**BAYCREST RESEARCH ETHICS APPLICATION**

# INSTRUCTIONS

* **All sections** of this application **MUST** be completed before it will be considered for REB review.
* A separate detailed protocol must be included (appendix 1).
* The Baycrest Research Ethics Board operates in accordance with:
	+ - The Tri-Council Policy Statement, available at <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html>
		- The Ontario Personal Health Information Protection Act (2004), available at

######  <http://www.ontario.ca/laws/statute/04p03>

* + - Any other relevant regulations or guidelines.
* The Baycrest Research Ethics Boards may request and share information related to the review, approval and continuing ethics review of research conducted at other sites.
* Please include the following attachments as part of your submission:
* *Appendix 1 – Study Protocol*
* *Appendix 2 – Consent Form(s)*
* *Appendix 3 – Recruitment Materials and Scripts (if applicable)*
* *Appendix 4 – Screening/Data Collection Forms (if applicable)*
* *Appendix 5 – Questionnaires & Surveys (if applicable)*
* *Appendix 6 – Participant debrief materials (if applicable)*
* *Appendix 7 – Itemized Budget*
* *Appendix 8 – Personnel log*

# SECTION I: GENERAL INFORMATION

## PRINCIPAL INVESTIGATOR (PI) NAME

If the PI is external to Baycrest, the on-staff investigator accepts the role and responsibilities of PI.

|  |  |  |
| --- | --- | --- |
| Title: | First Name: | Last Name: |
| Credentials (Md, PhD, etc): |

## STUDY TITLE

|  |
| --- |
| Full Study Title: |
| Short Study Title (if applicable): |

**2A. Study Period**

|  |
| --- |
| Expected start date: |
| Total study duration: |

**2B. If this protocol is directly related to a previously approved study at Baycrest (e.g., extension, rollover, subsequent to a pilot study), please specify the name of the PI and the REB file number of the previously approved study.**

[ ]  **Not applicable**

|  |
| --- |
| Name of Principal Investigator: |
| REB File number:  |

## INVESTIGATORS

**3A. Principal Investigator Contact Information and Signature**

**PRINCIPAL INVESTIGATOR AGREEMENT** – I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol and agree to conduct this study in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, Personal Health Information Protection Act (2004) and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the Protocol, the conditions of the REB, the research participant’s consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

|  |  |  |  |
| --- | --- | --- | --- |
| Title: | First Name: | Last Name: | Credentials (Md, PhD, etc): |
| Dept/Div: | Program: | Institution: |
| Street Address: | City: |  Province: | Postal Code:Email: |
| Room/Suite #: |  Telephone: | Email: |
| Signature of Principal Investigator: | Date: |

## 3B. Co-Investigator(s) Contact Information

## If one or more co-investigators is a student participating as part of an academic training program, 3C must be completed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | Title: | First Name: | Last Name: | Institution: |
| Dept/Div: | Program: | Email: |
| 2 | Title: | First Name: | Last Name: | Institution: |
| Dept/Div: | Program: | Email: |
| 3 | Title: | First Name: | Last Name: | Institution: |
| Dept/Div: | Program: | Email: |
| 4 | Title: | First Name: | Last Name: | Institution: |
| Dept/Div: | Program: | Email: |

**3C. Faculty Supervisor (for student/fellow/resident research studies)** [ ]  **Not applicable**

**NOTE:** If this research is part of an academic (University) **training program**, please provide the following information.

[ ]  Post-Doctoral [ ]  PhD [ ]  Masters [ ]  Undergraduate [ ]  Resident/Clinical Fellow

|  |
| --- |
| Name of Student:Program:Institution: |
| Name of Supervisor: | Title: |
| Dept/Div: | Program: | Institution: |
| Street Address: | City: |  Province: | Postal Code:Email: |
| Room/Suite #: |  Telephone: | Email: |

1. **STUDY COORDINATOR/CONTACT PERSON FOR THIS APPLICATION IF NOT THE PRINCIPAL INVESTIGATOR**

**(e.g., study coordinator, research administrative contact, student, institutional liaison)**

When the PI is external, **a Baycrest staff member** must be listed as the institutional liaison who will accept responsibility for the research activities at the institution, as well as serve as the administrative contact with the REB.

