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

PRINCIPAL INVESTIGATOR		President & Chief Scientist, Baycrest Academy for Research and Education	
Signature	Date	Signature	Date
RESEARCH SUBJECT COORDINATOR		RESEARCH ETHICS BOARD	
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	S
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Baycrest Hospital inpatients Baycrest Hospital outpatients Jewish Home for the Aged residents Baycrest Terraces residents Community Day Care Members Research Subject Pool Other	Number	Floor/Service N/A
RECRUITMENT AND CONSTRUCTION RELEVANCE OF THIS PROJECT	Balance and Inclus	sion of Elderly Subjects D AGE-RELATED DISORDERS
(ii) INCLUSION OF WOMEN SUB ☐ Project includes a balance of ge ☐ Project excludes women (justify ☐ Project excludes men (justify bel	nder below)	
(iii) INCLUSION OF ELDERLY SU ☐ Project includes elderly subjects ☐ Project excludes elderly subjects	S	

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

IMPORTANT NOTE: Investigators must obtain <u>prior agreement</u> from the Director of Department Head in <u>every</u> 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):	