HSREB Submission Checklist- For Reviewers

*This is an aid, for your reviews and for your documentation only

Reviewer Checklist

- This checklist is designed to aid in ethical review of research studies across various disciplines, including clinical research, health-related research, and social sciences research. It is intended to ensure that proposed studies adhere to ethical standards and principles. Reviewers should carefully assess each item and provide feedback accordingly.
- Please complete this checklist as you review the study application and attachments. Indicate whether the researcher has adequately considered and safeguarded the following areas of concern.
- Remember, the research ethics office (REO) has already conducted a preliminary ethical review of the study. They have included questions or comments for you in the review box on TRAQ or CTO. They have also ensured all required administrative elements are included in the studies.
- **Comments:** If you copy and paste into TRAQ or CTO, ensure it is written in question format that can be copied and pasted into the review letter back to the applicant.

	Completed	Comments
GENERAL REVIEWER QUESTION		
Is the study information consistent across documents?	☐	
Is the REB application completed in its entirety?	☐	
RESEARCH PROJECT DESCRIPTION		
Purpose & Background:		
Is the research question clearly stated?	☐	
Methodology/Procedures:		
Is the methodology/design adequately described to address ethical concerns? NOTE: evaluating methodology from the ethical perspective is the mandate of the REB. A scientific peer review would be looking at methodology as a whole.	☐	
RECRUITMENT OF PARTICIPANTS AND PARTICIPATION		
Inclusion / Exclusion Criteria:		
Are criteria for inclusion/exclusion equitable (i.e., no exclusions on basis of race, age, gender, etc., unless justified)?	☐	
Does the nature of the research impact the vulnerability for any of the groups listed? Check all that apply: ☐ People with relevant health issues ☐ People in medical emergencies ☐ People of Indigenous heritage ☐ People living in poverty ☐ People in long-term care ☐ People in prison ☐ People with mental health concerns ☐Children ☐Elderly ☐People who are unable to consent	☐	

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☐Other		
Participant Recruitment:		
Have the TCPS2 guidelines been followed in the recruitment of these individuals?	☐	
Is the initial point of contact (IPC) appropriate? (i.e. an IPC tool such as a poster, flyer, self-identification or someone within the participant's circle of care or within the organization (or someone known to the individual) made the initial contact on behalf of the investigator)?	☐	
Are recruitment procedures in any way coercive?	☐	
Community Engagement:		
Is there evidence of consultation with a community, if applicable? (i.e., First Nations, Indigenous, or a group of people that identify as a community).	☐	
RISK/BENEFIT RATIO		
Is this considered a minimal risk study? If no, has this been assigned to a Full Board Review?	☐	
Are there any of the following possible risks (check any that apply): ☐ Physical ☐ Psychological/Emotional ☐ Legal ☐ Social ☐ Economic ☐ Academic ☐ Other	☐	
Are the risks to participants minimized by a sound research design? (ie. Data safety monitoring board) Have the risks been properly mitigated or has the applicant provided justification for the lack of mitigation or minimization?	☐	
Is the risk/benefit ratio justified?	☐	
Are any possible risks to participants greater than those they might encounter in their everyday life (if yes, have they been adequately explained and justified)?	☐	
PRIVACY & CONFIDENTIALITY OF DATA		
Will data be collected at the lowest level of identifiability possible (e.g., initials instead of a name, partial DOB instead of full DOB, partial postal code rather than full postal code)?	☐	
Is data/privacy of participants protected as much as possible? Is confidentiality maintained to the extent outlined in the ICF/LOI?	☐	
Is there a data management plan to ensure confidentiality of data is adequate?	☐	

