TMU REB Consent Form Checklist

Before you start, please consider the following:

- This Consent Form Checklist is intended to be a guide rather than a comprehensive checklist. Not all items will apply to every study; there may also be additional considerations specific to your particular study.
- The checklist accompanies the consent form templates. Its subheadings correspond directly to template sections. Suggested wording for some items may be found on the templates themselves.
- Be sure to include information provided in your ethics protocol in the relevant sections of your consent form. The applicable protocol sections are indicated.
- For further guidance, please contact us at rebchair@torontomu.ca.

Checklist Item	Protocol Section	Yes	No	N/A
Formatting, Style and Grammar				
Include the Toronto Metropolitan University logo or "Toronto Metropolitan University"	N/A			
Add the logos of all partner organizations and funders, if possible	Sections 4 & 5			
Ensure that the consent form is written at a reading level appropriate for your target audience	N/A			
Avoid using acronyms/academic jargon and explain terms that a layperson may not be familiar with to ensure the clarity needed for informed consent.	N/A			
Use second-person pronouns (you/your) throughout the form when referring to participants, except on the signature page where you use first-person pronouns ("I")	N/A			
Consider ensuring that the consent form meets all accessibility requirements	N/A			

Title and Study Team Information				
The full title of the research study or a shortened title	Section 2			
Identify the principal investigator, co-investigators and all participant-facing research staff members	Section 2			
Provide the primary affiliation and position, contact information, and institutional email addresses of project investigators (avoid personal or private phone numbers or email addresses)	Section 2			
In the case of a non-faculty lead researcher, note that the principal investigator is a [undergraduate, masters, or doctoral] student or a postdoctoral fellow and identify the study supervisor, their academic affiliation and institutional email address	Section 2			
Study Funding and Conflict of Interest				
Identify the name of the study funder and the grant number	Section 4			
Include a statement declaring any real, perceived, or potential conflict of interests or commercialization (including research that involves the use of biological materials)	Section 10			
Outline all mitigation strategies related to conflicts of interest and/or commercialization	Section 10			
Study Introduction and Purpose				
Begin with a statement of invitation to participate in a research study	N/A			
Include a clear articulation of the research focus and the purpose of the study (or the relevant information in the case of incomplete disclosure/deception)				
Indicate the total number of participants sought	Section 11b			

Provide the eligibility requirements	Section 13a			
Brief Overview				
Highlight the key study information (as suggested by the consent templates)	N/A			
Include information regarding voluntary participation, time commitment, anonymity/confidentiality, privacy, risks/benefits, what they will be asked to do, nature of the incentive, whom to contact	N/A			
What You Are Being Asked to Do				
Outline exactly what participation entails and explain clearly what participants will be expected to do (each data collection activity should be explained separately)	Section 11			
Provide a description of what information will be collected about participants and for what purposes	Section 11			
Indicate the time commitment for participation (for each component, if relevant, plus total)	Section 11			
Indicate whether participants will be able to review data collected from and about them. If so, specify how this will be shared with participants, how they can provide their feedback and the final date for participants to do so	Section 11			
Potential Benefits				
Describe the potential benefits of the study both to participants (if applicable) and to groups, communities and/or society (in plain language)	Section 16d			
If there are no anticipated benefits to participants, include a statement that you cannot guarantee participants any direct benefits from their participation (incentives are not considered benefits)	Section 16d			
Potential Risks				

Identify and explain all associated risks (physical, psychological, social, financial, legal, dual-role risk, as applicable) as well as how each of these risks will be mitigated	Section 16			
If there are no anticipated risks to the participants, state: "There are no known or expected risks for participants in this study."	Section 16			
Provide a list of directly relevant support services with website and contact information. These resources should be free, accessible and culturally and/or geographically relevant. Where available, there should be at least one 24/7 hotline (e.g., Distress Centre)	Section 16			
Your Identity will be Confidential or **Your Identity will Remain Anonymous**				
Encourage participants to select a location with aural and visual privacy for interviews/focus groups or visual privacy for surveys	N/A			
Indicate if/how you will keep all participants' identifying information confidential and outline all applicable details (e.g., if and how the research team will de-identify and protect data) OR indicate whether participants' responses/data are anonymous (never had identifiers associated with it) and outline all applicable details	Section 17			
Advise participants not to share information outside of the focus group in order to respect the privacy and confidentiality of other participants	Section 17			
Include a note that you cannot guarantee participants' confidentiality due to the risk that other participants may share information from the focus group	Section 17			
Specify any limitations on the withdrawal of participant data (e.g., the challenge of identifying distinct contributions in the transcript or the influence that a participant may have had on other participants' contributions), if applicable	Section 17			
Indicate your duty to report child abuse/elder abuse in long-term care by law, if relevant to the nature of the study	Section 16 & 17			

