Western Research

HSREB Initial Application

1.1

1.1 *If this is the first time you are submitting this particular application/event form to the REB, select “Initial Submission”. If this application form has already been reviewed by the REB and they issued recommendations, select “Response to REB recommendations”:

- ○ Initial Submission
- ◉ Response to REB recommendations

1.2

1.2 *Does this study involve the London hospitals (see HELP text if you are unsure):

- ◉ No this study does not involve the London hospitals
- ○ Yes this study involves the London hospitals and this form has been exported from ReDA.
- ○ This study involves the London Hospitals but a ReDA submission has not been completed. NOTE: You cannot submit this application until the ReDA submission has FIRST been completed and you exported from ReDA to WREM.

*As this study is not taking place in the hospital, type in "Western Research Services" in the below Search User text box:

Name	Western
Email	gm-certification@uwo.ca

1.3

1.3 *Complete the Principal Investigator (PI) details:

*Prefix	*First Name	*Last Name
Dr.	Adrian	Owen

Address

City

Province/State

Postcode/Zip

Telephone

*Email adrian.owen@uwo.ca

Complete the additional PI details:

*Western Academic Faculty/Department:

Social Sci.-Psychology

Hospital Department/Division:

N/A

1.4

1.4 *Are there any additional study team members (from Western and/or its affiliate institutions) who are working on this study?

- (•) Yes there are additional study team members
- ( ) No other study team members involved

1.4 *Complete the following information for additional study team members (from Western and or its affiliate institutions) who are working on this study:

Prefix	*First Name	*Last Name
Ms.	Dawn	Pavich

Address

City

Province/State

Postcode/Zip

Telephone

*Email dpavich@uwo.ca

1.4 *ROLE and DUTIES assigned by the PI to this individual (e.g. John Doe - Research Assistant - involved in recruitment, interviews and analysis of data.):

Dawn Pavich (research support staff responsible for managing paperwork and overseeing study)

1.4a *Are there additional study team members to add?

- (•) Yes
- ( ) No

1.4a *Complete the following information for additional study team members (from Western and or its affiliate institutions) who are working on this study:

Prefix	*First Name	*Last Name
Ms.	Avital	Sternin

Address

City

Province/State

Postcode/Zip

Telephone

*Email asternin@uwo.ca

1.4a *ROLE and DUTIES assigned by the PI to this individual (e.g. John Doe - Research Assistant - involved in recruitment, interviews and analysis of data.):

Avital Sternin (graduate student responsible for recruitment, data collection, data analysis, write up),

1.4b *Are there additional study team members to add?

- ○ Yes
- ◉ No

1.5

1.5 *Enter the complete study title:

Assessing cognitive functioning in adult populations

1.6

1.6 *What is the acronym or nickname/short title for the study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and REB submissions.):

Cognitive Assessment in Adult populations

1.7

1.7 *What type of REB submission is this?

- ◉ Full Board
- ○ Delegated Level 2 - Prospective data collection
- ○ Delegated Level 1 - Retrospective study data and/or biological sample collection

1.8

1.8 *Are any of the investigator(s) based at any of the sites below or will the study utilize any patient data/biological specimens, staff resources or facilities within any of these sites? (Please indicate all applicable sites):

- [x] No

LHSC Sites

- [ ] Adult Eating Disorder Service (Riverview)
- [ ] Byron Family Medical Centre
- [ ] Children's Hospital
- [ ] Fowler Kennedy Sports Medicine
- [ ] Kidney Care Centre (Westmount)
- [ ] London Regional Cancer Program (LRCP)
- [ ] Southwestern Ontario Regional Base Hospital Program
- [ ] Stroke Prevention & Atherosclerosis Research Centre
- [ ] University Hospital (UH)
- [ ] Victoria Family Medical Centre
- [ ] Victoria Hospital (VH)

St Joseph's Sites

- [ ] Mount Hope Centre for Long Term Care
- [ ] Parkwood Institute – Main Building
- [ ] Parkwood Institute Mental Health Care
- [ ] Southwest Centre for Forensic Mental Health Care
- [ ] St. Joseph's Family Medical and Dental Centre
- [ ] St. Joseph's Hospital

1.9

1.9 *Is this study directly related to a previously approved study at this institution (e.g., is this study a sub-study, extension, rollover, subsequent to a pilot study)?

- ○ Yes
- ◉ No

1.10

1.10 *Is there a protocol/research plan for this study?

- ○ Yes
- ◉ No

*What measures are in place to ensure this study will be implemented consistently?

The study details that have been described throughout this application will be followed to maintain consistency in how testing is implemented.

1.11

1.11 *Is this an Investigator-initiated study?

