/> Is Attached <input checked="" type="checkbox"/> OR <input type="checkbox"/> Will be submitted to IRB Services when available		
<b>9</b>	<b>Has this study been submitted to any other Canadian IRB for review prior to submission to Institutional Review Board Services (IRB Services)?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If <u>YES</u>, attach a detailed explanation</b>		
<b>10</b>	<b>Are any biological specimens collected as part of this research?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b><i>If <u>YES</u>, specify invasive samples:</i></b> <input type="checkbox"/> Blood <input type="checkbox"/> Tissue <input type="checkbox"/> Spinal Fluid <input type="checkbox"/> Other (specify): _____  <b><i>If <u>YES</u>, check all that apply:</i></b> <input type="checkbox"/> Safety evaluations <input type="checkbox"/> Pharmacokinetic analysis <input type="checkbox"/> Genetic testing <input type="checkbox"/> Pharmacogenetic, pharmacogenomic, or biomarkers		



**APPLICANT CERTIFICATION:**

I request IRB Services to act as the IRB/IEC/REB for the above study. I confirm that to the best of my knowledge the information provided in this document is true and accurate. Consistent with my role (or the role of my organization) in this research, I /my organization will:

- conduct the study according to applicable human research protection laws, regulations and Good Clinical Practices, the approved protocol and consent form,
- conduct the study consistent with the applicable ethical norms (e.g., principles of Declaration of Helsinki, Belmont Report, Tri-Council Policy Statement on Research Involving Humans)
- accept the authority of, and will abide by, the decisions of this IRB/IEC/REB as the board of record,
- comply with IRB/IEC/REB requirements, including timely filing of progress reports, end of study reports, or other documents as required by the IRB/IEC/REB,
- provide a copy, upon request, of the written plan between the sponsor and the investigator that addresses medical care for research subjects with a research-related injury in order for the IRB to determine consistency with the language used in the informed consent document,
- acknowledge the right of the IRB/IEC/REB to conduct an audit of the study documentation and to observe the consent process, with appropriate notice,
- not initiate changes to the research without prior IRB/IEC/REB review and approval, except where necessary to eliminate an immediate hazard to subjects,
- report immediately to the IRB/IEC/REB any unanticipated problems in the research, significant protocol deviations, or changes increasing the risk to subjects or affecting significantly the conduct of the trial,
- report promptly all adverse reactions that are both serious and unexpected, and new information that may affect the safety of the subjects or the conduct of the trial, or subjects willingness to participate in the research,
- report promptly any findings of serious or continuing non-compliance detected during any monitoring activities that could affect the safety of participants or influence the conduct of the study,
- report promptly any routine and urgent reports of data and safety monitoring,
- report promptly a) findings that emerge after the study has ended that directly affect the safety of past participants and were not anticipated at the time that the study was designed or conducted, and b) proposed mechanisms for communication of the findings to participants,
- acknowledge that study documentation retained by the IRB/IEC/REB may be inspected by regulatory authorities (e.g., Health Canada, US Food and Drug Administration) or accrediting bodies, and be available for audit by sponsor-appointed auditors who have a legal right of access to confidential information relating to the study.
- If the study requires prior Health Canada/FDA authorization: I certify that the sponsor has provided assurances that the manufacture and formulation of investigational or unlicensed health products (drugs, biologics, medical devices, or natural health products) conform to federal regulations.

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**Printed Name of Individual Completing Form**

**Printed Title of Individual Completing Form**

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**Signature**

**Date of Signature**

(dd mmm YYYY)