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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 local (Holland Bloorview-affiliated)?<br>**Ensure that the PI has access to the project** | **4.1**<br>**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-I(s) Training Certificates** | ☐ | **TCPS2 CORE**<br>☐ Does the certificate indicate a completion date after 2022?<br>*Only need to submit TCPS2 of local PIs and Co-Is | **4.1**<br>**4.2.2**<br>**4.4** |
| | **CITI Certificates (RCR, GCP, and other applicable courses)**<br>HB Study Teams: these documents must be uploaded to each research team member's personal folder in the BRI Training Certificate Repository 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. | | |
| ☐ ***Multisite information*** | ☐ | *If a site does not require local REB approval, has a document/email explaining why local REB approval does not apply to the site been submitted?* | ***7.2.10***<br>***16.1,***<br>***16.2*** |
| | ☐ | *Was a site approval or confirmation of support document/email submitted for each external site?* | ***7.2.10.3*** |
| ☐ **Study Protocol** | | Does the protocol include:<br>☐ A title?<br>☐ A version date?<br>☐ Funding information?<br>☐ Contributors, Sponsor, Funder, other groups involved in the conduct?<br>☐ Research background, rationale and objectives?<br>☐ Design and detailed description of methodology?<br>☐ Eligibility criteria, description of the population to be studied?<br>☐ Recruitment and consent process?<br>☐ Research interventions (if applicable)?<br>☐ Treatment allocation (if applicable)?<br>☐ Blinding (if applicable)?<br>☐ Primary and secondary outcome measures?<br>☐ Assessment of safety?<br>☐ Sample size justification?<br>☐ Data analysis?<br>☐ Data management and monitoring? | **8.6** |

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| | ☐<br>☐<br>☐<br>☐ | Statistical methods?<br>Confidentiality<br>Declaration of Interests (if applicable)<br>Dissemination | |
| | ☐ | Does the version date have no conflicts with the Scientific Review date? | |
| ☐ **Scientific Review Form** | ☐ | Is the scientific review form signed and dated by reviewer? | **8.7** |
| | ☐ | *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 participant facing materials and recruitment materials:<br>☐ Does not include coercive language (no monetary values)?<br>☐ Includes REB # and version date?<br>☐ *Only includes Holland Bloorview-affiliated contact information?* | | **8.101**<br>**10.12**<br>**14.1.4** |
| | 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:<br>• Recruitment materials<br>• Phone scripts*<br>**If remote:*<br>☐ *Is the participant aware of the location where the study team is calling from?*<br>☐ *Confidentiality of the space (i.e. room in house where no one will be walking around, in home with no other individuals around, etc).*<br>☐ *Is the participant willing to continue with the call/visit?*<br>• Email Scripts*<br>☐*Is participants consent to receiving emails being sought?<br>☐*Do the scripts include informing the participants of the risks related to communication via email?<br>• Interview and focus group script guides<br>• Questionnaires/surveys<br>• Outcome measures<br>• Screening forms<br>• Data collection forms/Case Report Forms<br>• Diaries<br>• Interview guides<br>• Videos<br>• Volunteer certificates<br>• Safety brochures<br>• Devices instructions<br>• Online postings*<br>☐ *Draft to be submitted to Communications and Brand and Public Engagement for Approval<br>• ☐ Letter of Appreciation Template | | |
| | ☐ | ***BRI 'Participate in Research at Holland Bloorview' Flyer*** | **8.14.2** |

