**Study Title:**

**Principal Investigator:**

# ADDENDUM – BAYCREST (updated September 2023) HUMAN PARTICIPANTS RESEARCH APPLICATION

Baycrest has some specific requirements that are not always addressed in the submitted application form (i.e., CTO studies, external REB application forms, amendments with new institutional impacts). In these cases, the addendum form must be included with submission documents. Please check with REB office to determine if an addendum form is required with your application.

# DEPARTMENT/DIVISION/PROGRAM APPROVAL BAYCREST-SPECIFIC SIGNATURES

**Research Participant Coordinator**

If you are requesting participants from the Research Participant Database, the signature of the Participant Coordinator is required.

# President & Chief Scientist

All research at Baycrest must be signed-off by the President & Chief

Scientist (or designate). This section cannot be signed by the Principal Investigator or a Co- Investigator. An alternative approval signature is required.

# Research Ethics Board

This is signed after approval has been given by the Research Ethics Board

|  |  |
| --- | --- |
| ***Principal Investigator*** | ***President and Chief Scientist, Baycrest Academy for Research and Education (or designate)***Name:  Signature Date |
| Signature | Date |
| ***Research Participant Coordinator*** | ***Research Ethics Board Chair*** Signature Date |
| Signature | Date |

**Human Participants Research Application Baycrest ADDENDUM**

**Version Date: August 2023**

# CLINICAL TRIALS APPLICATION

It is important that the PI review the Clinical Trials Policy to ensure that all Baycrest requirements for clinical trials are addressed.

|  |  |  |
| --- | --- | --- |
| **PARTICIPANTS/CONTROLS****Source of Study Participants**Baycrest Hospital inpatients Baycrest Hospital outpatients Jewish Home for the Aged residents Baycrest Terraces residents Community Day Care Members Research Participant PoolOther | **Number**       | **Floor/Service**        |

# RECRUITMENT AND CONSENT

**Relevance to Aging, Gender Balance and Inclusion of Elderly Subjects**

1. **RELEVANCE OF THIS PROJECT TO AGING AND AGE-RELATED DISORDERS**
2. **INCLUSION OF WOMEN SUBJECTS**

**Project includes a balance of gender Project excludes women (justify below) Project excludes men (justify below)**

1. **INCLUSION OF ELDERLY SUBJECTS Project includes elderly subjects**

**Project excludes elderly subjects (justify below)**

# BUDGET

*Complete the chart below, or add attach an itemized study budget.*

|  |  |
| --- | --- |
| **Operating:** |  |
| **Equipment:** |  |
| **Grant/Contract obtained (specify agency/company)** |  |
| **Grant/Contract applied for (specify agency/company)** |  |
| **Covered by existing grant or other funds** |  |
| **–specify facility where the grant is administered** |

# BUDGET DETAILS:

**IMPACT ON BAYCREST STAFF AND SERVICES**

**IMPORTANT NOTE: Investigators must obtain prior agreement from the Director or Department Head in every area in which staff will be affected by the study. Approval to start the project will not be given until this is done. Consult with the REB office to 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:* |  |  |