Human Ethics Application Form

Start Checklist

You must select at least one checkbox below. The responses you provide will determine if your application is exempt, low risk or more than low risk.

This project aims to specifically recruit from the following participant groups. *Tick all that apply.*

- ☐ Aboriginal and Torres Strait Islander (ATSI) participants
- ☐ Women who are pregnant and the human fetus
- ☑ People with a cognitive impairment, an intellectual disability, or a mental illness, e.g. brain injury, dementia, ADHD, ASD etc..
- ☐ People considered to be a forensic patient, an involuntary patient or a security patient
- ☐ People with impaired capacity for communication
- ☐ Prisoners or people on parole
- ☐ Children who are Wards of State
- ☐ People highly dependent on medical care including a person who is unconscious
- ☐ Military personnel and / or veterans
- ☐ Victoria Police personnel
- ☐ Hospital patients

And / Or the project involves any of the procedures below: *Tick all that apply.*

- ☐ Use of identifiable/coded health information or biospecimens without consent e.g. medical records, data linkage
- ☐ Any physical/psychological/social/economic or legal risks greater than inconvenience or discomfort, in either the short or long term, resulting from participation, or use of data in this project
- ☑ Innovative interventions or therapies e.g. administration of drugs, clinical or psychological treatments
- ☐ Sensitive / contentious issues e.g. suicide, eating disorders, body image, trauma, violence, abortion
- ☐ Radioactive substances / Ionising radiation e.g. DXA, X-ray
- ☐ Intends to study/expose illegal activity
- ☐ Human genetics
- ☐ Derivation of human embryonic stem cells
- ☐ Assisted reproductive technology
- ☐ Deception of participants, concealment or covert observation
- ☐ Seeking disclosure of information which may be prejudicial to participants

This project does not involve any of the participants or procedures listed above. *Selecting this option will uncheck any boxes you selected above.*

- ☐ None of the above

This project does not involve recruiting participants and will only involve: *Selecting any of the options below will uncheck the boxes you selected above.*

- ☐ Secondary analysis of existing non-identifible data
- ☐ Non-identifiable samples from a biobank

Application Details

Please note that most questions are mandatory and must be completed. If a question is not applicable, type NA in the text field. You will not be able to submit the form if you leave fields blank or questions unanswered.

A1 Project Title.

The project title will be retrieved from the main project.

The Gut Brain Axis in Huntington's Disease

The investigator field blocks are locked and can't be edited. The information is retrieved from the Monash University identity management system (SAP HR etc..).

A2 Chief Investigator Details

- **For student research projects, the main Monash supervisor should be listed as the Chief Investigator (CI).**
- The information below has been retrieved from the profile of the user creating this application. If this is not the CI, you must transfer the project to the CI who should submit it to MUHREC. Refer to the Manage an ethics Application Quick Reference Guide for instructions on how to transfer a project.

Title	First Name	Surname
Mr	Cory	Wasser

Organisation	Monash University (Student)
Department	Psychology
Faculty	Faculty Of Medicine, Nursing And Health Sciences
Campus	Clayton
Email	ciwas1@student.monash.edu

A3 Please list who we contact regarding questions related to the assessment of this project.

Full Name	Preferred phone number
Cory Wasser	0448774420

Other Investigators

Monash staff or students may not automatically show up in the directory and may need to log into ERM once in order for their profile to be created. This allows their name to come up in the search directory so you can add them and share or transfer applications to them.

A4 Other investigators involved in this research include:

Note: *adding investigators in this section will not automatically give them access to the application. You must share the project with them and set their access permissions as required.* Refer to the Manage an ethics Application Quick Reference Guide for instructions on how to share a project.

- [x] Co-investigator
- [ ] Project Co-ordinator
- [ ] Research Assistant
- [x] Student
- [ ] Other - external (non Monash)
- [ ] None

Please list all the co-investigators involved.

