This form is meant for Island Health affiliated researchers to prepare and attach to their research ethics application for any research that involves the use of a mobile device or app and where an Island Health research ethics board (REB) is the Board of Record (BoR) or partner board. Not all questions will be relevant for all cases and should only be used as a starting guidance to prepare the REB for review.

Any questions that emerge from this worksheet should be discussed further with respect to the particular study under review and can be directed to our inbox ResearchEthics@islandhealth.ca.

|  |  |
| --- | --- |
| **Study ID number:** |   |
| **Principal Investigator (PI):** |  |
| **Board of Record (BoR):** |  |
| **Date:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Questions | Yes | No |
| 1. | Has the research team made clear on the application and to participants what kinds of data or applications may be incidentally captured or accessed by the app (e.g., contacts, location data, microphone, camera, bookmarks, etc.)?  |   |   |
| 2. | If participants need to already own their own mobile device and data plan to join the study, is this stated in the study inclusion criteria?  |   |   |
| 3. | Is the use of the app necessary to fulfill the research question(s)? |   |   |
| 4. | Is the name and institutional affiliation of the app developer noted in the application and to participants?  |   |   |
| 5. | If there a possible conflict of interest (e.g., the creator of the app or device could stand to profit from research outputs), has it been disclosed and appropriately mitigated? If there is no such possible conflict, check ‘Yes’.  |  |  |
| 6. | Does the research team understand whether this app or device requires a privacy review or any data use agreements prior to research deployment? If you do not know, leave blank and e-mail privacy@islandhealth.ca.  |   |   |
| 7. | Will any results based on the data collected through the app be shared or made available to participants?  |   |   |
| 8. | Has the research team explained whether app users will have the option of disabling some of the apps core features post-installation and how to go about deleting the app after the research study concludes? |   |   |
| 9. | Will the study team ensure that participants do nothave to incur any kind of costs in order to download, access, or use the app or device?  |   |   |
| 10. | Is the app format and content appropriate to the participant population? (e.g., is the text the right size for participants to read; is the content written in lay language; would the images be difficult to navigate for a colour-blind user?)  |   |   |
| 11. | Will any app-generated data be stored and accessed only by servers located within Canada? |   |   |
| 12. | Will any app-generated data only be shared with and accessed by the research team and not any third parties? |  |  |
| 13. | If app-generated data is to be stored and later repurposed for future research, are participants separately consenting to this secondary use as per [TCPS2 Article 3.13](https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf)? If there is no plan for secondary use, check ‘Yes’. |  |  |
| 14. | Are passwords or pins necessary to use the app? |   |   |
| 15. | Do the researchers receive consent from participants *prior* to downloading and using the app? |    |   |
| 16. | Does the informed consent form (ICF) explain how app-generated data is subject to the app's Terms of Use agreement, which may change over time? |    |   |
| 17. | Is the Terms of Use information understandable to users? If no, are relevant features and/or a summary provided to participants in the consent form?  |   |   |
| 18. | Will participants receive support for the technology (i.e., for troubleshooting, for accidental disclosures, for suspected interception)? |   |   |
| 19. | Are the End User License Agreements (EULAs), Terms of Use, or Privacy Policies pertaining to the app uploaded to the ethics application? |  |  |
| 20. | Does the consent form include all third parties to whom research-generated information may be shared with and for what purposes, including the risk of a third party intercepting data unbeknownst to the research team?  |  |  |

Please fill out the following questions:

|  |  |
| --- | --- |
| 1. | Is the app collecting any **physiological** **data** of its users, such as heart rate, blood glucose, blood pressure, respiration rate, temperature, etc.? If so, please mention what kind of data and whether it’s collected through a wearable technology (e.g., Fitbit, Apple Watch, Garmin, motion actigraphs, etc.) or through a standard Apple or Android device.  |
| 2. | **User Support:** How will software updates, new phones, and study cancellation/closure be handled with respect to the app, its data, and its users?  |
| 3. | **Market Status:** Is the app commercially available or will be in the future?  |
| 4. | **Data Monetization & Sharing:** Will any data collected from this app be re-purposed or sold at any point before, during, or after the research activities? If so, please specify (i.e., demographic information, unique device identifiers (UDIDs), location data, and personality and behavioural assessments of users). Please state if any research data could be used in cross-contextual behavioural advertising. |

|  |
| --- |
| **Additional Comments (Optional):**  |

REB Wording Suggestions

• If a participant will be asked to sign a Terms of Use, Privacy Policy, or End User License agreement (e.g., be required to download a mobile app or device in order to participate in the study), please add to the consent form a statement such as the following:

“As part of this research study you will need to use the XYZ app. In order to use the app, you will be asked to agree to the Terms of Use, which will appear on your mobile device’s screen when you first start using the app. If you decide that you do not want to agree, then you should not participate in the research. While using the app, data about you, including personal health information, location and internet usage will be collected and transmitted to the researchers and may also be transmitted to people outside of the research study. A complete description of this data collection and sharing is found in the Terms of Use. The Terms of Use provides instructions on how to request deletion of your personal data if you decide to do that in the future.”

• Suggested language for the risks section of the consent form:

“Although every reasonable effort has been made, confidentiality during internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.”

* If there are potential Data Use Expenses anticipated by the research team:

“Participating in the research may impact your mobile device’s Data Usage Plan. You may incur expenses for which you are responsible.”