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

STUDY INFORMATION FORM

To be completed by Study Sponsor or Investigator *(if Investigator Initiated Trial or government sponsored trial)*

Section A – Study Information					
1	**Protocol Title:**				
2	**Protocol Number:**	**Version Date:**			
3	**Sponsor Name:**				
3a	**Sponsor Contact Name:**				
3b	**Sponsor Contact Address:** *(Street, City, Province, Postal Code or Foreign Address, if applicable)*				
3c	**Sponsor Contact Phone:** (____) _____	**Sponsor Contact Fax:** (____) _____	**Sponsor Contact E-mail:**		
4	**Is a Contract Research Organization (CRO) involved in this research?** *If No, proceed to Question 5*			**Yes** ☐	***No** ☐
4a	**CRO Name:**				
4b	**CRO Address:** *(Street, City, Province, Postal Code)*				
4c	**CRO Contact Name:**				
4d	**CRO Contact Phone:** (____) _____	**CRO Contact Fax:** (____) _____	**CRO Contact E-mail:**		
5	**Will a Site Management Organization (SMO) be involved in this research?** *If No, proceed to Section B*			**Yes** ☐	***No** ☐
5a	**SMO Name:**				
5b	**SMO Address:** *(Street, City, Province, Postal Code)*				
5c	**SMO Contact Name:**				
5d	**SMO Contact Phone:** (____) _____	**SMO Contact Fax:** (____) _____	**SMO Contact E-mail:**		

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STUDY INFORMATION FORM

Section B – Principal Investigator for Overall Study

1	**N/A** ☐ **Principal Investigator Name**:		
1a	**Mailing Address:** *(Street, City, Province, Postal Code or Foreign Address, if applicable)*		
1b	**Phone:** (____) _____	**Fax:** (____) _____	**E-mail:**

Section C – Research Information

1	**Has this research study been disapproved or terminated by another REB / IRB?** **If Yes, please attach provide the REB/ IRB disapproval or termination letter or details*	***Yes** ☐	**No** ☐
2	**Do any of the Sites have an obligation to use another REB / IRB for this study?** *If Yes, please identify:	***Yes** ☐	**No** ☐
3	**Will this research enroll any participants from the following "vulnerable" categories?** **If Yes, please list all vulnerable participant groups:* ☐ Mentally ill ☐ Mentally disabled ☐ Nursing home residents ☐ Institutionalized ☐ Chronic condition ☐ Terminally ill ☐ Hospitalized ☐ Pregnant women ☐ Limited or non-readers ☐ Poor/uninsured ☐ Children ☐ Others vulnerable to coercion (Specify) _____	***Yes** ☐	**No** ☐

Section D – Central Recruitment **Not Used** ☐

1	**Check any of the following methods that will use to recruit participants for this study:** ☐ From a database other than the PI's personal contacts. Please describe the type of database (e.g., CRO/SMO database), the protections for confidentiality and the method by which participants will be contacted:_____ ☐ 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 be required to receive authorization from the participant or a waiver of authorization before you can use or disclose health information for research purposes. (See PIPEDA information on www.CSERB.com)**		
2	**Are 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	**Please indicate the language(s) of the participants anticipated**. *The consent form must be in a language easily understood by the participant, and all consent form translations must be approved by CSERB.* ☐ English ☐ French ☐ Other: _____		

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STUDY INFORMATION FORM

Section E – Billing Information *(if not completed PI will be billed)*

1	**Company Name:**		
2	**Attn.:**		
3	**Address**: (street, city, province / state, postal code / zip, country)		
4	**Phone:** (____) _____	**Fax:** (____) _____	**E-mail**:
5	**Please describe any special billing instructions:** **None** ☐		

Section F - Confirmation of Information

1

_____

Printed or Typed Name and Title of Person Completing This Form

I certify that the information contained above is accurate. I acknowledge Canadian SHIELD Ethics Review Board has the authority to oversee this study at the sites named by the sponsor and reviewed by this Board, and suspend the study if necessary to protect the rights and welfare of the study participants. I agree to provide Canadian SHIELD Ethics Review Board with the information they require to conduct initial and continuing review of this study on a timely basis and that if the information is not provided, Canadian SHIELD may suspend the study.

_____ _____

Signature **Date**

(____) _____

Phone number

TO BE COMPLETED BY CANADIAN SHIELD ETHICS REVIEW BOARD:

Protocol Tracking Number: _____ Sponsor: _____

Protocol Number: _____ Date of Protocol: _____

Date of Consent Form: _____

Date of Receipt: _____ Date of Board Review: _____

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