Title	First Name	Surname
Dr	Yifat	Glikmann-Johnston

Department	Psychology
Faculty	Faculty of Medicine Nursing & Health Sci
Email	Yifat.Glikmann-Johnston@monash.edu

Please list all students involved.

Student projects from the Faculty of Law must be reviewed by the Law Advisory Panel on Empirical Research prior to submission for ethical review. Refer to the help text on the right for further information.

Title	First Name	Surname
Mr	Cory	Wasser

Department	Psychology
Faculty	Faculty Of Medicine, Nursing And Health Sciences
Email	ciwas1@student.monash.edu

A5 Briefly outline the experience and qualifications of the research team that are necessary for the conduct of this research.

Maximum of 1500 characters including spaces.

Cory is a DPsych student who has significant experience with participant liaison and assessment in this particular clinical population throughout undergraduate studies. He is also the project manager of another research project related to Huntington's disease.

Background and Aims

A6 In plain language, provide a succinct description of the background and the potential significance of the research project.

Maximum of 2000 characters.

Huntington’s disease (HD) is an inherited neurological disorder affecting movements, cognition, and behaviour. Apart from these symptoms, there is strong clinical evidence of gastrointestinal problems. HD patients suffer from weight loss, abdominal discomfort, and fail to retain nutrition. The mechanisms behind these problems are unclear.

There is a plethora of emerging evidence suggesting a relationship between the gut and the brain. Altering the gut microbiome was found to have beneficial effects on cognition, behaviour, and psychiatric symptoms in a variety of diseases and conditions. Despite strong clinical indications of gut problems in HD, the gut microbiome is yet to be characterized, and research has not investigated the gut as therapeutic target in HD.

A7 Clearly state the aims and/or hypotheses of the research project.

Maximum 2000 characters, including spaces

Aims and Hypotheses:

Aim One: To characterize the gut microbiome (proportions of E. coli, Enterobacteriaceae and Prevotellaceae) in pre-symptomatic and symptomatic HD, compared to healthy controls.
H1: We expect overall levels of Prevotellaceae to be lower and levels of E. coli and Enterobacteriaceae to be higher in the pre-symptomatic and symptomatic HD groups compared to controls.

Aim Two: To examine the relationship between the gut microbiome (E. coli, Enterobacteriaceae and Prevotellaceae), cognitive function (memory, executive functioning and psychomotor functioning), and psychiatric symptoms (depression and anxiety).
H1: We expect cognitive function to be positively associated with proportion of Prevotellaceae and negatively associated with proportion of Enterobacteriaceae and E. coli.
H2: We expect symptoms of depression and anxiety to be positively associated with proportion of Enterobacteriaceae and E. coli and negatively associated with proportion of Prevotellaceae.

Aim Three: To test whether the probiotic intervention will alter the gut microbiome (proportion of E. coli, Enterobacteriaceae and Prevotellaceae), cognition (memory, executive functioning and psychomotor functioning), and psychiatric symptoms (depression and anxiety) in pre-symptomatic HD, symptomatic HD and healthy controls.
H1: We expect that gut microbiome, cognition and psyhicatric symptoms measured at baseline to improve following probiotic intervention.

Research Scope

A8 This research involves:

Tick all that apply. To avoid delays in assessment, you must tick at least one of the boxes below.

- [x] Recruitment or observation of human participants
- [x] Use of existing data or biospecimens

A8(i) The project also involves:

Tick all that apply and only if applicable to this research.

- [x] Clinical Trial
- [ ] Genetic testing or analysis of genetic material
- [ ] Administration of ionising radiation

Benefits and Risks

A9 Please outline the benefits to participants and /or to the community as a result of this research being conducted.

Our study will be the first to characterize the gut microbiome in HD. Additionally, we will examine the gut microbiome in pre-symptomatic and symptomatic HD, which may provide valuable understanding about disease progression. Despite strong evidence in animal model studies, highlighting the interplay between the gut microbiome and cognition, there is lack of translation between these studies and evidence in humans. We intend to address this gap, by assessing cognition and executive functioning in the context of a randomized controlled trial.

