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eREB Application Checklist

Study Name:

PI:

Please note that items in italics may not be applicable to your study.

Section			eREB Section
Study Contact Information	☐	Are the investigators all <u>local</u> (Holland Bloorview-affiliated)?	**4.1** **4.2** **4.4**
	Note: Multisite studies- For studies involving activities performed at other sites, please include each site with their respective PI and site contact person separately in Section 7.1		
Local PI and Co-PI(s) Training Certificates	☐	**TCPS2 CORE** ☐ Does the certificate indicate a completion date after 2022? *Only need to submit TCPS2 of local PIs and Co-PIs	**4.1** **4.2.2** **4.4**
	CITI Certificates (RCR, GCP, and other applicable courses) Study Teams: these documents must be sent to Freshdesk prior to any research activities. It is the PI's responsibility to ensure training of research team is documented.		
☐ **Study Budget**	☐	Does the budget include all research activities (including monitoring activities)?	**6.19**
	Please note that the study Budget will be reviewed by BRI once the application has been submitted in eREB.		
☐ **Study Protocol**		Does the protocol include:	**8.6**
	☐	A title?	
	☐	A version date?	
	☐	Funding information?	
	☐	Contributors, Sponsor, Funder, other groups involved in the conduct?	
	☐	Research background, rationale and objectives?	
	☐	Design and detailed description of methodology?	
	☐	Eligibility criteria, description of the population to be studied?	
	☐	Recruitment and consent process?	
	☐	Research interventions (if applicable)?	
	☐	Treatment allocation (if applicable)?	
	☐	Blinding (if applicable)?	
	☐	Primary and secondary outcome measures?	
	☐	Assessment of safety?	
	☐	Sample size justification?	
	☐	Data analysis?	
	☐	Data management and monitoring?	
	☐	Statistical methods?	
	☐	Confidentiality	
	☐	Declaration of Interests (if applicable)	
	☐	Dissemination	
	☐	Does the version date have no conflicts with the Scientific Review date?	
	☐	Is the scientific review form signed and dated by reviewer?	**8.7**

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☐ **Scientific Review Form**	☐	*Is there an itemized response by the research team to the comments from the reviewer(s), referencing changes made to the protocol?*	
Participant-facing Materials	For all recruitment materials: ☐ Does not include coercive language (no monetary values)? ☐ Includes REB #? ☐ *Only includes Holland Bloorview-affiliated contact information?*		**8.101**
	Material submitted to the REB must be an exhaustive list of everything that will be given to, read to, or seen by participants, including, but not limited to: • Recruitment materials • Phone scripts* **If remote:* ☐ *Is the participant aware of the location where the study team is calling from?* ☐ *Confidentiality of the space (i.e. room in house where no one will be walking around, in home with no other individuals around, etc).* ☐ *Is the participant willing to continue with the call/visit?* • Email Scripts* ☐ *Did the participants consent to receiving emails? ☐ *Were the participants informed of the risks related to communication via email? • Interview and focus group script guides • Questionnaires/surveys • Outcome measures • Screening forms • Data collection forms/Case Report Forms • Diaries • Interview guides • Videos • Volunteer certificates • Safety brochures • Devices instructions • Online postings* ☐ *Draft to be submitted to Brand and Public Engagement for Approval		
	☐	***BRI 'Participate in Research at Holland Bloorview' Flyer***	**8.14.2**
	☐	***REDCap Data Collection Documents/Variable List*** ☐*URL(s) provided?*	**8.14.2**
	☐	***connect2research Recruitment materials*** ☐*connect2research decision letter uploaded?* ☐*all recruitment materials using connect2research recruitment templates submitted?*	**10.11** **10.12**
Governance document(s)	*For each biobank/repository where specimens will be located* *For each database/repository where data will be entered for future use*		**8.84** **12.29.8**
Institutional Approval	*If recruiting from a third-party organization*		**10.2.4.1**

