**APPENDIX E: WAIVER OF CONSENT CONSIDERATIONS**

The Personal Health Information Protection Act (PHIPA) and the Tri-Council Policy Statement (TCPS2) allow for research conduct in the absence of participant consent in certain situations.

The following questions will facilitate assessing whether the criteria to waive, defer or alter consent are met for this study.

Date form completed:

**Study Title:**

1. **Please indicate which research-related consent you are requesting a waiver and/or deferral of consent for** (select all that apply):

|  |  |
| --- | --- |
|  | Consent for retrospective collection and use of personal information/personal health information or biological sample analysis ***(if this is the only research-related consent you are requesting a waiver for, do not complete this form, please complete appendix B)*** |
|  | Consent for screening |
|  | Consent to contact |
|  | Consent for study enrollment |
|  | Consent for use of biological material |
|  | Consent for continued study participation |
|  | Consent for secondary use of data containing personal information/personal health information |
|  | Consent for prospective collection and use of personal information/personal health information |
|  | Consent for genetic testing |
|  | Consent for registry |
|  | Other (please specify): |

1. **Waiver of Consent Consideration in Emergency Health Situations N/A**

The TCPS2 states that REB's can allow research to be carried out without consent in medical emergencies if all of the following apply.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Please provide justification point by point for waiver of consent based on the requirements from the TCPS2 as listed below: | **Yes** | **No** | **Justification** |
| Is there a serious threat to the prospective participant that requires immediate intervention? |  |  |  |
| Is there standard efficacious care or does the research offer a real possibility of direct benefit to the participant in comparison with standard care? |  |  |  |
| Is the risk of harm no greater than that involved in standard efficacious care, or is it clearly justified by the direct benefits to the participant? |  |  |  |
| Does the prospective study participant need immediate treatment and are they unconscious or lack capacity to understand risks, methods and purposes of the research (lacks the capacity to consent)? |  |  |  |
| Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so. |  |  |  |
| Will you confirm that no relevant prior directive of the study participant is known to exist? |  |  |  |

**Please note:** As soon as the individual regains consciousness or capacity, or an authorized third party is found, consent should be sought promptly for continuation in the project, and for any follow-up examinations or test related to the research.

1. **Waiver/Alteration of Consent Consideration (Personal Health Information Protection Act and Tri Council Policy Statement Guidelines (TCPS2))**
2. Please indicate whether you are seeking a waiver, deferred or alteration of consent?

The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided that the REB finds and documents that the following requirements of the PHIPA and the TCPS2 have been met:

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Please provide justification point by point for waiver/alteration of consent based on the requirements from *PHIPA and TCPS2 as listed below:* | **Yes** | **No** | **Justification** |
| Does the study involve no more than minimal risk to individual study participants? (Minimal risk is defined as "no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research") |  |  |  |
| Is the lack of the study participants’ consent unlikely to adversely affect the welfare of the study participant? |  |  |  |
| Is it impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the study participant is required? |  |  |  |
| Whenever possible and appropriate, after participation, or at a later time during the study, will study participants be debriefed and provided with additional pertinent information about the study and provided the opportunity to refuse consent? |  |  |  |
| Is it possible for the study to achieve the research goals without using personal health information? |  |  |  |
| Are there adequate safeguards in place to protect the privacy of study participants and preserve the confidentiality of their personal health information? |  |  |  |
| Is there public interest in conducting the research which would outweigh any risk to the privacy of the individuals whose information is being disclosed? |  |  |  |

**For Registries**

|  |  |  |  |
| --- | --- | --- | --- |
| Is there no known preference regarding deposit or re-contact **and** is seeking consent impracticable? “Impracticable” refers to undue hardship or onerousness in seeking participants’ consent; it does not mean inconvenience for the researchers. It is impracticable when participants or their authorized third party may be deceased or difficult to track due to insufficient identifiers, cost, or time elapsed. |  |  |  |

***Please ensure that adequate justification is provided in the protocol for waiver/ alteration of consent.***