- (•) Yes
- ( ) No

1.12

1.12 *Who is the Study Sponsor?

- [ ] Industry Sponsored
- [ ] External Non-Profit
- [ ] External PI
- [x] Local PI
- [ ] Self

1.13

1.13 *Is this a student project?

- [ ] No
- [ ] Yes - Resident/Fellow
- [ ] Yes - MD
- [ ] Yes - Post-doctoral Fellow
- [x] Yes - PhD
- [ ] Yes - Masters
- [ ] Yes - Undergraduate
- [ ] Yes - Other

1.14

1.14 *Has the study undergone a formal scientific or peer review (i.e., internal peer review or external review (e.g., CIHR, NSERC, NIH, etc.))?

- ( ) Yes
- (•) No

1.15

1.15 *Has the study been reviewed and approved by another REB in Canada?

- ( ) Yes
- (•) No

1.16

1.16 *Has the study been rejected by any other REB?

- ○ Yes
- ◉ No

1.17

1.17 *Is this research study supported by the United States federal government (including a study funded by a US government agency)?

- ○ Yes
- ◉ No

1.18

1.18 *Is this a multi-centre study?

- ○ Yes
- ◉ No

1.21

1.21 *Is there an external third party (Coordinating or Contract Research Organization) overseeing the study?

- ○ Yes
- ◉ No

1.22

1.22 *Indicate how the results will be communicated to participants and other stakeholders (e.g.; advocacy groups, scientific community).

***To Participants:**

- ☐ Debriefing Script
- ☐ Group debriefing
- ☐ End of study letter
- ☑ Publication(s)
- ☐ Other
- ☐ No Plan

***To Other Stakeholders:**

- ☑ Presentation(s)
- ☑ Publication
- ☐ Other
- ☐ No plan

1.23

1.23 *Provide a brief lay/non-scientific summary of the study (max 250 words)

Cognitive abilities change with age, however little research has been done to quantify how those changes manifest. The purpose of the current project is to investigate how various cognitive functions change as adults age, and to determine the best mechanism for the assessment of cognitive abilities in older adults.

2.4

2.4 *Will you collect biological specimens in this study?

- ○ Yes
- ◉ No

2.5

2.5 *What are the study hypotheses or research question(s) or purpose of this study?

The purpose of this study is to to quantify the changes in cognitive functioning in older adults using multiple validated cognitive assessment tools (Cambridge Brain Sciences Battery (CBS), Montreal Cognitive Assessment (MoCA), Mini Mental State Exam (MMSE)) and to compare how these three tools relate to each other in their ability to accurately quantify cognitive function in this population.

2.6

2.6 *What is the rationale for this study (why is it being done)? In your response ensure to include relevant background information from previous studies that have been done. Cite references where appropriate and add as a separate attachment (do not include within your response).

Cognitive abilities change with age, however little research has been done to quantify how those changes manifest. There are two validated assessments that are widely used to assess cognitive function in adults: the Mini-Mental State examination (MMSE; Folstein et al, 1975) and the Montreal Cognitive Assessment (MoCA; Nasreddine et al, 2005). However, these two assessments are grounded in behavioural assessments of cognition. Recently, the Cambridge Brain Sciences (CBS) battery was developed and provides a measure of cognitive abilities in tasks that are grounded in neuropsychological research (Hampshire et al, 2012). These tasks are a more direct measure of brain function. However, little is known about how the scores on the CBS battery change in older adults or how the scores relate to the current gold-standard of assessment tools (MMSE and MoCA). In this study we will determine: 1) how CBS battery, MoCA, and MMSE scores change with age, 2) how CBS scores relate to the current gold-standards, and 3) whether CBS tasks provide a more complete assessment of cognitive functioning than the existing MMSE and MoCA.

Upload any references used above (if applicable):

Type	Name	File Name	Date	Version	Size
References	2.6References	2.6References.docx	23/Nov/2017 12:00:00 AM	1	56.1 KB

2.7

2.7 Provide a brief summary of the study design type and methodology being employed in this study. NOTE: Information about objectives, inclusion/exclusion criteria, study procedures, sample size calculations and data analysis should be described when prompted elsewhere in the application.

The current project is an exploratory, cross-sectional, correlational study. Participants will complete validated cognitive tasks and we will statistically investigate and correlate scores with various demographic variables. Cognitive tasks will be delivered either via a tablet computer or via an interview-style questionnaire session with a research assistant. No random assignment or manipulation of variables will be used during this study.