Identify any potential limits to confidentiality (e.g., legal, professional)	Section 16 & 17			
Provide information regarding any third-party apps/software used during data collection and/or analysis (also provide links to their privacy/security policies)	Section 17 & 18			
Indicate that participants' IP addresses will not be collected by the research team (e.g., indicate that this function has been disabled in the survey platform used)	Section 17 & 18			
How Your Data Will Be Used				
Outline all the dissemination methods and processes for study findings	Section 19			
Indicate whether the data collected will be analyzed for a MRP/thesis/dissertation	Section 18			
Indicate whether participants will be identified in the dissemination materials and provide an option for participants to consent to being identified	Section 17, 18 & 19			
Indicate whether participants' data may be used for future research studies, by other researchers, and provide additional information (see TCPS2 Article 3.13 and the TMU Consent Form Template)	Section 17, 18 & 19			
Outline how participants can access the final study results. Provide a direct link to a source (e.g., lab website, TMUs RShare, social media page) and expected timeline for dissemination, if available	Section 19			
How Your Identity Will Be Protected				
Indicate where (all locations) and how each type of study data will be securely stored	Section 18			
Outline who will have access to either the identifiable or indirectly identifiable data	Section 17 & 18			
Indicate whether their data may be accessed by institutional representatives and/or third-party regulatory agencies/personnel (e.g., Health Canada)	N/A			

Specify each type of data collected (audio recordings, consent forms, identifiable data, de-identified data) and how long they will be stored	Section 17 & 18			
Indicate if/how interested participants can still participate in the study if they do not wish to be audio/video recorded	Section 13a			
Incentive for Participation				
Provide the details regarding any incentive/reimbursements	Section 20			
Specify any gift card type(s)	Section 20			
Indicate when and how (e.g., e-transfer, cash) the incentive will be distributed to participants (and if the method of payment is different for in-person participants and virtual participants)	Section 20			
Outline any payment schedules (for multiple visits/phases) and/or payment plans	Section 20			
Indicate that participants are entitled to the full amount of the incentive in case of withdrawal from the study (unless inconsistent with the payment schedule or third-party crowdsourcing platforms)	Section 20			
Cost of Participation				
Identify any costs to participation, (e.g., travel costs) whether they will be reimbursed and how.	Section 20			
If there are no costs to participation, please remove this section	Section 20			
Your Rights as a Research Participation				
Include a statement about the voluntary and confidential nature of participation	Section 15 & 17			
Indicate that a decision to not participate in the study will not result in the waiving of the participant's legal rights	Section 15			

Specify that withdrawal will also not affect participants' relations with TMU and/or any research team members/collaborating institutions involved in the research	Section 15			
For research involving student populations, add that: “Participation is voluntary and you can decline to participate in any aspect of the research without any impact on your academic standing.”	Section 15			
For research involving patient populations, add that: “Participation is voluntary, and you can decline to participate in any aspect of the research without any penalty or impact on your medical or health care.”	Section 15			
Indicate how participants can withdraw their participation and/or data from the study both during and after data collection	Section 14 & 15			
For surveys: Inform participants that they can stop their survey participation simply by closing their browser or that they must skip to the end of the survey to receive the incentive	Section 15 & 17			
Include a final date to withdraw participant data (MM/YYYY or X weeks/months after participating) or indicate that responses cannot be withdrawn once they press submit at the end of the survey	Section 15 & 17			
Questions				
Indicate whom participants may contact regarding any questions they may have and how they can do so	N/A			
Indicate that participants may contact the REB directly regarding any questions about their rights or concerns regarding their treatment in the study and provide the email (rebchair@torontomu.ca; add additional direct contact information if applicable)	N/A			
Include a note that the ethics protocol for this study has been “reviewed and approved by the Toronto Metropolitan Research Ethics Board (REB # 20YY-XXX)”	N/A			
Include other institutional REB approvals (for investigators, data collection)	Section 5			

Confirmation of Agreement				
Provide a Consent Summary Statement	N/A			
State that participants are not giving up their legal rights by consenting to participate in the study	Section 15			
Provide a checkbox/signature line for consent to participate in the study	N/A			
Provide a separate checkbox for broad consent to potential future use of participants' de-identified/identifiable study data by the research team or by other researchers; indicate that participants can still participate in the study if they do not consent to the possible future use of their data	Section 17, 18 & 19			
Provide separate checkboxes for other types of consent specific to the nature of participation in the research study, if applicable (e.g., recording, use of quotes, identification in the publications)	Section 17, 18 & 19			
If obtaining oral consent, provide a script (with the same questions asked on the written consent form) and include a space for the name, signature and date of the signing person who is obtaining oral consent	Section 14			
For anonymous online surveys, you may include a statement at the end of the consent form/preamble that states "By clicking submit, I am consenting to participate in this study"	N/A			