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☐ ***Departmental Approval Form***	☐	*Letter of Approval submitted?*	**10.2.9**
	Applicable only if research involves recruitment of HB clients		
☐ ***Capacity Assessment Documents***			**11.4.1**
☐ **Informed Consent Forms (ICF)**	☐	For prospective observational, interventional, biobank, and genetic research: were the HB templates and checklist from the HB REB website followed?	**11.29**
	Upload all consent-related materials, including Screening Consent Forms, Main consent forms, Optional consent forms, verbal consent script, implied consent documents		
☐ **Assent Forms**	☐	*Was the assent form template followed?*	**11.36**
ICES Materials	*If study is conducted using ICES' Data and Analytics Services platform, include ICES materials to be submitted to the REB* ☐ ***ICES Confirmation of Feasibility***		**12.17**
☐ ***Contracts and Agreements***	*For studies involving any external collaborations, services and/or research data or biological samples transferred outside of Holland Bloorview* *For transfers:* ☐ *materials transfer agreement* ☐ *information sharing agreement* ☐ *service provider agreement* ☐ *vendor agreement*		**12.40**
	☐	*BRI Contract Request Form auto email submitted?*	**16.2**
☐ ***Research Safety/Management Plans***	*e.g. Community Safety Plan, Mental Health Research Safety (if applicable)*		**13.11-13.81**
☐ ***DSMB/C Charter***			**13.13.3**
☐ ***Certificates of Translation***	☐	*Translated materials submitted?*	**16.2**
☐ **PI Signature**	Initial Application must be signed by the PI (subsequent subform signatures could be delegated under the discretion of the PI)		**20.1**
☐ ***Senior MRI Technologist Signature***	*If study involves the MRI unit*		**20.3**

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Additional Checklist – Studies Involving Regulated Drugs/NHPs/Medical Devices

☐ ***Risk Assessment Documentation/Device Manuals***	*For studies involving Class 2, 3, and 4 medical devices, assistive devices or related technologies.*	***8.56.7***
☐ ***Investigator's Brochure***	*For regulated drug trial submissions only*	***8.49.1***
☐ ***Product Monograph***	*For regulated drug trial submissions only*	***8.49.1***
☐ ***No Objection Letter (NOL)***	*For Health Canada Clinical Trial Application*	***8.50.1***
☐***Notice of Authorization***	*For Clinical Trial Applications involving Non-prescription and Natural Health Products*	***8.54.1***
☐***Letter of Authorization***	*For Clinical Trial Applications involving unlicensed class II, III, or IV medical devices*	***8.56.6.1***
☐ ***Pharmacy Approval Document/Pharmacy Decision Letter***	*For studies requiring pharmaceutical services at Holland Bloorview*	***8.51***
☐ ***MAC Approval***	*For all regulated clinical trials involving inpatients*	***9.6***

Additional Checklist – Studies Involving Indigenous Populations

Indigenous Community Documents	☐	*Preliminary or formal research agreement*	***10.10.2.1***
	☐	*Written decision/documentation to approve/decline research*	***10.10.2.2***
	☐	*Summary of advice*	***10.10.2.3***
ICES Materials	*If study is conducted using ICES' Data and Analytics Services platform, include ICES materials to be submitted to the REB* ☐ ***ICES Confirmation of Feasibility***		***12.17***

Additional Checklist – Studies Involving Transfer TO Open Access Data

☐ ***Open Access Consent Form***	☐	*Does the consent form indicate that inclusion of data in the open access database is optional?*	***11.29***
	☐	*Is the optional consent for to Open Access a separate ICF (not embedded in the main ICF)?*	
☐ ***End User License Agreement***			***12.61.9***
☐ ***Approval from Privacy***			***12.41.2***
☐ ***Approval from IMT***			***12.41.2***
☐ ***Contracts and Agreements***	☐	*BRI Contract Request Form auto email submitted?*	***16.2***