Risks

A11 Outline any potential risks, in either the short or long term, of participation in this project.

e.g. physical, psychological, social, economic or legal risks greater than inconvenience or discomfort.

Whilst we do not anticipate any risks arising from this project some participants may experience some discomfort when providing biospecimens in the form of stool samples. Additionally, some participants may experience very minor discomfort when consuming the probiotic substance (people with lactose allergies or intolerance will be exlcuded).

A12 Are all these risks outlined on the Explanatory Statement and, where relevant, on the Consent Form?

- (•) Yes
- ( ) No

A13 Is an appropriate list of counselling services included in the Explanatory Statement?

- (•) Yes
- ( ) No

A14 Outline the arrangements planned to minimise the risks involved in these procedures.

Risks will be minimized by ensuring that participants understand the explanatory statement of our study. The exclusion criteria will minimize the majority of risks, as participants who may experience discomfort when taking the probiotic supplements will be excluded. Additionally, an appropriate list of counselling services is provided if participants experience significant stress or discomfort.

Risk Management

A15 What will you do in cases where serious events or emergencies occur as a result of participation in this project and what facilities are available to deal with such incidents?

Whilst serious events are not an anticipated, the researchers involved in the project are experienced in conducting research and have appropriate skills to deal with any distressing events (such as participants feeling distressed). Counselling services are also provided. The researchers will also be following up on participants weekly to ensure that everything is going well and that there are no adverse reactions to the probiotics supplements.

A16 Please outline the strategies you have in place to reduce any risks to the researchers.

Please include in your response whether an OHS risk assessment has been prepared. You can attach a copy as supporting document at the end of the form in QK1.

The researchers will conduct the testing session at Monash university and will thus be near other staff and colleagues in case a risky situation arises. Researchers will also keep the mobile phones (containing security numbers and staff numbers) on at all times in case an emergency text or call is needed. Testing will always take place in between the hours of 9am-5pm.

A17 Is this research project likely to reveal information relating to child sexual abuse that must be disclosed to police?

- ( ) Yes
- (•) No

Project Details

A18 Is this project related to other Monash University human ethics applications?

- ○ Yes
- ◉ No

A19 Will this project be submitted to other Human Research Ethics Committees (HRECs)?

- ◉ Yes
- ○ No

Please provide details in the table below. You must inform all other HRECs that you are applying to MUHREC for approval.

The Research Ethics and Ethics Committee (REEC) at Calvary Health Care Bethlehem (CHCB).	○ Approved ◉ Pending

---

To add another HREC, click the "Add another button below.

Type of Research

A20 Type of Research:

- ☐ Staff research
- ☑ Student research
- ☐ Unit project

A20(i) Select the degree:

- ☐ Honours
- ☐ Masters
- ☐ PhD
- ☑ Other

Please provide the full title of the degree.

Doctor of Psychology in Clinical Neuropsychology

A21 Type of Research - 2

- ☐ Action Research
- ☑ Clinical Research
- ☐ Epidemiological
- ☐ Medical Research
- ☐ Public Health and Safety
- ☐ Quantitative
- ☐ Case study
- ☐ Qualitative
- ☐ Oral history / Biographical
- ☐ Social Science
- ☑ Clinical Trial/use of drug or therapeutic device
- ☐ Other

Other Organisations

A22 Does your research involve recruiting participants or collecting data at other organisations?

- ◉ Yes
- ○ No

Please provide details in the table below. To add another organisation, click the "Add another" button.

Organisation	Contact name	Position
Calvary Health Care Bethlehem Hospital	Ruth Hosken Nurse Statewide Progressive Neurological Disease Service	

Financial Details

A23 Do any of the investigators have a personal or financial interest in a) the outcome of this research, b) any of the organisations involved with the research, or c) any of the organisations funding this project?

- ○ Yes
- ◉ No

A24 Has external funding been obtained for this project?