 [ ]  **Not applicable**

|  |  |  |
| --- | --- | --- |
| Title: | First Name: | Last Name: |
| Dept/Div: | Program: | Institution: |
| Street Address: | City: |  Province: | Postal Code:Email: |
| Room/Suite #: |  Telephone: | Email: |

**Indicate to whom correspondence should be sent** [ ]  Principal Investigator [ ]  Study Coordinator/Contact person

**5. DEPARTMENT/DIVISION/PROGRAM HEAD APPROVAL**

Approval must come from Head of the same Department / Division / Program as the Baycrest PI OR Baycrest staff member if PI is external.

**5A. Department/Division/Program Head Approval** - I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study”. **This attestation cannot be signed by the Principal Investigator or a Co-Investigator.** An alternative approval signature is required (please inquire with Research Ethics Office.)

|  |  |  |
| --- | --- | --- |
| Title: | Last Name: | First Name: |
| Signature: | Date: |

**5B. President and Chief Scientist of Research (or designate) Approval** - I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study. **This attestation cannot be signed by the Principal Investigator or a Co-Investigator.** An alternative approval signature is required (please inquire with Research Ethics Office.)

[ ]  **President and Chief Scientist of Research (or designate) signed as department head in 5A (skip to 6)**

|  |  |  |
| --- | --- | --- |
| Title: | Last Name: | First Name: |
| Signature: | Date: |

**6. FUNDING – Attach an itemized study budget as Appendix 6**

The budget should reflect all costs to complete the study (e.g., database extraction student payments, participant reimbursement, etc.). The REB will examine the budget to ensure the funding is adequate and assess potential conflicts of interest.

[ ]  **No study budget**

|  |
| --- |
| Explain: |

**6A. Source of Funding**

|  |
| --- |
| Specify: |

**6B. Status of Funding**

|  |
| --- |
| [ ]  Funding Obtained |
| [ ]  Funding applied for | Expected date of decision: |
| [ ]  No funding required | Explain: |

**6C. If funding is not awarded, do you plan to proceed with the study?** [ ]  **Yes** [ ]  **No** [ ]  **Not applicable**

## 7. MANAGING CONFLICTS OF INTEREST (Conflicts of Interest do not imply wrong-doing.)

**7A.** It is the responsibility of the PI to determine if **any of the conflicts** listed below apply to **any persons** (listed in question 3) involved in the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. A conflict of interest may also arise with regard to the disclosure of personal health information. **NOTE:** This disclosure does not replace institutional guidelines and requirements for declaration and management of Conflicts of Interest

[ ]  **Not applicable: There are no Conflicts of Interest to disclose**

|  |
| --- |
| [ ]  Function as an advisor, employee, officer, director or consultant for the study sponsor |
| [ ]  Have direct or indirect interest in the drug, device or technology employed in this research study (including inventorship, patents or stocks) |
| [ ]  Receive an honorarium or other personal benefits from the sponsor (apart from fees for service) |
| [ ]  Using services of a family member or a company in which you or a family member has a direct interest. |
| [ ]  Receive direct or indirect financial benefit from the disclosure of personal health information |
| [ ]  Competing interest (situations in which the researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the researcher or a family member has an opposing interest related to the research, including a legal suit against a company or sponsor or a financial interest in a competing company or product) |
| [ ]  Other (describe): |

**7B. Describe and detail any conflicts of interest.**

|  |
| --- |
| (Max¼ page)  |

**7C. How will conflicts of interest be managed?**

|  |
| --- |
| (Max¼ page)  |

## 8. OTHER INSTITUTIONAL ETHICS REVIEW

In order to facilitate the REB review process through harmonization and coordination of REB activity, identify if the study has been reviewed and/or approved at another institution, please specify the institution and status of the review. Please include any review correspondence and the letter of approval. The study may go through an expedited (delegated) review.

