

Toronto Academic Health Sciences Network (TAHSN)

**ADDENDUM – Baycrest Site (updated September 2017)
HUMAN SUBJECTS RESEARCH APPLICATION**

Baycrest has some specific requirements that are not addressed in the application form and thus this addendum must be included when submitting the application form.

The sections below correspond to sections in the application form. As with the original application all sections **MUST** be completed before it will be considered for Research Ethics Board (REB) review. If not applicable, indicate N/A.

DEPARTMENT/DIVISION/PROGRAM APPROVAL

BAYCREST-SPECIFIC SIGNATURES

Research Subject coordinator

If you are requesting subjects from the Research Subject Pool, the signature of the Subject Coordinator is required.

Vice-President, Research

All research at Baycrest must be signed-off by the Vice-President, Research.

Research Ethics Board

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

<i><u>PRINCIPAL INVESTIGATOR</u></i>		<i><u>V.P. RESEARCH</u></i>	
Signature	Date	Signature	Date
<i><u>RESEARCH SUBJECT COORDINATOR</u></i>		<i><u>RESEARCH ETHICS BOARD</u></i>	
Signature	Date	Signature	Date

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.

SUBJECT/CONTROLS

Source of Study Subjects

	Number	Floor/Service
Baycrest Hospital inpatients	_____	_____
Baycrest Hospital outpatients	_____	_____
Jewish Home for the Aged residents	_____	_____
Baycrest Terraces residents	_____	_____
Community Day Care Members	_____	_____
Research Subject Pool	_____	N/A
Other	_____	_____

RECRUITMENT AND CONSENT

Relevance to Aging, Gender Balance and Inclusion of Elderly Subjects

(i) RELEVANCE OF THIS PROJECT TO AGING AND AGE-RELATED DISORDERS

(ii) INCLUSION OF WOMEN SUBJECTS

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

(iii) 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.

<input type="checkbox"/> Operating:	\$
<input type="checkbox"/> Equipment:	\$
<input type="checkbox"/> Grant/Contract obtained (specify agency/company)	
<input type="checkbox"/> Grant/Contract applied for (specify agency/company)	
<input type="checkbox"/> Covered by existing grant or other funds –specify facility where the grant is administered	

BUDGET DETAILS:

IMPACT ON BAYCREST STAFF

IMPORTANT NOTE: Investigators must obtain prior agreement from the Director of 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.

DEPARTMENT/SERVICE

NAME OF PERSON WHO GAVE APPROVAL

(Original signature required)

LABORATORY (if specimen collection or processing is involved)

MEDICAL RECORDS (if charts need to be reviewed)

MEDICAL SERVICES (if study involves medical interventions)

Behavioural Neurology

Geriatric Medicine

Psychiatry

NURSING (Head Nurses must be informed if residents, inpatients, outpatients, or clinic patients are involved)

Baycrest Hospital

Jewish Home for the Aged

PHARMACY (if dispensing or storage is required)

SOCIAL WORK (includes contact with families)

Baycrest Hospital

Apotex Centre Jewish Home for the Aged

Baycrest Terrace

Community Day Care Members

OTHER, e.g. Communication Disorders, Dentistry, Occupational Therapy, Physiotherapy (specify):
