

**SITE INFORMATION FORM (PHASE II – IIIB) PAGE 1 OF 4**

*As part of the requirements for Ethics Approval, CSERB must be assured that the Investigator, who is legally responsible for the conduct of the research, has sufficient resources (ICH E.6 4.) to manage all responsibilities assigned as part of the study, including the protection of the trial participants. In addition, the Investigator must be able to personally oversee the proposed research (21 CFR 56.102 (b)).*

**This form is required for all trials where a Canadian CTA or USA IND has been, or will be filed**

Study Sponsor:	_____
Protocol Number:	_____
Protocol Name:	_____
	_____
	_____

**Section A - Principal Investigator Information**

1	<b>Full Name:</b>		
2	<b>Mailing Address:</b> <i>(Street, City, State / Province, Zip / Postal Code)</i>		
3	<b>Phone:</b> (____) _____	<b>Fax:</b> (____) _____	<b>E-mail:</b>
4	<b>Preferred method to receive study documents?</b> <i>(check one)</i> <input type="checkbox"/> E-mail <input type="checkbox"/> FAX <input type="checkbox"/> Regular Mail		
5	<b>General Practice:</b> <input type="checkbox"/> <b>Specialty:</b> <input type="checkbox"/> explain:		
6	<b>Medical License #:</b>	<b>Restrictions?:</b> No <input type="checkbox"/> *Yes <input type="checkbox"/> *explain:	<b>Expiration Date:</b> <b>State / Province:</b>
7	<b>Has the PI ever received an FDA Warning Letter?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	<b>Has the PI ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority or is the PI currently involved in such a proceeding?</b> <i>*If Yes, please attach explanation</i>	<input type="checkbox"/> *Yes <input type="checkbox"/> No	<input type="checkbox"/> *Yes <input type="checkbox"/> No

**Section B - Study Coordinator Information**

1	<b>Full Name:</b>		
2	<b>Site Address:</b> <i>(Street, City, State / Province, Zip / Postal Code)</i> same as Mailing Address (A2) <input type="checkbox"/>		
3	<b>Phone:</b> (____) _____	<b>Fax:</b> (____) _____	<b>E-mail:</b>
4	<b>Preferred method to receive study documents?</b> <i>(check one)</i> <input type="checkbox"/> E-mail <input type="checkbox"/> FAX <input type="checkbox"/> Regular Mail		



**SITE INFORMATION FORM**

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4	<p><b>What precautions will be used to maintain the confidentiality of identifiable health information?</b></p> <p><input type="checkbox"/> Paper based records will be kept in a secured location and only accessible to personnel involved in the study.</p> <p><input type="checkbox"/> Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.</p> <p><input type="checkbox"/> Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information.</p> <p><input type="checkbox"/> Whenever feasible, identifiers will be removed from study-related information.</p> <p><input type="checkbox"/> Other: <i>(specify)</i>: _____</p>											
<b>Section E – Recruitment, Consent &amp; Participant Payment Information:</b>												
1	<p><b>Check any of the following methods that this Site will use to recruit participants for this study:</b></p> <p><input type="checkbox"/> Central advertising supplied by Sponsor (<i>All recruitment materials must be approved before use, see #2</i>)</p> <p><input type="checkbox"/> From Personal Contact (e.g. Patients, other Physicians, etc)</p> <p><input type="checkbox"/> Referrals (<i>please note that referral bonuses require confirmation, please call CSERB for details</i>)</p> <p><input type="checkbox"/> From a database other than the PI's personal contacts. Please describe the type of database (e.g., disease registry, CRO/SMO database), the protections for confidentiality, and the method by which participants will be contacted:</p> <p>_____</p> <p><input type="checkbox"/> Site specific advertising (<i>All recruitment materials must be approved before use, see #2</i>)</p> <p><input type="checkbox"/> Other (specify): _____</p> <p><b>PLEASE NOTE – All research involving medical record review requires Ethics Approval. In addition, you may be required to receive authorization from the participant or a waiver of authorization before you can use or disclose health information for research purposes. (For additional information, please go to <a href="http://www.CSERB.com">www.CSERB.com</a>)</b></p>											
2	<p><b>Are any site-specific recruitment materials attached?</b></p> <p><i>*If yes, check all that are attached:</i></p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Newspaper</td> <td><input type="checkbox"/> Letter</td> <td><input type="checkbox"/> Posting</td> </tr> <tr> <td><input type="checkbox"/> Brochure</td> <td><input type="checkbox"/> Web Site</td> <td><input type="checkbox"/> Public Service Announcement</td> </tr> <tr> <td><input type="checkbox"/> TV (<i>script; tape</i>)</td> <td><input type="checkbox"/> Radio (<i>script; tape</i>)</td> <td><input type="checkbox"/> Other:</td> </tr> </table>	<input type="checkbox"/> Newspaper	<input type="checkbox"/> Letter	<input type="checkbox"/> Posting	<input type="checkbox"/> Brochure	<input type="checkbox"/> Web Site	<input type="checkbox"/> Public Service Announcement	<input type="checkbox"/> TV ( <i>script; tape</i> )	<input type="checkbox"/> Radio ( <i>script; tape</i> )	<input type="checkbox"/> Other:	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> Newspaper	<input type="checkbox"/> Letter	<input type="checkbox"/> Posting										
<input type="checkbox"/> Brochure	<input type="checkbox"/> Web Site	<input type="checkbox"/> Public Service Announcement										
<input type="checkbox"/> TV ( <i>script; tape</i> )	<input type="checkbox"/> Radio ( <i>script; tape</i> )	<input type="checkbox"/> Other:										
3	<p><b>Have any of these recruitment materials been previously approved by CSERB?</b></p> <p><i>*If yes, please attach a copy of the previously approved item(s).</i></p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>									
4	<p><b>Are you submitting any recruitment materials that reference a web site?</b></p> <p>WEB Page URL: _____</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>									
5	<p><b>Who at your site will perform the screening examinations to determine if they are eligible from advertising campaigns? (if applicable)</b></p>	N/A <input type="checkbox"/>										
6	<p><b>Please indicate the language(s) of the participants the PI plans to enroll. The consent form must be in a language easily understood by the participant, and all consent form translations must be approved by CSERB.</b></p> <p><input type="checkbox"/> English</p> <p><input type="checkbox"/> French</p> <p><input type="checkbox"/> Other: _____</p>											