**8A. Has this research been reviewed/approved by any other Research Ethics Boards prior to this submission?**

[ ]  **Yes** (to facilitate further review, please attach all relevant documents)[ ]  **No**

If **Yes**, please specify the institution and status of the review

|  |
| --- |
| (Max¼ page)  |

**8B. Has the research undergone other scientific/scholarly review prior to this REB submission?**

[ ]  **Yes** [ ]  **No**

If **Yes**, please specify:

|  |
| --- |
| (Max¼ page)  |

## 9. RESEARCH IS SUBJECT TO HEALTH CANADA REGULATION

## [ ]  Not applicable (skip to 10)

## 9A. DOES THIS STUDY INVOLVE SUBMISSION TO HEALTH CANADA UNDER THE FOOD AND DRUG ACT?

## [ ]  Yes [ ]  No

## If YES, is a Health Canada “No Objection Letter” or other regulatory authorization attached? [ ]  Yes [ ]  No

## If No, has an application been made? [ ]  Yes [ ]  No When?:

**NOTE:** The REB review **may be held** and **final approval will not be granted** until the appropriate regulatory approvals have been received.

## 9B. Who is the Regulatory Sponsor (i.e., who is listed on the clinical trial application?

|  |
| --- |
| Specify: |

##

## 9C. Provide the FDA IND number (Drug Studies) or PMA Number (Device Studies)

##  FDA IND#: [ ]  Pending [ ]  Not applicable

##  PMA #: [ ]  Pending [ ]  Not applicable

###### **10. CLINICAL TRIAL REGISTRATION**

###### **(NOTE: this question may be relevant even if Question 10, above is not applicable).**

The International Committee of Medical Journal Editors (ICMJE) has indicated that clinical trials will not be published without the registration of that trial prior to participant enrolment. In June 2007, the ICMJE adopted the World Health Organization’s definition of clinical trial: "Any research study that prospectively assigns human participants of groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-care changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration." Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

**10A. Given the above definition, is this study a clinical trial?** [ ]  **Yes** [ ]  **No**

It is important that the PI review the Clinical Trials Policy to ensure that all Baycrest requirements for clinical trials are addressed. The policy can be found on the Baycrest Research Ethics Office website.

**10B. Will this trial will be registered (e.g.,** [**www.clinicaltrials.gov,**](http://www.clinicaltrials.gov/)[**www.controlled-trials.com/isrctn/**](http://www.controlled-trials.com/isrctn/)**).**

[ ]  **Yes** [ ]  **No**

If **Yes**, provide:

|  |
| --- |
| Registration website: |
| Name of study sponsor: |
| Clinical Trial Registration # (if available): |

If **No**, please justify:

|  |
| --- |
| (Max ¼ page) |

# SECTION II: STUDY SUMMARY

(The full protocol must still be attached – appendix 1)

## 11. ABSTRACT (suitable for a public access or lay audience).

|  |
| --- |
| (Max ¼ page) |

**11A. Does your research involve a clinical population?** [ ]  **Yes** [ ]  **No (skip to 12)**

If **Yes**, please describe:

|  |
| --- |
| (Max ¼ page) |

**11B. Does the study involve changes in clinical care?** [ ]  **Yes** [ ]  **No**

If **Yes**, describe the accepted Standard of Care for this/these population(s):

|  |
| --- |
| (Max ¼ page) |

**11C. Will management/treatment/usual therapy of a participant’s condition be prolonged, delayed, withdrawn, or denied because of this study?** [ ]  **Yes** [ ]  **No**

If **Yes**, please explain:

|  |
| --- |
| (Max ¼ page) |

**11D. Indicate the additional risks associated with the study as compared to usual standard of care. Do not refer to other areas of this form.**

|  |
| --- |
| (Max ¼ page) |

**12. PARTICIPANTS**

[ ]  **The inclusion and exclusion criteria have been described and justified in the protocol (Appendix 1)**

[ ]  **The sample size has been justified in the protocol**

**12A. What are the time requirements for study participation? Please indicate the length, duration, frequency and number of test sessions and any extra time?**

|  |
| --- |
| (Max ¼ page) |

**12B Will the participants be subject to any restrictions (e.g., lifestyle) as a result of this study?** [ ]  **Yes** [ ]  **No**