- ○ Yes
- ◉ No

Participant Groups

B1 Describe who the participants in each group are and where they will be recruited from.

Participant group	Recruited from	No. of participants
Pre-symptomatic & Symptomatic Huntington's Disease Participants	Calvary Health Care Bethlehem & ENRU-CCN Database	40

To add another group, click the "Add Another" button below.

Participant group	Recruited from	No. of participants
Healthy Controls	Monash Memo, ENRU-CCN Database & MICCN's Sona Research Participation System.	30

To add another group, click the "Add Another" button below.

B2 Are any participants children under 18 years of age?

- ○ Yes
- ◉ No

Participant Details

B5 Is there a pre-existing (unequal) relationship between anyone involved in recruiting and/or collecting data and anyone from any of the participant groups?

e.g. teachers/students, health care providers/patients.

- ○ Yes
- ◉ No

B6 Does this research involve people in countries other than Australia?

- ○ Yes
- ◉ No

B7 Do any of the participant groups have any cultural needs?

- ○ Yes
- ◉ No

B8 Do you have any criteria for exclusion from any of the participant groups listed in B1 above?

- ◉ Yes
- ○ No

Please list the relevant groups and describe and justify this exclusion.

Group (as listed in B1)	Exclusion criteria
1. Symptomatic and Pre-symptomatic Huntington's disease. 2. Healthy Controls.	Exclusion criteria for all participants include inability to consume daily dosage of probiotics (due to lactose intolerance or other difficulties), diagnosis of any other major neurological disorder, traumatic brain injury, drug or alcohol dependency (in the last 3 months), recent diagnosis of major depression or psychosis, consumption of oral antibiotics (in the past 6 months), daily consumption of probiotic or fermented foods (foods preserved in high amounts of bacteria) within six weeks prior to the study.

To add another group, click the "Add Another" button below.

Recruitment Methods

B9

Indicate which method(s) you will use to recruit participants for this research:

- ☑ Email
- ☐ Personal contacts
- ☑ Advertisement
- ☐ Participants from previous study
- ☐ Participants will be observed without their knowledge and will not be actively recruited
- ☐ Mail out
- ☐ Snowballing
- ☑ Telephone
- ☐ Participants approached in person
- ☐ Other

Please note that you cannot recruit Monash University students who were enrolled prior to 2016 via their student email accounts.

Inviting Participants

B10 Indicate how you will obtain the contact details of potential participants:

- ☐ From the participants themselves
- ☐ From a public domain source
- ☐ From a private or third party source
- ☑ Other

Other: Please clarify how you will obtain these contact details.

Huntington's disease or healthy control participants who have voluntarily registered on the ENRU-CCN database (a database for people with HD and healthy controls to participate in research) will be contacted after their phone or email have been forwarded or if they have indicated their interest in participating in research are reading a poster advertisement at Calvary Health Care Bethlehem Hospital.

Healthy controls will also be contacted if they have expressed interest in participating from either the Monash Memo or MICCN's Sonar system.

B11 For each group listed in B1 above, please explain who will invite potential participants to be involved in this project and how will they be invited.

Participant group	Invite details
pre-symptomatic and symptomatic Huntington's disease	Participants will be invited to participate in the study after speaking with Cory Wasser (student researcher). They will initially be contacted via either phone or email to confirm their interest in the study. They will then be asked (over the phone) a variety of questions to ensure that they are eligible and willing to participate in the study.

Participant group	Invite details
Healthy Controls	Participants will be invited to participate in the study after speaking with Cory Wasser (student researcher). They will initially be contacted via either phone or email to confirm their interest in the study. They will then be asked (over the phone) a variety of questions to ensure that they are eligible and willing to participate in the study.

Reimbursement of Participants

B12 Will you be offering payment or any other incentives to any of the participants?

- ◉ Yes
- ○ No

Please explain how much, what form the incentive will take and justify why this will not be an inducement.

