# Canadian SHIELD Ethics Review Board

OHRP Registration IORG0003491 FDA Registration IRB00004157 Registered with CAREB, NCEHR

501 Deerhurst Drive, Suite 102, Burlington, ON L7L 5T1 Phone: (905) 681 8661 Fax: (905) 681 8668 www.cserb.com

# 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

-	Sponsor:						
Protocol Number: Protocol Name:							
Proto	Protocol Name:						
	Section A - Principal Investigator Information						
1	Full Name:						
2	Mailing Address: (Street, City, State / Province, Zip / Postal Code)						
3	<b>Phone:</b> ()	Fax: ()		E-mail:			
4	Preferred method to receive study documents? (check one)						
5	General Practice:  Specialty:  explain:						
6	Medical License #:	<b>Restrictions?:</b> No □ *Yes □ *explain:	Expi	ration Date:	State / Province:		
7	Has the PI ever received an I	TDA Warning Letter?				Yes	No
8	Has the PI ever been convicted disciplined by a licensing aut	he PI ever been convicted of a crime, disciplined by a public or private medical organization, olined by a licensing authority or is the PI currently involved in such a proceeding?  *If Yes, please attach explanation  *Yes □  *No □					
		Section B - Study Coordina	ator I	nformation			
1	Full Name:						
2	Site Address: (Street, City, State / Province, Zip / Postal Code) same as Mailing Address (A2)						
3	<b>Phone:</b> ()	Fax: ()		E-mail:			
4	Preferred method to receive study documents? (check one)						

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# SITE INFORMATION FORM (PHASE II-IIIB)

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		Section C – Si	te Information		
1	What resources are available at this site to treat emergencies resulting from study-related procedures?  ACLS trained personnel and crash cart Emergency drugs and supplies to stabilize participant until emergency personnel arrive Emergency response team within facility Call 911 Other (specify):				
2	Medical facility to be used in a	an emergency:			N/A
3	Does the PI have staff privileg	es at this facility?		Yes □	No
4	Where will the research data t	o be stored by the PI.	Will the data be stored on s	site 🗌 or	off site
	Please describe the roles of those members of the study team who are involved in the consent process and execution of trial (Sub-investigators, study coordinators – <u>NOTE: for Sub-investigators, list MD License # in Role/Notes</u> )				
	Name/Site(s)	<u>Title</u>	Role/ Notes		
	Example: John Doe, M.D.	PI	Provide medical oversight for study participants. Responsible for all study related issues.		
5					
			or Time Commitments		
1	For this protocol, how many of		Study Coordinato	•	
2	How many of the following do Active Research Studies: Locations:	Approx. Num	rise? (total) aber of Active Participants: b-Investigators:	Research Staff :	
3	Approximate percentage of time dedicated to research studies overall:				

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# **SITE INFORMATION FORM**

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4	What precautions will be used to maintain the confidentiality of identifiable health information?  Paper based records will be kept in a secured location and only accessible to personnel involved in the Computer based files will only be made available to personnel involved in the study through the use of privileges and passwords.  Prior to access to any study-related information, personnel will be required to sign statements agreeing security and confidentiality of identifiable health information.  Whenever feasible, identifiers will be removed from study-related information.  Other: (specify):	f access	et the
	Section E – Recruitment, Consent & Participant Payment Information:		
1	Check any of the following methods that this Site will use to recruit participants for this study:  Central advertising supplied by Sponsor (All recruitment materials must be approved before use, see in From Personal Contact (e.g. Patients, other Physicians, etc)  Referrals (please note that referral bonuses require confirmation, please call CSERB for details)  From a database other than the PI's personal contacts. Please describe the type of database (e.g., disease CRO/SMO database), the protections for confidentiality, and the method by which participants will be	ase registr	
	Site specific advertising (All recruitment materials must be approved before use, see #2)  Other (specify):  PLEASE NOTE – All research involving medical record review requires Ethics Approval. In addition, you may receive authorization from the participant or a waiver of authorization before you can use or disclose health infresearch purposes. (For additional information, please go to <a href="https://www.cserb.com">www.cserb.com</a> )		
2	Are any site-specific recruitment materials attached?  *If yes, check all that are attached: Newspaper Letter Posting  Brochure Web Site Public Service Announcement  TV (script; tape) Radio (script; tape) Other:	*Yes	No
3	Have any of these recruitment materials been previously approved by CSERB?  *If yes, please attach a copy of the previously approved item(s).	*Yes	No
4	Are you submitting any recruitment materials that reference a web site? WEB Page URL:	Yes	No
5	Who at your site will perform the screening examinations to determine if they are eligible from advertise campaigns? (if applicable)	sing	N/A
6	Please indicate the language(s) of the participants the PI plans to enroll. The consent form must be in a launderstood by the participant, and all consent form translations must be approved by CSERB.    English   French   Other:	anguage e	asily

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# SITE INFORMATION FORM (PHASE II-III)

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	Section E – Recruitment, Consent & Participant Payment Information:		
	ormation to be listed in the Consent Form:		
	e and phone number for <b>questions about the study</b> :		
	er(s): (check all that apply)		
()	Office Hours 24 hours Pager		
Contact nam	e and phone number for use in the event of <b>research-related injury</b> :		
Name			
Phone numb	er(s):  Office Hours 24 hours Pager (check all that apply)		
Please provi	ide participant payment information:		
☐ Participa	nts will not be paid.		
	nts will be reimbursed for travel and or parking as follows:		
Таптогра	and will be relimbalised for duver and of parking as follows:		
☐ Participa	nts will be paid according to attached payment schedule or as stated in submitted consent form. <b>OR</b>		
☐ Participa	nts will be paid as follows:		
	completed visit: \$		
	risits in this study:  y visits not paid:		
Total	\$		
•	Section F - Confirmation of Information		
Printed or	Printed or Typed Name of Person Completing This Form		
oversee this Canadian SH	the information contained above is accurate. I acknowledge Canadian SHIELD Ethics Review Board has the authority to study and suspend the study if necessary to protect the rights and welfare of the study participants. I agree to provide HELD Ethics Review Board with the information they require to conduct initial and continuing review of this study on a and that if the information is not provided, Canadian SHIELD may suspend the study.		
Signature	Date		
( ) Phone num	shor.		