If **Yes**, please explain:

|  |
| --- |
| (Max ¼ page) |

**12C. Indicate how many participants will be enrolled.**

|  |
| --- |
| Total study enrollment: |
| For multisite studies, number of participants to be enrolled at Baycrest: | Total Number of charts to be reviewed at Baycrest\* |
| Time period for enrollment: |
| Approximate size of eligible population from Baycrest (number, or number/year): |

**\*NOTE:** If medical charts are being reviewed at Baycrest, approval must be granted by the Director, Health Records (Section VII)

**12D. Source of study participants**

|  |  |
| --- | --- |
| Source | Number |
| [ ]  Baycrest Hospital inpatients |  |
| [ ]  Baycrest Hospital Outpatients |  |
| [ ]  Jewish Home for the Aged residents |  |
| [ ]  Baycrest Terraces Residents |  |
| [ ]  Community Day Care Members |  |
| [ ]  Research Participant Database |  |
| [ ]  Other; please specify: |  |

 **NOTE:** If you are requesting participants from the Research Participant Database, the signature of the Participant

 Coordinator is required. For other recruitment sources, please indicate and obtain the appropriate signatures in Section VII.

|  |  |
| --- | --- |
| Signature of Participant Coordinator:: | Date: |

**13. REMUNERATION**

**13A. What compensation OR payment(s) will be provided to participants or substitute decision makers (if applicable)?**

|  |
| --- |
| [ ]  Reimbursement for expenses incurred as a result of researchAmount: specify (e.g., travel, meals): |
| [ ]  Gifts for participationValue: |
| [ ]  Other forms of compensation: |

**13B. Provide justification for compensation or lack thereof. Participant compensation should be large enough to be respectful, but not so large as to be considered coercive.**

|  |
| --- |
| (Max ¼ page) |

# SECTION III: ETHICAL ISSUES

## 14. RECRUITMENT AND CONSENT

## *Attach the consent form(s) (Appendix 2), recruitment materials (e.g., recruitment posters/letters, phone/email script) (Appendix 3), screening/data collection forms (Appendix 4), and questionnaires/surveys (Appendix 5).*

**14A. Are you seeking a waiver or permission to do research without consent?** [ ]  **Yes** [ ]  **No**

If **Yes**, explain how your request is in accordance with TCPS 2 Articles 3.7 - 3.11 and PHIPA 44, 3c and d.

|  |
| --- |
| (Max ¼ page) |

**14B. What tools will be used to identify potential participants for recruitment into the study?**

|  |
| --- |
| (Max ¼ page) |

**14C. Provide the roles of all individuals who will be involved in identifying potential study participants (e.g., treating clinician, research assistant, research student, volunteer, administrative assistant, postdoctoral fellow, not PI):**

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**14D. How will the initial contact with potential participants or an authorized third party be made** (e.g., in person, phone, letter, e-mail, website) **and by who? Is this individual (s) already known to the participant or authorized third party?** Attach a copy of the recruitment scripts or any written materials, if applicable, in Appendix 3.

|  |
| --- |
| (Max ¼ page) |

**i) Is there a relationship between the participants and either of the following?**

Person obtaining consent [ ]  **Yes** [ ]  **No**

Investigator [ ]  **Yes** [ ]  **No**

If **Yes**, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to avoid the perception of undue influence.

|  |
| --- |
| (Max ¼ page) |

**14E. Describe the consent process** (e.g., will consent be written, oral, telephone (include script). If the study population requires special consent considerations (e.g., child, incompetent adult, unable to communicate), refer to 14G.