Upload a flow diagram (if applicable):

2.8

2.8 *Will this study include the following population(s): (select all that apply):

- ☐ Patients
- ☐ People who are unable to consent
- ☑ Healthy Volunteers
- ☐ Caregivers/Study Partner
- ☑ Cognitively impaired individuals
- ☐ Students
- ☐ Adult individuals temporarily unable to provide consent (i.e. unconscious)
- ☐ Staff/Health care providers
- ☐ Pregnant Women
- ☐ People with mental health issues
- ☑ Elderly people
- ☐ People institutionalized
- ☐ People with palliative disease
- ☐ Prisoners/persons in detention
- ☑ People in long-term care
- ☐ People in poverty
- ☐ Minors
- ☐ People in medical emergencies
- ☐ Other

2.13

2.13 *Does this study include a non-patient group (e.g., caregiver, student, employee, etc.)?

- (•) Yes
- ( ) No

*For all non-patient participants describe all study related procedures and any study specific testing that will be done (i.e., how are you doing it?).

To investigate how cognitive function changes with age, 500 older adults over the age of 50 will be recruited to the study. Recruitment will occur through poster advertisements and word of mouth. Interested participants will indicate their interest using the method indicated on the poster and the researchers will follow up to schedule a testing session. Participation in the study will occur in a place that is convenient for the older adult (testing space within the Brain and Mind Institute, dedicated research space in a nursing/retirement home, etc). The exact location will be determined when scheduling sessions with participants. Because we are interested in a natural, representative sample of older adults it is possible that we will receive volunteers with mild cognitive impairment and/or participants who currently reside in long-term care facilities (section 2.8) however, we are not actively seeking out these populations.

Each participant will be assigned a unique identifier code in order to appropriately anonymize the data.

Before testing begins, participants will receive a letter of information that outlines all of the study relevant information. Participants will be given the option of receiving the LOI when their session scheduled. Receiving the LOI in advance allows participants to read through it on their own and come to the session with any potential questions. If participants choose to receive their LOI at the beginning of their scheduled session they will have as much time as they need to review the LOI. Any questions will be answered at this point. All participants will provide their own consent. Following completion of the consent form, data collection will be done using computerized cognitive tasks and paper/pencil questionnaires and assessments. Participants will be asked to complete a short battery of cognitive assessments from Cambridge Brain Sciences on a tablet computer. Sample tests are available online at www.cambridgebrainsciences.com. The cognitive assessments are presented as interactive games appropriate for all ages. A brief description of the 12 tasks has been attached to section 2.15. Participants will be given a chance to practice each of the twelve tasks before their scores are recorded. The researchers will also administer a MoCA and a MMSE to each participant. These two assessments will be done with paper and pencil. The order of all of the tasks will be randomized and breaks will be encouraged to prevent fatigue. Participants will also be asked to fill out a demographic questionnaire.

The total time to complete the questionnaires, tasks, and practice will be approximately 60-90 minutes.

After completion of all tasks participants will have the opportunity to enter a raffle (if they so choose) to win a prize (odds 1/100)

We will collect participant's scores on all of the administered tasks and statistical analyses will be performed on these data.

2.14

2.14 *Is this a collaborative community-based project?

- ( ) Yes
- (•) No

2.15

2.15 *Indicate your data collection tools/forms by selecting the relevant option(s) below:

- [x] Paper Survey(s)/Questionnaire(s)
- [ ] Online Survey(s)/Questionnaire(s)
- [ ] Interview Guide(s)
- [ ] Focus Group Guide(s)
- [ ] Non-Participant Observation Guide(s)
- [ ] Participant Observation Guide(s)
- [x] Other (e.g., visual stimuli, participant diary, data collection forms, etc.)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

*Upload the paper survey(s):

Type	Name	File Name	Date	Version	Size
Paper Survey	Demographic	Demographic.pdf	22/Dec/2017 12:00:00 AM	2	81.5 KB

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

*If Other is selected, specify:

CBS tasks will be administered via a tablet computer (Description of tasks attached)
MoCA
MMSE

*Upload any Other data collection instruments that will be used during the study:

Type	Name	File Name	Date	Version	Size
Other Data Collection Instruments	CBS Tasks	CBS Tasks.docx	23/Nov/2017 12:00:00 AM	1	413.0 KB
Other Data Collection Instruments	MoCA-Test-English_7_1	MoCA-Test-English_7_1.pdf	23/Nov/2017 12:00:00 AM	1	435.2 KB
Other Data Collection Instruments	MMSE	MMSE.pdf	23/Nov/2017 12:00:00 AM	1	96.5 KB

2.16

2.16 *How will the data collection tool(s)/form(s), completed by the participant, be administered (e.g. in person, paper, electronic)?

All data collection will be done in person. CBS tasks will be collected on a tablet computer. The health and demographic questionnaire, MoCA and MMSE will be collected on paper.

