**REB SUBMISSION CHECKLIST FOR RESEARCHERS**

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| **DOCUMENT TITLE** | **Included or Completed** |
| **Preliminary Review completed by REB office, and study has been assigned an REB#.**  *\*Please note that all REB submissions must undergo preliminary review prior to being submitted for ethics review. The submission deadline on the REB Calendar refers to submissions that have already undergone preliminary review.* |  |
| **Study Information Sheet**  *\*Please note this is mandatory for all new ethics submissions.* |  |
| **Checklist of Resources**   * If the Research Unit Director (RUD) is the study PI or one of the co-investigators, please contact the REB office |  |
| **Privacy Acknowledgement Form**   * Signed by PI |  |
| **TCPS2 Certificates**   * Required for all investigators & research personnel |  |
| **Approval Letter from Board of Record**   * If ROHCG REB is not the BOR, please provide the ethics approval letter from the BOR, and any amendment approval letters/documents * You may submit the approved REB Application and Protocol; You are not required to fill out the ROHCG REB Application |  |
| **Data Sharing Agreement**   * For all studies that will be transferring, sharing or storing data at another institution, please contact REB office for assistance. |  |
| **REB Application**   * Investigator Signatures * Section 21 or 11 signature by RUD * Information is consistent with Protocol |  |
| **Research Protocol**   * Page numbers * Version Date: Version 1 for all new submissions (for sponsored studies, you must use the sponsor version date) * Written in plain, easy to understand language * Acronyms are clearly spelled out at the beginning of the document * Information is consistent with REB Application * Objective/hypothesis * Literature Review(with references) * Methodology: Participant selection with inclusion/exclusion criteria * Sample size justification (power analysis) * Procedure * Description & copies of measures to be used * Statement of statistical procedures applied to the data |  |
| **Informed Consent Form(s)**   * ROHCG REB Template * If using sponsor ICF, ensure the REB contact info includes the following statement:   This study has been reviewed and approved by the Royal Ottawa Health Care Group REB as study #\*\*\*\*\*. If you have any ethical concerns about the study, or the  way it is conducted, please contact the REB office: [kristi.wilde@theroyal.ca](mailto:kristi.wilde@theroyal.ca)   * Page numbers * Version Date: Version 1 for all new submissions (for sponsored studies, you must use the sponsor version date) * Included a chart outlining study visits/requirements/times, etc., for participants. * Written between a grade 6-8 reading level, using plain language.   \*Please note: ICF’s that written over a grade 8 reading level, and do not use plain language, will be returned for revision. |  |
| **Participant Materials**   * Recruitment materials (poster, social media ad etc. with appropriate institutional logos). \*For all posters, please use the template for guidance. * Written in plain, succinct language * Page numbers * Version Date: Version 1 for all new submissions (for sponsored studies, you must use the sponsor version date) |  |
| **Other Language Participant Documents**   * If you are recruiting other language speaking participants, please provide all translated materials (ICF’s, recruitment materials, etc.) * Page numbers * Version Date: Version 1 for all new submissions (for sponsored studies, you must use the sponsor version date) |  |
| **Budget**   * Page numbers * Version Date: Version 1 for all new submissions |  |
| **CVs**   * required for investigators listed on the REB Application |  |
| **ADDITIONAL ITEMS FOR CLINICAL TRIALS** |  |
| **Copy of Health Canada “No Objection Letter” (NOL)**   * For clinical trials involving new investigational drugs, a marketed drug (or if using a marketed drug outside of approved indication), or using a medical device, a Clinical Trial Application (CTA) must be submitted to Health Canada. Forward NOL upon receipt to REB |  |
| **Additional:**   * All previous decisions, if known, by other REBs or Regulatory Authorities for a proposed biomedical clinical trial (whether in the same location or elsewhere), and indication of modification(s) of the protocol made, and the reasons for previous negative decisions |  |
| **Investigator’s Brochure or Product Monograph**   * For all studies involving a drug or device |  |
| **Genetic Addendum:**   * For all studies that include a biological/genetic component, whether during the study proposed, or for future considerations, a Genetic Addendum is required |  |
| **Health Canada REB Attestation Form**   * Submit to the REB office for signature |  |
| **Review & Monitoring Fee** (if Industry-sponsored)   * Consult with the REB office for invoicing & fund transfer procedure |  |
| **Fully Executed Project Funding Recovery Form and Clinical Trial Agreement**   * For all industry sponsored research |  |
| **FOR PET/MRI IMAGING STUDIES** |  |
| * Brain Imaging manager has signed off on the Checklist of Resources |  |