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**14F. How much time will be given to participants to review the information before being asked to give consent?**

|  |
| --- |
| (Max ¼ page) |

**14G. Does your research involve any of the following?**

## [ ]  Children

## [ ]  Emergency patients

## [ ]  Individuals temporarily unable to consent

## [ ]  Individuals who lack the capacity to consent

## [ ]  None of the above (skip to 14H)

**i) Describe by whom and how capacity to consent will be assessed for these individuals.**

|  |
| --- |
| (Max ¼ page) |

**ii) If participants are incapable of providing consent, what procedures will be in place to determine assent/dissent?**

|  |
| --- |
| (Max ¼ page) |

**iii) If participants are incapable of providing consent, how will substitute decision-makers be identified?**

|  |
| --- |
| (Max ¼ page) |

**iv) When inability/ability to provide an informed consent is expected to be temporary, describe what procedures will be used to regularly assess capacity and to obtain consent if the individual later becomes capable/incapable of providing consent.**

|  |
| --- |
| (Max ¼ page) |

## vi) Individuals with communication difficulties (check all that apply):

## [ ]  Individuals who may require translation

## [ ]  Individuals who are illiterate.

## [ ]  Participants who have trouble understanding and/or producing speech (and require special support including the use of

## assistive devices

## [ ]  None of the above (skip to 14F)

## vii) Provide an explanation of what procedures will be used to address any communication difficulties (e.g., the use of translated forms, translator, impartial witness).

|  |
| --- |
| (Max ¼ page) |

## 14H. What steps will be taken to determine if the participants are already enrolled in other studies or are likely to be enrolled in other studies during the term of this study? If enrollment in multiple studies is likely to be an issue in this population, indicate how this will be addressed.

|  |
| --- |
| (Max ¼ page) |

**SECTION IV: RISKS, BENEFITS AND SAFETY**

**15. RISK/BENEFIT ESTIMATES**

[ ]  **Potential harms (injury, discomfort and inconvenience) to participants (including psychological factors) that may result from study participation have been disclosed in the study protocol and consent form.**

[ ]  **Potential benefits to participants have been disclosed in the protocol and consent form.**

**15A. For studies involving placebo, washout, or withholding treatment, list any risks** related to withdrawal or absence of treatment.

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**16. MONITORING**

**16A. Is there a safety monitoring plan for the study?** [ ]  **Yes** [ ]  **No** [ ]  **Not applicable**

If **Yes**, please describe.:

|  |
| --- |
| (Max ¼ page) |

**16B. Is an interim analysis planned?** [ ]  **Yes** [ ]  **No** [ ]  **Not applicable**

If **Yes**, please describe:

|  |
| --- |
| (Max ¼ page) |

**16C. Is there a steering committee?** [ ]  **Yes** [ ]  **No** [ ]  **Not applicable**

**NOTE:** If **Yes**, attach a copy of the terms of reference (mandate) of the steering committee.

 **16D. Is there a Data and Safety Monitoring Board (DSMB)?**

[ ]  **Yes** [ ]  **No** [ ]  **Not applicable**

If **Yes**, forward a copy of the DSMB charter when available or provide a description of the DSMB, including its purpose, membership, relationship to the sponsor, and whether the committee will review unblinded study data etc. **Refer to the protocol as needed.**

|  |
| --- |
| (Max ¼ page) |

**16E. Is the DSMB independent of the sponsor?** [ ]  **Yes** [ ]  **No**

**17. FEEDBACK/DISSEMINATION OF RESULTS**

**17A. What information will participants receive either during or immediately after they have completed their involvement in the study, such as at the end of an interview or survey completion?** (e.g., resource list, links to further information, more information about the study, etc.). Please include details of how this will be communicated. (e.g., debriefing

script, letter of appreciation). *Please include as part of Appendix 7 (debrief materials).*

|  |
| --- |
| (Max ¼ page) |

**17B. Indicate how the results of the study will be communicated to participants and other stakeholders (e.g., advocacy groups, scientific community, etc.) If no plan is in place to provide information to participants or stakeholder, provide justification.**

|  |
| --- |
| (Max ¼ page) |

**17C. Has the funding agency or sponsoring company placed any restrictions on publication of findings (e.g., timing of manuscripts; approval process of manuscripts) or on reporting interim results?**

[ ]  **Not applicable**

[ ]  **Yes** [ ]  **No** [ ]  **Pending**

If **Yes or Pending**, explain.

|  |
| --- |
| (Max ¼ page) |

**SECTION V: PRIVACY AND CONFIDENTIALITY**

**18. COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION**

The Baycrest Research Ethics Board operates in accordance with the Personal Health Information Protection Act (PHIPA), with the privacy and confidentiality and consent guidelines outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans and other requirements and guidelines as per the TAHSN Principles for Development of Policy and Guidelines on Security of Personal Health Information Used for Research Purposes (February 4, 2008).

