| YES | Required Elements |
|---|---|
| **General Information** | |
| ☐ | **DO NOT** include a statement that GREB has reviewed/approved/cleared the study for ethical concerns/compliance |
| ☐ | Institution/Department identified (e.g., logo, letterhead, written description) |
| ☐ | Study title on first page |
| ☐ | Identify Principal Investigator/Co-Principal Investigator(s)/Supervisor(s)/Co-Investigators - optional |
| ☐ | Age/education-appropriate reading level - refer to 'How do I check the reading level of a document in Microsoft WORD?' posted under 'FAQ's' on GREB's website |
| **Introduction** | |
| ☐ | Invite participants to participate in the research study |
| ☐ | Include a broad overview of study purpose/rationale in plain language, avoiding field-specific jargon |
| ☐ | In plain language describe what the participants will be doing in this study (i.e. methods, nature of participation and responsibilities of participants) |
| ☐ | Report the length of time of participation for the study and at each stage of the research if appropriate |
| ☐ | State the RISKS and BENEFITS of participating. If no risks, add statement of no risk. If there is no direct benefit to participant, add statement of no direct benefit to participant |
| ☐ | **NEW - REQUIRED FOR ALL IN-PERSON RESEARCH DUE TO COVID-19: "There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes".** |
| ☐ | Include statement that 'Participation is **voluntary** and you can decline to participate in the research or any aspect of the research at any time without penalty/loss of benefits AND/OR impact on academic standing - edit appropriately |
| **Confidentiality** | |
| ☐ | State who will have access to participant data during and after collection (e.g., study team, transcriber, statistician, regulatory authorities, REBs) |
| ☐ | A statement to reflect participants' confidentiality will be protected to the extent permitted by applicable laws - N/A for anonymous research if data can't be linked back to participants |
| ☐ | Add the statement: "The Queen's General Research Ethics Board (GREB) may request access to study data to ensure that the researcher(s) have or are meeting their ethical obligations in conducting this research. GREB is bound by confidentiality and will not disclose any personal information."<br>**Note:** If you are collecting anonymous or publicly available information do not include the last sentence. Also, the statement may be adjusted on a case-by-case basis but if you deviate from this wording, please explain why in your application. |
| **Research Data** | |
| ☐ | Include an indication of what information will be collected about participants, for what purposes, and a description of the anticipated uses of data |
| ☐ | Describe if the data being collected is anonymous, identifiable and/or if it will be de-identified/anonymized |

| | |
|---|---|
| ☐ | Specify storage/disposal/retention plans for research data. The Queen's University retention policy for research records is a **minimum of 5 years** |
| ☐ | Specify storage/disposal/retention plans for any identifying files (e.g., file linking name to study number, contact information collected for compensation purposes, information to determine eligibility) |
| ☐ | Describe how participants can withdraw the data they have provided during AND/OR after the study. Include any limitations to this withdrawal of the data (i.e. can't withdraw after submission of an anonymous survey/following publications, must withdraw no later than MM/DD/YYYY). If withdrawal of data is not possible (i.e. data is anonymous) this must be stated |
| ☐ | Include plans for publication/dissemination of the research results. Specify if participants will be identified/not identified during publication/dissemination |
| | **If applicable**:<br>A. For Focus Groups, Add a statement of the potential harm that could exist if confidentiality is violated by another participant. Explain that: 1) the researchers are capable of assuring their own confidentiality of information, but 2) cannot guarantee that privacy will be maintained by the other participants.<br>B. For Focus Groups, communicate that the withdrawal of your data may not be possible if your responses compromise information provided from other participants in the Focus Group. |
| ☐ | **If applicable**: Specify plans to link participant data with other data sets and discuss the potential for the generation of identifiable information if databases will be linked (this includes linking data from multiple sites for multi-site research) |
| ☐ | **If applicable**: Indicate if de-identified data could be re-identified at a later time |
| ☐ | **If applicable**: Include any plans to share the data (e.g., with other researchers, data repository) |
| **Whom do participants contact for questions?** | |
| ☐ | Specify whom to contact if participants have any questions about the research study (i.e. PI). Students must include their research supervisor(s) email and work telephone.<br>**Students should not include personal telephone numbers or addresses** |
| ☐ | Add this statement: "If you have any ethics concerns please contact the General Research Ethics Board (GREB) at 1-844-535- 2988 (Toll free in North America) or email chair.GREB@queensu.ca."<br>**Use 1-613-533-2988 if outside North America. Please note that GREB communicates in English only.** |
| **Consent Process** | |
| ☐ | Include a method to obtain/document informed consent:<br>1) If obtaining written consent:<br>✓ Include the signature and date of participants or their substitute decision-maker/legally authorized representative as applicable<br>✓ Include the signature and date of the person conducting the informed consent discussion<br>✓ Include a statement to reflect participants have had all of their questions answered, they have been provided a copy and have returned a copy to the Researcher<br>2) If obtaining online study consent: Include the option to click a "consent box" OR indicate survey completion will represent consent |
| ☐ | Include the statement: "You have not waived any legal rights by consenting to participate in this study." |
| **Add as applicable:** | |
| ☐ | Name of Sponsor(s)/Funder(s) |
| ☐ | Information about the presence of any real, potential or perceived conflicts of interest AND/OR the possibility of commercialization of research findings |
| ☐ | Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury |

| | |
|---|---|
| ☐ | Duty to report concerns over potential abuses (e.g., child abuse/neglect, elder abuse) |
| ☐ | Participants will be provided with any new information that may be relevant to their decision to continue or withdraw from study participation |
| ☐ | Information about when researchers may remove participants from the study without their permission (e.g., due to safety considerations, end points reached, not following study safety guidelines)<br>Mandatory for Clinical Trials |
| ☐ | Include tick boxes to request explicit consent for each of the following:<br>☐ Yes/No Audio recording<br>☐ Yes/No Video recording<br>☐ Yes/No Use of quotes |