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Are the data being stored in appropriate locations during and after the study? Do only the appropriate members of the study team have access to the data?		
Is there a data management plan to ensure movement of data (e.g., into and out of the institution, including external devices, hard copy to soft copy) is secure and is it adequate?	☐	
Is there a data management plan for the deletion or long-term retention of the data? https://www.queensu.ca/accessandprivacy/guidance/storing-university-records	☐	
If recontact after participation is suggested has this been clearly documented in the ICF/LOI? If yes, ensure the length of time on this recontact list and the terms of how recontact is to take place are clearly stated.		
Is there a plan to share the data outside of the study team once the study is completed? If so, has it been properly outlined in the ICF/LOI and has proper consent been asked for/obtained from participants?		
LETTER OF INFORMATION SHEET AND/OR CONSENT FORM		
Has the Queen's University consent form template been used? If not, does the consent form have the required elements? (**NOTE:** the REO team will ensure all the required statements are included in the consent forms. Please ensure from the researcher perspective that all the elements of informed consent are present - see below for details).	☐	
Are information/consent documents free of unexplained technical terms, acronyms & jargon? Ensure the consent form is written in simple language at a level of the intended audience.	☐	
Are information/consent documents free of language that waives the participant's legal rights, or that releases the investigator, institution, or sponsor from liability?	☐	
LOI/ICF Purpose of the Study:		
Is the purpose of the study clearly described?	☐	
Is the expected duration of participation in the study described and accurate as per the application?	☐	
Is the eligibility of participants to be involved in the study described?	☐	
LOI/ICF Study Procedures:		
Are participant responsibilities described (e.g. order of procedures, amount of time required)?	☐	
LOI/ICF Risks & Benefits:		

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Are the foreseeable risks clearly described and the probability of their occurrence given (if applicable)?	☐	
Are the potential benefits described? If there is no direct benefit to the participant, is this clearly stated?	☐	
LOI/ICF Compensation or Reimbursement:		
If participants are to be compensated or reimbursed for their participation, are the conditions and the amount of the compensation described including what happens should the participant withdraw from the study? Do any study Draws/Lotteries adhere to the REB guidelines?	☐	
LOI/ICF Conflict of Interest & Commercialization:		
Are any conflicts of interest clearly described?	☐	
LOI/ICF Privacy & Confidentiality:		
Are the procedures to ensure confidentiality of data and anonymity (if applicable) of participants' data included?	☐	
Has the location of storage of the data during the study been included?	☐	
Has the length of retention of data after the study is completed included? Has a description of what data will be retained, who will have access to that data, and who will be responsible for its deletion (or continued retention) been included?	☐	
If information will be released to any other party, does it state the reasons and to whom? Do you have any concerns with the parties listed? Is this clearly detailed in the LOI?	☐	
Is it clearly stated that the study [de-identified?] data will only be shared temporarily with peer reviewers?		
If the researcher has opted to upload the de-identified study data to a research data repository, is this clearly stated? Does the LOI ensure that participants can ask to have their data removed from this dataset? Does the LOI clearly state that this data may be used for future studies by other researchers?		
LOI/ICF Withdrawal:		
Is it clear what aspects of the study are mandatory and optional?	☐	
PARTICIPANT FACING MATERIALS		
Are there any concerns with the recruitment materials? Are all materials in line with REB guidelines and templates?	☐	
Are there any concerns with the debriefing	☐	

materials/forms?		

Select the Review Option:	
Pending	
Approved	You as a reviewer have reviewed and approved this submission. The proposal is ethically sound, and the project can commence without ethical concerns. For GREB: Reminder: Once approved, please complete the DRR and Key Takeaways (if any).
Requires modification from Researcher	You have reviewed this but require some modifications from the researcher before approval can be granted.
Acknowledge	You as a reviewer have reviewed and acknowledged this submission (for items that do not require approval).
Request information from REO	You reviewed and require some clarification from the REO.
Withdrawn	
Event closed by REO	
Reviewed by Unit REB	This will be removed soon.
Preliminary Ethical Review Completed by REO	The old 'admin review complete'. This means the REO team completed their ethical and administrative review and the REO does not have any further administrative concerns.
Conditional Approval	This means you have reviewed, you have a few comments that require modification, but you do not need to see this again. You are entrusting the REO to ensure the changes are made and once done, the REO will issue the approval. This should be used in situations when the remaining items are administrative items or very simple situations (not when ethical clarification is required).
Exempt from REB Review	For QA/QI/PE studies and some case report studies/series.