It is a requirement of the institution that a **complete PERSONNEL LOG** be kept for each study and for the duration of the study to identify all personnel who have access to personal health information for research purposes. The REB or the Institution may require access to this log as part of the monitoring process or for investigational purposes. This log must be kept as part of the recruitment and study conduct processes.

**18A. Please submit a PERSONNEL LOG (Appendix 8) and identify all persons including non-institutional service providers that will have access to the personal health information now or in the future, their roles in the study** (e.g., chart review)**, their reason for access** (e.g., eligible study recruits**). This log should be updated and submitted to REB for review throughout the course of the study.**

###### **18B. List the identifying and identifiable information that will be collected, used, or disclosed from the records for the purposes of recruitment only. Attach a copy of the screening/data collection** **form** *(Appendix 4)*

|  |  |
| --- | --- |
| [ ]  Name | [ ]  Images (e.g., photographic, x-ray, MRI scans*)* |
| [ ]  Address | [ ]  Social Insurance Number |
| [ ]  Telephone/Fax numbers | [ ]  Medical Record Number |
| [ ]  Email Address/IP Address/URLs | [ ]  Date of Birth |
| [ ]  Health Card Number | [ ]  Health Information: (e.g., relating to inclusion /exclusion criteria, medications) |
| [ ]  Other information (specify): |
| [ ]  No information will be collected, used, or disclosed from records |

**18C. Describe the security measures that will be taken to protect the confidentiality of this information**.

|  |
| --- |
| (Max ¼ page) |

**18D. What will happen to this information at the completion of the recruitment process**? If information will be destroyed, provide the **name of the person responsible** and **at what point** the destruction will occur.

|  |
| --- |
| (Max ¼ page) |

**NOTE: The following questions deal with the ongoing study; for information specific to recruitment see 18B.**

**18E. List all personal health information and personal identifiers (e.g., name, DOB) required to be collected and included as part of study data. Please attach data collection forms. (Appendix 4)**

|  |
| --- |
| (Max ¼ page) |

**18F. Explain why the research cannot reasonably be accomplished without using personal identifiers.**

|  |
| --- |
| (Max ¼ page) |

**18G. Indicate how long the personal health information will remain identifiable and explain why.**

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**18H. Identify all potential sources of personal health information for recruitment or study purposes**

|  |
| --- |
| [ ]  Permanent health record/clinical chart (specify source)\*: |
| [ ]  Existing Database (specify):* Does the Principal Investigator maintain the database? [ ]  Yes [ ]  No
* If **NO**, identify the entity that maintains the database:
* Has access/use for research purposes been granted? [ ]  Yes [ ]  No [ ]  Yes pending REB approval

 **NOTE** The creation and maintenance of a database for research purposes is a research activity that may require a  separate REB application. Consult the Baycrest REB office. |
| [ ]  Directly from the participant |
| [ ]  From other institutions (specify): |
| [ ]  Other (specify): |

**\*NOTE:** If data is being collected from health records, approval must be granted by the Director, Health Records (Section VII)

**i) If you intend to access personal health records/clinical charts for recruitment or study data please explain how these data will be used and why they are necessary. Please describe how consent will be obtained.**

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**ii) If you are seeking permission to access health records/clinical charts without consent, an alteration or permission to do research without consent must be granted by the REB. Explain how your request for an alteration of consent will comply with TCPS2 Chapter 3, TCPS2 Articles 5.5 and/or 12.3 (human biological materials) and PHIPA 44, 3c, 3d. (**[**https://ethics.gc.ca/eng/policy-politique\_tcps2-eptc2\_2022.html**](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)**)**

**(**[**http://www.e-laws.gov.on.ca/html/statutes/english/elaws\_statutes\_04p03\_e.htm**](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm)**)**