Maximum 2000 characters.

All participants will be reimbursed $50 for attending each testing session (two testing sessions in total). Participants are being reimbursed for their time as well the expense of travelling to Monash University.

Explanatory Statement

B13 Will you use a written Explanatory Statement to inform the participants about this project?

Please refer to the Monash Explanatory Statement template and modify to suit your project.

- (•) Yes
- ( ) No

Please upload a copy of the Explanatory Statement(s). If you have multiple documents for different groups of participants, please clearly label each Explanatory Statement for ease of reference.
To upload more than one document, click the "Upload Document".

Type	Name	File Name	Date	Version	Size
Explanatory Statement	Explanatory Statement HD 2017	Explanatory Statement HD 2017.doc	17/04/2017 12:00:00 AM	1	150.5 KB
Explanatory Statement	Explanatory Statement Control 2017	Explanatory Statement Control 2017.doc	17/04/2017 12:00:00 AM	1	150.5 KB

Limited Disclosure or Deception

B14 Will all participants in this research be fully informed about the true nature of the research?

- (•) Yes
- ( ) No

Consent Process

B15 Please clarify how you will obtain informed consent from participants?

Please refer to the Monash Consent Form template and modify to suit your project.

- [ ] Implied Consent
- [ ] Opt-Out Consent
- [x] Consent Form
- [ ] Other

Please explain the process by which the participants will give consent and how will they return the consent form to the researchers.

Participants will first read the explanatory statement. Researchers will clarify anything if needed. Participants will then read the informed consent form, tick the boxes and sign and date there consent. If anything is unclear the researchers will ensure that the participant is fully informed before signing the consent. Participants are also free to withdrawn at anytime and there participation is entirely voluntary.

Please attach a copy of the Consent Form(s). If you are using multiple forms, please ensure you clearly label each document. To upload more than one document, click the "Upload Document".

Type	Name	File Name	Date	Version	Size
Consent Form	Consent Form GBA Study	Consent Form GBA Study.docx	17/04/2017 12:00:00 AM	1	298.4 KB

Capacity to Consent

B16 Are all the participants in this project able to consent for themselves?

- (•) Yes
- ( ) No

Data Collection

C1 This research will include the following data collection methods:

- [x] a) Questionnaires / Surveys
- [ ] b) Interviews
- [ ] c) Photography / videography
- [ ] d) Focus groups
- [ ] e) Observations
- [x] f) Psychological inventories
- [x] g) Responses to tasks or stimuli
- [x] h) Collection of biospecimens
- [ ] i) Administration of radiation
- [x] j) Administration of a substance
- [ ] k) Other

Data Collection Details

C1a Please provide details about the questionnaires / surveys and how these will be returned, e.g. paper based or online surveys, fully identifiable, coded surveys (potentially identifiable) or anonymous (can never be identified).

Participants will be assigned a research ID prior to the commencement of testing. All tests will be completed either on paper or pencil or on a CANTAB tablet. Data will be completely unidentified. Participants will complete a demographic questionnaire and also a weekly food and bowel habits diary.

Please upload a copy of the questionnaires / surveys.

Type	Name	File Name	Date	Version	Size
Questionnaires / Surveys	Demographic Questionnaire	Demographic Questionnaire.docx	17/04/2017 12:00:00 AM	1	574.7 KB

C1f Please provide details about the Psychological inventories - the Committee is unable to assess the risks without access to the inventories.

Participants will complete the State-Trait Anxiety Inventory and the Self-Report Depression Scale. These measures are both validated in the assessment of depression and anxiety in various populations (including Huntington's disease). Inventories cannot be uploaded due to copyright issues.

Please upload a copy of the inventories.

C1g Please provide details about the Tasks, Stimuli or Simulations.