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| | ☐ | ***REDCap Data Collection Documents/Variable List***<br>*☐URL(s) provided?* | **8.14.2** |
| | ☐ | ***connect2research Recruitment materials***<br>*☐connect2research decision letter uploaded?*<br>*☐all recruitment materials using connect2research recruitment templates submitted?* | **10.11**<br>**10.12** |
| ***Governance document(s)*** | ☐ | *For each biobank/repository where specimens will be located* | **8.83** |
| | ☐ | *Governance document(s) for each database/repository where data will be entered for future use* | **12.29.8** |
| | ☐ | *If study data is intended to be entered into an external database/repository for future use, has the Director of Research Operations and Business Development been informed of this?* | **12.29.9** |
| ***Institutional Approval*** | *If recruiting from a third-party organization, please note that it is the PI's responsibility to ensure that institutional approval or confirmation of support was secured prior to recruiting from third party organizations* | | **10.2.4.1** |
| ☐***Departmental Approval Form*** | ☐ | *Letter of Approval submitted?* | **10.2.9** |
| | *Applicable only if research involves recruitment of HB clients through clinical departments* | | |
| ☐ ***Capacity Assessment Documents*** | ☐ | *Was the capacity assessment template from the HB REB website used and updated with study-specific information, including the eREB #, PI name, and version date?* | **11.4.1** |
| ☐**Informed Consent Forms (ICF)** | ☐ | For prospective observational, interventional, biobank, database/databank, and genetic research: were the HB templates and checklist from the HB REB website used/followed, and do they have the eREB # and the version date? | **11.29** |
| | ☐ | *If the informed consent process is occurring remotely, do(es) the ICF(s) include the wording on the appendix of Ethical Considerations for Remote Consent and Assent?* | |
| | 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 used/followed, and do they have the eREB number and version date?* | **11.36** |
| ☐ ***Debriefing materials*** | ☐ | *If there is a plan to debrief participants or if any additional information that may offer participants the possibility of refusing consent and/or withdrawing data or specimens will be provided, have the debriefing materials been submitted?* | ***11.10.2*** |
| | ☐ | *If there are proposed alterations to the consent procedures, have the debriefing materials been submitted, or has the absence of debriefing been justified?* | ***11.21.2***<br>***11.21.3*** |
| ☐ ***Database*** | ☐ | *If the study involves access to a database not maintained by the PI, has access/use for research purposes been granted, and has the approval document (or equivalent) been submitted?* | **12.12.3.3.1** |
| ☐ ***ICES Materials*** | *If study is conducted using ICES' Data and Analytics Services platform, include ICES materials to be submitted to the REB*<br>☐ ***ICES Confirmation of Feasibility*** | | **12.17** |

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| ☐ ***External Platforms*** | ☐ | *If an external platform will be used to store data, has approval documents from both the Privacy Office and IMT been submitted, or if the platform does not require review by Privacy and IMT, has this been justified?* | **12.32.4**<br>**12.32.5** |
| ☐***Contracts and Agreements*** | *For studies involving any external collaborations, services and/or research data or biological samples transferred outside of Holland Bloorview*<br>*For transfers:*<br>*☐ materials transfer agreement*<br>*☐ information sharing agreement*<br>*☐ service provider agreement*<br>*☐ vendor agreement* | | ***12.40***<br>***15.1*** |
| | ☐ | *BRI Contract Request Form auto email submitted?* | ***15.1.3*** |
| ☐***External Organizations and Individuals*** | ☐ | *If data is being shared with/transferred to external organizations and individuals, have all these external organizations/individuals been identified?* | ***12.46*** |
| | ☐ | *If data is being received from or transferred by external organizations and individuals, have all these external organizations/individuals been identified?* | ***12.47*** |
| ☐ ***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** |

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

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|---|---|---|
| ☐ ***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***<br>***8.53.1*** |
| ☐ ***Product Monograph*** | *For regulated drug trial submissions only* | ***8.49.2***<br>***8.53.2*** |
| ☐ ***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*** |

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| ☐***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 8.55*** |
| ☐ ***MAC Approval*** | *For all regulated clinical trials involving inpatients* | ***9.6*** |

***Additional Checklist – Studies Involving Indigenous Populations***

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|---|---|---|---|
| ***Indigenous Community Documents*** | ☐ | *Preliminary or formal research agreement* | ***10.10.2.1*** |
| | ☐ | *Written decision/documentation to approve/decline research* | ***10.10.2.2*** |
| | ☐ | *Written 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*<br>☐ ***ICES Confirmation of Feasibility*** | | ***12.17*** |

***Additional Checklist – Studies Involving Transfer TO Open Access Data***

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|---|---|---|---|
| ☐ ***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 form for Open Access a separate ICF (not embedded in the main ICF)?* | |
| ☐ ***End User License Agreement*** | | | ***12.61.9*** |
| ☐ ***Approval from Privacy*** | | | ***12.32.5*** |
| ☐ ***Approval from IMT*** | | | ***12.32.5*** |
| ☐ ***Contracts and Agreements*** | ☐ | *BRI Contract Request Form auto email submitted?* | ***15.1.3*** |