[ ]  **Not applicable**

|  |
| --- |
| (Max ¼ page) |

**18I. Indicate how study participants will be de-identified on data collection forms (e.g. study number, initials).**

|  |
| --- |
| [ ]  Participant Identification # |
| [ ]  OtherIf using other, please specify: |

**18J. Indicate how data will be stored.**

|  |
| --- |
| [ ]  Computerized filesSpecify: [ ]  Server [ ]  Desktop [ ]  Laptop Server (specify): [ ]  Internal [ ]  Contracted Service Provider [ ]  Other [ ]  Third party  |
| [ ]  Hard copy |
| [ ]  Audio Recordings |
| [ ]  Video Recordings |
| [ ]  USB key or similar portable storage device |
| [ ]  Other (specify): |

**18K. Indicate where the data will be stored**

|  |
| --- |
| [ ]  On-site |
| [ ]  Off-site; specify location(s) including institution name, city and country:If off-site, will a back-up copy be stored on site [ ]  Yes [ ]  No If **No, justify:** |

**18L. Indicate what measures will be undertaken to protect the confidentiality and security of the data, including any physical and technical safeguards.**

|  |
| --- |
| (Max ¼ page) |

**18M.** **Will study data and/or personal health information be transferred to or from Baycrest?**

[ ]  **Yes (refer to 20C – Transfer agreement)** [ ]  **No** [ ]  **Not applicable**

Justify and describe how this information will be transferred and any security measures to be used (e.g., de-identified data, secure network upload or download).

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| (Max ¼ page) |

**18N. Will any information that could potentially identify study participants be disclosed outside of the custody of Baycrest** (e.g., names, initials, DOB, OHIP #)

[ ]  **Yes** [ ]  **No**

If **Yes**,to whom?

|  |
| --- |
| (Max ¼ page) |

**18O. If personal health information is to be linked to other databases (e.g., health registries, Statistics Canada information) provide the following details:**

[ ]  **Not applicable**

Describe the data to which the personal health information will be linked, and how the linkages will be made, and why these linkages are required.

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| (Max ¼ page) |

**18P. Indicate who will have access to study data in the future?**

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| (Max ¼ page) |

**18Q. Indicate what, if any, further measures will be taken at the end of the study (e.g., whether data will be anonymized at that point, data will be coded, etc.)**

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| (Max ¼ page) |

**18R. Describe how and when the personal health information will be disposed of, or returned to Baycrest (if disclosed externally).**

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| (Max ¼ page) |

**18S. Describe any harms that could arise if personal health information was inappropriately released** (e.g., embarrassment, refusal of employment or insurance coverage, stigmatization of individuals / groups) and how any consequences would be addressed.

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| (Max ¼ page) |

**19. STORING AND/OR SHARING OF DATA FOR FUTURE USE**

NOTE: As set out in TCPS Articles 3.2 and 12, explicit consent from participants is needed to re-use study data to answer research questions not described in the consent forms.

 **19A. Is there any possibility that you will want to store and/or share the study data for future research use(s)? (**Future use includes your own re-use of the data to answer other questions, sharing the data with collaborators for their future use, or depositing data in an online data repository accessible to other researchers.)

[ ]  **Yes** [ ]  **No**

If **No**,explain why and skip to 20.

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| (Max ¼ page) |

**19B. Is the future research use(s) currently unknown/unspecified?**(i.e., exact details are not yet known)

[ ]  **Yes** [ ]  **No**

If **yes**, please include in the consent form a description and separate consent option for the storage and future unspecified use of data and/or human biological materials as set out in TCPS Articles 3.2 and 12 (**Please refer to Baycrest Academy Open Science Policy Companion Document on REB office website for more information**)

If **No**, please describe these purposes of future research use in the consent form.