2.17

2.17 If you are directing participants to a website or electronic materials, provide the web address (as applicable):

Tasks will be administered on a tablet computer. The description of the tasks is attached to section 2.15. Samples of the tasks that will be administered can be viewed at www.cambridgebrainsciences.com.

2.18

2.18 *Are there any associated sub-studies or companion studies?

- ○ Yes
- ◉ No

2.20

2.20 *What is the local sample size?

400

2.21

2.21 *Is the sample size justified in the study protocol/research plan or sponsor protocol?

- ○ Yes
- ◉ No

*Provide the sample size justification

A power analysis using G-Power and information from previous literature indicated that a sample size of 400 participants is 100 participants more than the number required to get a representative sample of the older adult population. The extra participants were included to ensure that the minimum number of participants is achieved allowing for attrition and participants who don't complete the study.

2.22

2.22 Describe the method(s) for data analysis.

The behavioural data collected will be analyzed using statistical processing software such as SPSS to implement such analyses as correlations and regressions. Correlations will be used to relate scores from the various tests and regressions will be used to uncover which CBS test scores best predict the MoCA and MMSE scores.

2.23

2.23 *Provide the inclusion criteria:

Adults over the age of 50 years with normal to corrected-to-normal vision and English language fluency

2.24

2.24 *Provide the exclusion criteria.

Participants will be excluded if they are under the age of 50, if their vision is not corrected to normal, or if their English language proficiency or other cognitive factors (such as inability to pay attention for the duration of the task, or inability to follow serial instructions) that do not allow them to understand the tasks.

2.25

2.25 *What is/are the primary objective(s) of the study and briefly describe how it/they will be measured. NOTE: For qualitative research studies-If this is not applicable indicate "NA"

The primary objective of the study is to quantify cognitive changes in older adults. Cognitive changes will be measured by scores on the CBS tasks, the MoCA, and the MMSE.

2.26

2.26 What is/are the secondary objective(s) (if applicable) of the study and briefly describe how it/they will be measured.

The secondary objective is to relate the CBS task battery to the gold-standard tests (MoCA and MMSE). Regression analyses performed on the task scores will help us understand this relationship.

2.27

2.27 *Does this study include any use of deliberate deception or withholding of key information that may influence a participant's performance or response?

- (•) Yes
- ( ) No

*Explain and justify:

Participants will be told prior to participating that they will be completing a number of cognitive tests in order for the researchers to understand how cognitive abilities change with age. Prior to participating, participants will not be told that the researchers are also interested in comparing how the CBS, MoCA, and MMSE compare to each other in their abilities to measure cognitive functioning. This information will be withheld in case participants have prior biases towards the tests that may influence their performance.

*Describe how and when the participants will be debriefed:

Upon completion of all parts of the experiment participants will be given a debriefing form that describes the three goals of the study outlined in section 2.6.

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.c.

*Upload the debriefing letter of information and consent.

Type	Name	File Name	Date	Version	Size
Debriefing Letter	Debrief	Debrief.docx	20/Dec/2017 12:00:00 AM	1	571.8 KB

2.28

2.28 *Will study participants be subject to restrictions (lifestyle) during the study?

- ○ Yes
- ◉ No

2.29

2.29 *Describe the circumstances under which a participant may be withdrawn from the study.

A participant may be withdrawn from the study if they are unable to complete all of the tasks.

3.1

3.1 *Is this a clinical trial?

- ○ Yes
- ◉ No

11.1

11.1 *Describe any direct benefits to the study participants.

This study will not result in any direct benefit to the participant. However, participating provides a learning experience during which participants are exposed to current research in cognitive neuroscience. They will have the opportunity to discuss the experiment with the researcher.

11.2

11.2 *What is the overall anticipated public and scientific benefits of the study?

This study will provide valuable information about how cognitive abilities change with age, which may have implications for how cognitive abilities are assessed in older adults.

11.3

11.3 *List and describe the known risks/harms/inconveniences of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only (including approximate rates of occurrence, severity and reversibility). This information must be included in the informed consent documentation.

The proposed research will involve minimal risk to the participants. It will not involve any risks beyond what an individual might experience in daily life. Participants may feel some fatigue due to exposure to a tablet screen.

11.5

11.5 *For the study risks listed above, describe the monitoring to be undertaken during and following the study conclusion.

The tasks will be explained to participants before they are asked to complete them, and they will also be given a chance to practice, ask questions, and take a break at any point. The experimenter will ask the participant if they would like breaks between the tasks, and will monitor the participant to ensure they do not become fatigued.

11.6

11.6 *Are there any reproductive risks associated with participation in the study?

