**APPENDIX B: RETROSPECTIVE CHART REVIEW, RETROSPECTIVE BIOLOGICAL SAMPLE ANALYSIS AND SECONDARY ANALYSIS**

**Please note:** This appendix should only be completed if there is a retrospective component to your research study. **If completing this form, d*o not complete Appendix E (waiver of consent considerations).***

Date form completed:

**Study Title:**

1. **RETROSPECTIVE CHART REVIEW** [ ]  **N/A**
	1. **STUDY TIME PERIOD**
2. Please indicate the earliest and latest dates that data will be abstracted for this study:

| Earliest Date:       | Latest Date:       | *Latest date cannot exceed date of this REB application* |
| --- | --- | --- |

1. **RETROSPECTIVE BIOLOGICAL SAMPLE ANALYSIS** [ ]  **N/A**
	1. **SAMPLE IDENTIFICATION**
2. Anticipated number of samples that will be analyzed:
3. How are samples being identified?

| [ ]  Physician/Clinician | [ ]  Health record search |
| --- | --- |
| [ ]  Existing database | [ ]  Other (please specify):       |

1. What criteria are being used to select the samples that will be analyzed?
	1. **SAMPLE SOURCE AND SAMPLE TYPE**
2. What are the sources of the samples that will be analyzed in this study?

| [ ]  Discarded or left over sample | [ ]  Research study bank sample |
| --- | --- |
| [ ]  Archived pathology sample | [ ]  Other (please specify):       |

1. Details of research study bank (*if research study bank sample is selected above*):

| REB # of study bank:       | PI of study bank:       |
| --- | --- |

1. Type of sample(s) (select all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  Cell lines | [ ]  Blood | [ ]  Urine |
| [ ]  Excised organ | [ ]  Excised tissue | [ ]  Leftover biopsy |
| [ ]  Saliva | [ ]  Bone marrow | [ ]  Other: (please specify):       |

* 1. **PRIVACY CONCERNS AND ETHICAL CONCERNS**
1. Was consent for future use of these samples obtained from the patient/participant? [ ]  Yes [ ]  No
2. If no, please justify:
3. Will there be genetic testing on any of the samples in this study?

[ ]  Yes [ ]  No

If yes,

1. Complete Appendix C: Genetic/Biobank Research
2. Will samples and/or the results of the analysis of samples be linked to other information about the participant? [ ]  Yes [ ]  No
3. If no, is it possible to link samples to the identity of the participant?

[ ]  Yes [ ]  No

1. Describe the measures that will be used to protect the privacy of the participants:
2. **SECONDARY ANALYSIS OF EXISTING DATA/SAMPLE** [ ]  **N/A**

*Secondary analysis relies on the use of data (including human biological materials) that was previously collected by someone else for another purpose.*

* 1. **DATA/SAMPLE IDENTIFICATION**
		1. Provide a description of data set(s)/samples to be analyzed:
		2. Initial purpose of collection:
		3. When data was collected:
		4. Who collected initial data:
	2. **JUSTIFICATION FOR USE OF SECONDARY DATA/SAMPLES**
		1. How will the secondary dataset/samples be used?
	3. **PRIVACY CONCERNS AND ETHICAL CONCERNS**
		1. Have you obtained permission from the custodian or agent (Department or Person) to use their previously collected data/samples: [ ]  Yes [ ]  No
1. If no, please explain why:
	* 1. Was the original data set/samples collected under a waiver of consent?

 [ ]  Yes [ ]  No

1. If no, was consent obtained for secondary uses? [ ]  Yes [ ]  No
	* 1. If no, a justification for waiver of consent will be required. Please complete Section 4 of this form.
2. **WAIVER OF CONSENT CONSIDERATIONS (Tri Council Policy Statement Guidelines (TCPS2))**

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.

In order for the REB to approve a waiver of consent the REB must be satisfied, and document, that all of the following apply to the study (PHIPA and Tri-Council Policy statement 2 (TCPS2)).

* 1. **The following questions will facilitate assessing whether the criteria to waive consent are met for this study:**

|  |  |  |  |
| --- | --- | --- | --- |
| *Please provide justification point by point for waiver 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? |[ ] [ ]        |

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