**19C. Please explain your plan for sharing of data for future use.**Include details about (a) the means by which the data would be shared (e.g., data transfer agreement, confidentiality agreement, online repository (restricted or public)) platform details; (b) any portions of the data that won't be shared; and (c) any relevant considerations (e.g., sensitivity and (re-identifiability of the data, legal or commercial constraints and data sovereignty) **Please refer to Baycrest Academy Open Science Policy Companion Document on REB office website for more information.**

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| (Max ½ page) |

**SECTION VI: CONTRACTS AND AGREEMENTS**

**20. CONTRACTS AND AGREEMENTS**

**20A. Contract/Research Agreement**

Is there **any party** external to the institution involved with the research that will be entering into an agreement or contract with the institution (i.e., issues related to ownership, publication, intellectual property, etc.)? [ ]  **Yes** [ ]  **No** (If no, please skip to 20C.)

If **Yes**, provide names and roles of those involved (i.e. Regulatory Sponsor, contract research organization, funder, collaboration institution, vendor or researcher).

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| (Max ¼ page) |

**20B. Has the contract/research agreement been submitted for review and signing?** [ ]  **Yes** [ ]  **No**

**20C. Transfer Agreement**

If study data, biological materials (e.g. blood, other bodily fluids, tissues) or identifiable information (e.g. data, video and audio and other data) will be transferred to or from an external party involved in this research, has an agreement related to the transfer (e.g., Material Transfer Agreement, Information Sharing Agreement, Service Provider Agreement, Vendor Agreement) been approved?

[ ]  **Yes** [ ]  **No** [ ]  **Pending** [ ]  **Not applicable**

If **No**, explain.

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| (Max ¼ page) |

 **NOTE**: If you suspect a transfer agreement is required, but has not yet been drafted/approved, please contacted the Grants and

 Contracts Office.

**21. LIABILITY**

**Who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided if a participant suffers an injury as a result of participation in the study?** [ ]  **Not applicable**

|  |
| --- |
| [ ]  Regulatory Sponsor (as listed above, Question 9B) |
| [ ]  Funder |
| [ ]  Institution |
| [ ]  Other (specify): |

**SECTION VII: INSTITUTIONAL IMPACT**

**22. IMPACT ON BAYCREST DEPARTMENTS**

**IMPORTANT NOTE: Investigators must obtain prior approval from the Director or Department Head in every area in which they would need to engage in the conduct of this the study. Approval to start the project will not be given until this is done. You may consult with the REB to help determine which approvals are required.**

|  |  |  |
| --- | --- | --- |
| DEPARTMENT/SERVICE | Name and title of person giving approval | Signature / Date (Required) |
| [ ]  **Apotex** |  |  |
| [ ]  **Ambulatory Services** (Geriatric Dental Centre, Chiropody, Hearing Services, Medical Specialty Clinics, Neurology Clinics, Sam and Ida Ross Memory Clinic & Virtual Behavioural Medicine [Austin centres], Ambulatory Mental Health, Central Intake, Day Treatment Centre and Psych day Hospital, geriatric Psychiatry Community Services, Integrated Community Care Team, Falls Prevention, Outreach Teams, Seniors Support Program)*Specify:* |  |  |
| [ ]  **Culture and Arts** |  |  |
| [ ]  **Day Care Program** (Adult Day Programs, Connected Communities and Neighbors, Digital Health)*Specify:* |  |  |
| [ ]  **Environmental, Food and Nutrition Services** |  |  |
| [ ]  **Business Intelligence, Health Records, Privacy Office** |  |  |
| [ ]  **Hospital Stores** |  |  |
| [ ]  **Hospital – Interprofessional Practice** (i.e., Pharmacy, Nursing, Social Work, Dieticians, Speech Language Pathology, Occupational Therapy, Physiotherapy, Therapeutic Recreation)*Specify:* |  |  |
| [ ]  **Hospital – Inpatient Services** (i.e., Transitional Care Unit, Inpatient Mental Health, Behavioural Neurology, Complex Continuing Care, Palliative Care, Inpatient Rehabilitation)*Specify:* |  |  |
| [ ]  **Human Resources and Occupational Health** |  |  |
| [ ]  **Laboratory** (if specimen collection or processing is involved) |  |  |
| [ ]  **Spiritual Care** |  |  |
| [ ]  **Jewish Home for the Aged** (Terraces and 2 Neptune)*Specify:* |  |  |
| [ ]  **Other***Specify:* |  |  |