- ○ Yes
- ◉ No

11.7

11.7 *If a research participant fathers a child while in the study, will access to the health records of the pregnant partner and/or her child be required and/or will the woman and/or child be monitored by this study during and/or after the pregnancy?

- ○ Yes
- ◉ No

11.8

11.8 *Does participation in this study affect alternatives for future care or eligibility for future research?

- ○ Yes
- ◉ No

11.9

11.9 *Is there a data and safety monitoring board (DSMB) or committee (DSMC)?

- ○ Yes
- ◉ No

*Provide justification

There is no DSMB because our study is not a clinical trial. It is not a medical device trial and we do not use our data collection equipment for prevention, diagnosis, mitigation, or treatment.

11.10

11.10 *Are there any plans to perform an interim analysis?

- ◉ Yes
- ○ No

*Describe:

We will analyze the data we collect in an ongoing fashion. As we gather more data it will be added to the pool of analyzed data.

11.11

11.11 If applicable, describe how incidental findings will be managed and under what circumstances they would be disclosed to study participants:

12.1

12.1 *Will Personal Information (PI) and/or Personal Health Information (PHI) be used to identify potential participants (pre-screening)?

- ○ Yes
- ◉ No

12.2

12.2 *Is a waiver of the requirement to obtain informed consent being requested for this study?

- ○ Yes
- ◉ No

12.3

12.3 *Is there a broad recruitment plan (e.g. recruitment database, call centre, advertising)?

- ◉ Yes
- ○ No

*Describe:

Recruitment will be done through posters and word of mouth.

12.4

12.4 *How will you recruit potential participants?

- ☐ Investigator or other study member who is part of the circle of care will approach patients
- ☐ Investigator or other study member who is part of the circle of care will approach the substitute decision maker
- ☐ Investigators will receive referrals from other healthcare providers
- ☐ Investigators will recruit a non-patient group (e.g. caregiver, students, employees, etc.)
- ☑ Advertising (e.g., brochures, flyers, poster, newspaper ad or web-based)
- ☐ Existing database
- ☑ Other

*Specify other:

Word of mouth: allows our participants to tell their friends/social groups about the study they participated in to increase our range of recruitment.

12.5

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

12.5 *Upload all advertising material(s):

Type	Name	File Name	Date	Version	Size
Recruitment Materials	poster	poster.pdf	23/Nov/2017 12:00:00 AM	1	616.9 KB

12.8

12.8 *Who will make initial contact with potential participants?

1. Participants will contact the researcher to indicate their interest in participating.
2. If posters are placed in retirement/nursing homes, a sign-up sheet may be left with an administrator. Residents will be able to leave their contact information with the administrator. The administrator will then forward the contact information to the researchers and the researchers will reach out and contact those interested.

12.9

12.9 *How will initial contact be made with potential participants?

- [x] In person
- [ ] Email (include: If email communication will be used please ensure that participants understand that email communication is not a secure form of communication)
- [ ] Letter
- [x] Telephone
- [ ] Other

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

*Upload Telephone Script

Type	Name	File Name	Date	Version	Size
Telephone Script	Telephone_Script	Telephone_Script-clean.docx	20/Dec/2017 12:00:00 AM	2	157.7 KB
Telephone Script	Telephone_Script	Telephone_Script-tracked.docx	20/Dec/2017 12:00:00 AM	2	158.3 KB

12.11

12.11 *Describe the consent process (for patient and/or non-patient population):

All potential participants will be given a Letter of Information. Any questions will be answered. Participants will then sign a paper consent form.

12.12

12.12 *Who will be obtaining consent?

The researcher administering the tasks will obtain consent before beginning any testing. Researchers may include: Adrian Owen, Avital Sternin, or future research assistants who are assigned to assist with this project and who will be added to this ethics application as necessary.

12.13

12.13 *Which of the following will be used, select all that apply:

- ☐ Assent Form(s)
- ☑ Letter of Information/Consent (LOI/C) Form(s) - (including Sub-study LOI/C, Optional LOI/C, etc)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

*Upload clean version(s) of the Letter of Information/Consent form(s):

Type	Name	File Name	Date	Version	Size
Written Consent/Assent	LOI_Consent	LOI_Consent-clean.docx	20/Dec/2017 12:00:00 AM	2	578.1 KB

12.14

12.14 *Is there a relationship between the participant and the person obtaining consent?

- ○ Yes
- ◉ No

12.15

12.15 *Does this study have competitive enrollment

- ○ Yes
- ◉ No

12.16

12.16 *Will persons not capable to consent for themselves be included in the study?

- ○ Yes
- ◉ No

12.17

12.17 When the inability to provide an informed consent is expected to be temporary, describe what procedures that will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent. Alternatively, if diminished capacity is anticipated for the study population, describe the procedure used to assess capacity and obtain ongoing consent.

12.18

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

Participants will be given as much time as they need to review the LOI before being asked to sign the consent form.

12.19

12.19 *Does the study exclude any participants based on culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, sex or age?

- ○ Yes
- ◉ No

12.20

12.20 *List any anticipated communication difficulties:

- ☑ None
- ☐ Individuals who may require translation
- ☐ Individuals who are illiterate
- ☐ Individuals unable to communicate

12.21

12.21 *Are potential participants allowed to enroll in other studies while in the current study?

- (•) Yes
- ( ) No

13.1

13.1 *(For patient orientated research studies.) Do you plan now or in the future to link your study data to the large healthcare databases held at the Institute for Clinical Evaluative Sciences (ICES)? For example, this would allow you to follow patients passively life-long, determine their healthcare costs, assess how similar your patients are compared to Ontario citizens, and help identify control groups.

- ( ) Yes
- ( ) No
- (•) N/A

13.2

13.2 *Are you collecting personal identifiers for this study?

- (•) Yes
- ( ) No

13.3

13.3 *Identify any personal identifiers collected for this study. Select all that apply.

- [x] Full Name
- [ ] Initials
- [ ] Ontario Health Card Number
- [ ] Address
- [ ] Full Postal Code
- [ ] Partial Postal Code
- [x] Telephone Number
- [x] Email Address
- [ ] Family Physican or other care provider names
- [ ] Full Date of Birth
- [x] Partial Date of Birth
- [ ] Full Date of Death
- [ ] Partial Date of Death
- [ ] Sex/Gender
- [x] Age
- [ ] Hospital Number
- [ ] Medical Device Identifer
- [ ] Full Face Photograph
- [ ] Voice/Audio Recording
- [ ] Other

*Explain and justify full name and if it will be stored on paper or electronically:

The full name will be collected when consent is obtained. The name will be written on the paper consent form but will not be associated with the identification code assigned to the rest of the participant's data.

*Explain and justify telephone number and if it will be stored paper or electronically

Telephone number will be collected to be able to communicate with participants to set up testing sessions. Not all older adult participants will have email addresses.

*Explain and justify email address code and if it will be stored on paper or electronically

Email addresses will be collected to be able to communicate with participants to set up testing sessions.

*Explain and justify partial date of birth and if it will be stored on paper or electronically

Our study explores how cognitive functioning changes with age. We will collect date of birth to determine exact age of participants

*Explain and justify age and if it will be stored on paper or electronically

Our study explores how cognitive functioning changes with age. We will collect age to determine exact age of participants.

13.4

13.4 *Will there be a unique code linking identifiers to the study participant?

- (•) Yes
- ( ) No

*Who will have access to the code?

Only researchers listed on this application will have access to the unique code linking identifiers to the study participant.

13.5

13.5 *Where will information collected as part of this study be stored (applies to both paper copy and electronic copy)? (select all that apply)

- ☐ University or Hospital network drive
- ☑ University or Hospital local hard-drive
- ☑ Office/Lab of PI or Research team member on Institutional Property
- ☐ Laptop
- ☑ Memory Stick
- ☐ Cloud Storage
- ☐ Off-site
- ☑ Other

*Specify Other:

The CBS data will be stored on an encrypted disk partition at the internet service provider (ISP) server farm in Oregon, USA (as well as on the BMI mirror database - encryption details in 13.7 and 13.8). CBS data will be encrypted using the AES-256-CBC encryption scheme. Data can only decrypted by persons with access to all of the following: 1) the symmetric encryption keys, which are themselves encrypted using RSA2048; 2) the CBS application source code containing the RSA private key to decrypt the encryption keys; and 3) access rights (e.g., administrator userid and password) to the database in order to copy the encrypted data. Access to the databases is password protected, allowed only though secure tunnels that require secure SSH key files, and is restricted by a firewall. In previous studies, there have been no problems with malicious attacks on the CBS server. The CBS web platform is built using Ruby on Rails, and the above encryption schemes will be implemented using the SymmetricEncryption gem based on OpenSSL, which meets PCI compliance.

13.6

13.6 *Indicate the measures in place to protect the confidentiality and security of any study data including Personal Information (PI) or Personal Health Information (PHI) that is accessed, collected and used (select all that apply):

- ☐ Access to medical records and/or study data will be limited to authorized personnel
- ☑ Access to electronic data will be password protected and encrypted
- ☑ Electronic data will be stored on a Western, hospital or other institutional server with firewalls and other security and back-up measures in place
- ☑ Study data stored on external hard drive, laptop(s) and/or mobile device(s) will be encrypted
- ☑ Paper copies of study data will be stored in locked filing cabinets in a secure location
- ☑ A master linking log with identifiers will be stored separately from the study data
- ☐ Other

13.7

13.7 Describe where the electronic and/or paper copies for all data collected for this study will be kept (this will include signed Letters of Information and Consent; completed surveys; electronic databases)

Any paper surveys will be kept in a secure, locked cabinet at the Brain and Mind Institute.
All CBS task data and databases created from the paper surveys will be kept at the Brain and Mind Institute on an encrypted disk in a secure server.

13.8

13.8 *If participant information is stored on an external hard drive, laptop(s) and/or portable device(s), the device must be encrypted. Describe the encryption type and software being used.

Data will be encrypted using the AES-256-CBC encryption scheme (e.g. from Apple iOS).

13.9

13.9 *Please specify the study data custodian (who is responsible for maintaining the study data).

Avital Sternin will be responsible for maintaining the study data. The PI (Adrian Owen) has delegated the duty of maintaining the study data to Avital Sternin.

13.10

13.10 *Are you transporting materials (paper, devices and/or media) that include Personal Information (PI) and/or Personal Health Information (PHI) between sites? (See Confidentiality and Data Security guidelines)

- (●) Yes
- ( ) No

*Describe what safeguards you will have in place to ensure the safety of information being transported.

If data is collected offsite then paper copies will be transported in a secure, locked container. Any electronic data will be transported on an encrypted USB drive.

13.11

13.11 *Will you be sending/sharing data off-site for this study?

- ( ) Yes
- (●) No

13.12

13.12 *Who will have access to the identifiable data?

Only the researchers listed on this application will have access to the identifiable data.

13.13

13.13 *How long will you retain identifiable data?

- (•) 7 years as per UWO policy
- ( ) 15 years as per Lawson policy
- ( ) 25 years as per Health Canada policy
- ( ) Other

13.14

13.14 *How will you destroy the identifiable data after this period (if applicable)?

The key file linking individuals to identifier codes will be erased once data collection and analyses are completed using the secure data tool Eraser (http://eraser.heidi.ie/). Any paper with identifiable data will be shredded.

13.15

13.15 *Will you link the locally collected data with any other datasets, databases or registries (e.g., health registries, Statistics Canada)?

- ( ) Yes
- (•) No

13.16

13.16 *Is the purpose of this study to establish a registry/database?

- ( ) Yes
- (•) No

13.17

13.17 *Indicate the extent the study participant is able to withdrawal their study data from the research study and any limitations on the withdrawal

If a participant chooses to withdraw from the study, all data collection will be stopped and any data will be destroyed as descried in section 13.14

14.1

14.1 *Is this study funded?

- (•) Yes
- ( ) No

14.2

14.2 *How is the study funded?

- ☐ Industry
- ☐ Internal Grant (departmental/faculty, VP, IRF/SRF, etc.)
- ☑ External Grant (Tri-Council (e.g., CIHR, SSHRC, NSERC, NCE), government, charitable foundation, etc.)
- ☐ Other

*Specify External Funder(s):

Canada Excellence Research Chair (CERC), Dr. Adrian Owen, ROLA #0000025914

14.3

14.3 *Are any of the research accounts, for this submission, held at Lawson or Western University?

- ☐ Lawson
- ☑ Western University

*As funds for this study are held in a research account at Western please type in "Western Research Services" in the below Search User text box:

Name	Western
Email	gm-certification@uwo.ca

*For research award(s) held through Western, provide one of the following for each award supporting this study: (1)ROLA reference number, or (2)Agency reference number, or (3) Account speed code:

CIHR PIN#209907

14.4

14.4 *What is the status of funding from this source?

- ◉ Obtained
- ○ Awarded but not received

14.5

14.5 Indicate what compensation, if any, will be provided to participants and include a justification for compensation. If this question is N/A indicate so:

At the end of participation, participants who leave their information specifically for the raffle purposes will be entered into a raffle where multiple prizes will be available (for example, but not restricted to, gift cards valued at up to $100, gift baskets, etc). The chance of winning any of our prizes will be 1/100.

14.6

14.6 *Will participants be reimbursed for out of pocket expenses (e.g., parking, travel, food, etc.) incurred as a result of participation

- (•) Yes
- ( ) No

14.7

14.7 *In the event of a study related illness, injury or adverse event, who will cover out-of pocket expenses that is not covered by provincial or healthcare insurance (select all that apply)?

- [x] Sponsor
- [ ] Funder
- [ ] Institution
- [ ] Other

14.8

14.8 *Will the sponsor and/or institution and/or funder cover the cost of the investigational agent(s) used in the study for the duration of the study?

- ( ) Yes
- ( ) No
- (•) N/A

14.9

14.9 *Will the sponsor and/or institution and/or funder cover the cost of comparator drugs used in the study for the duration of the study?

- ( ) Yes
- ( ) No
- (•) N/A

14.10

14.10 *Are there mechanisms in place to provide ongoing access to the investigational agent post study if participant is benefiting from treatment?

- ○ Yes
- ○ No
- ◉ N/A

15.1

15.1 *Are translated participant materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.) included in this study and require HSREB approval?

- ○ Yes
- ◉ No

16.1

16.1 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal financial benefit in connection with this study?

- ○ Yes
- ◉ No

16.2

16.2 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) receive any personal (financial or otherwise) benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?

- ○ Yes
- ◉ No

16.3

16.3 *Is the PI or Co-Investigator(s) aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?

- ◉ Yes
- ○ No

*Describe the relationships, interests or incentives:

The Cambridge Brain Sciences Battery was created by Professor Owen. Although he has an unrestricted academic license to use this software he stands to gain nothing financially (or otherwise) from its use in this research project. The software was developed in his lab, primarily for research purposes, and is being used currently in numerous academic research studies. There is no conflict of interest.

*Describe the proposed management plan:

see specification above

16.4

16.4 * Is the PI to Co-Investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?

- ○ Yes
- ◉ No

16.5

16.5 * Does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?

- ○ Yes
- ◉ No

16.6

16.6 *Will or does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)

- ○ Yes
- ◉ No

16.7

16.7 *Are you or your institution the sponsor of this investigator-initiated/sponsored study?

- ◉ Yes
- ○ No

*Describe any real, potential, or perceived conflict of interest

This study is supported by a grant award to Dr. Owen. Although Dr.Owen is the sponsor of the study he does not stand to gain anything financially (or otherwise) from the completion of this study.

*Describe the proposed management plan:

N/A
see above

16.8

16.8 * Are there any other real, potential or perceived conflict of interest to declare to the REB?

- ○ Yes
- ◉ No

18.1

18.1 *Upload Principal Investigator Response to REB request for modification letter (if applicable):

Type	Name	File Name	Date	Version	Size
REB Response Letter	RevisionsReply	RevisionsReply.docx	03/Jan/2018 12:00:00 AM	1	218.4 KB
REB Response Letter	RevisionsReply - 2	Response to Revisions-2.docx	09/Jan/2018 12:00:00 AM	2	12.9 KB

18.2

18.2 If changes have been made to a previously submitted consent/assent form(s) at the request of the REB, upload track-changes versions of all proposed consent and/or assent form (e.g. screening, main, optional), if applicable:

Type	Name	File Name	Date	Version	Size
Tracked Changes Document	LOI_Consent-tracked	LOI_Consent-tracked.docx	22/Dec/2017 12:00:00 AM	2	582.3 KB

18.3

18.3 If changes have been made to a previously submitted study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.) at the request of the REB, upload the track-changes version(s):

Type	Name	File Name	Date	Version	Size
Tracked Changes Document	Demographic-track	Demographic-track.pdf	22/Dec/2017 12:00:00 AM	2	87.0 KB

18.4

18.4 Please provide any additional comments for the REB to consider (if applicable):

19.1

19.1 *Please confirm that if this is the first time you are submitting this particular application/event form to the REB, select “Initial Submission”. If this application form has already been reviewed by the REB and they issued recommendations, select “Response to REB recommendations”:

- ○ Initial Submission
- ◉ Response to REB recommendations

19.3

19.3 *Principal Investigator OR Delegate Signature:

The Principal Investigator may choose to sign off electronically on all **re-submissions** (i.e., response to REB recommendations) or he/she may delegate this task to another qualified individual. **NOTE:** The PI is still fully responsibility for the scientific and ethical conduct of the study at this institution.

- I attest that this application as submitted is in compliance with the TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND, if applicable, with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND, with all other applicable laws, regulations or guidelines (e.g., if applicable, Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that this application contains the current and complete protocol, including, if applicable, any sub-studies;
- I acknowledge that I am responsible for promptly reporting any of the following to the REB:
  - modifications or amendments, such as changes in PI, changes in Co-investigator (if

applicable), specific required changes to the Letter of Information/consent form, etc.;
    - all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the study;
    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - study completion or termination;
- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information (PHI)/Personal Information (PI) and the privacy of individuals with respect to that information;
- I will ensure that the PHI/PI is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of the study participants' personal information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the PHI/PI is maintained in accordance with the Personal Health Information Protection Act (PHIPA) and/or Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement

Signed: This form was signed by Ms. Avital Sternin (asternin@uwo.ca) on 09/Jan/2018 10:54