Participants will complete the following tasks:
• Emotion Recognition, (Stout, 2014)
• Hopkins Verbal Learning Test (HVLT-R; Brandt & Benedict, 2001)
• Paced Tapping Test (PTAP; Julie C Stout et al., 2014)
• Symbol Digits Modalities Test (SDMT; Smith, 1968)
• Trails Making Test Parts A and B (TMT; Reitan, 1955)
• One Touch Stockings of Cambridge (OTS; CANTAB, 1996)

These tasks are validated in the neuropsychological assessment of cognitive, psychomotor and executive functioning.

C1h Please provide details about the collection of human biospecimens and the protocols used.

Subjects will be supplied with fecal collection tubes kits with at baseline & 6 weeks post-intervention. gDNA & amplicon diversity profiling will be conducted on fecal matter and separated into different species of bacteria by the Australian Genome Research Facility.

C1j Please provide details about the Administration of a Substance including the protocol that will be used.

Participant Groups and Data Collection Methods

C4 Please list in the table below which of the method(s) indicated in C1 will be used for each group of participants.

Participant group	Relevant data collection method(s)
Symptomatic and presymptomatic Huntington's disease Participants	All methods in C1 will be used.

To add another group of participants, click the "Add Another" button.

Participant group	Relevant data collection method(s)
Healthy Controls	All methods in C1 will be used.

To add another group of participants, click the "Add Another" button.

Research Procedures

C5 Please provide details about what you are asking participants to do or what is to be done to them.

Include a step-by-step description of what participants will experience if they choose to take part in this project.

All participants will initially undergo a pre baseline assessment session to control for practice effects. Participants will be divided randomly into two groups and will receive either the milk containing probiotic mixture (intervention group) or plain milk (placebo group) for a period of 6 weeks. Participants will be requested not to alter their physical activity, diet or nutritional supplement intake during this time. A food and exercise diary will be recorded at baseline and every 2 weeks to monitor lifestyle factors. Gut microbiome analysis, cognitive and psychiatric measures (see measures) will be completed at baseline and 6 weeks post-intervention. Participants will supply stool samples using a stool analysis kit at baseline intervention and 6 weeks post intervention.

C6 How much time are you asking of participants and when will the time be required?

E.g. 30 min after class

Duration of testing is approximately one and half hours for each session and 1 hour for pre-assessment. Total time of 4 hours (pre-assessment = 1 hour, baseline = 1.5hours and post-assessment = 1.5 hours).

C7 Where will the data be collected and by whom?

E.g. Public library, University meeting room.

Demographic and neuropsychological data will be collected at Monash University by Cory Wasser. Stool samples will be collected at home by participants and then sent to the Australian Genome Research Facility.

Procedures and Qualifications

C8 Does the research involve the administration of any tests or procedures that require particular qualifications?

- ○ Yes
- ◉ No

C9 Does the research involve measures or procedures that are diagnostic or indicative of any medical or clinical condition, or any other situation of concern?

- ◉ Yes
- ○ No

C9(i) Please describe the criteria you will use to assess when participants in your research have results indicating that they or others are 'at risk'.

Participants who score in the severe-high ranges in measures of depression and anxiety (STAI & self-report depression scale), would be identified as "at risk".

C9(ii) How will you deal with your duty of care to participants in your research identified as 'at risk'?

Participants will be offered a list of available counselling services. In the event of an emergency the chief investigator (Professor Julie Stout) will be notified and appropriate action will be taken.

C9(iii) Have you acquired the necessary competence to administer, score and interpret the proposed measures and procedures, with the type of participants being used in this research?

- (•) Yes
- ( ) No

C9(iv) Will you indicate the procedure(s) proposed above to potential participants in your Explanatory Statement?

- (•) Yes
- ( ) No

Existing Data or Biospecimens

E1 This research involves the use of existing identifiable:

- [ ] Data previously collected by an another organisation or government agency
- [ ] Data previously collected by any of the current investigators for another project
- [ ] Data previously collected by other investigators for another project
- [ ] Human biospecimens

Clinical Trials

G1 Type of Trial

- [x] Drug
- [ ] Device
- [ ] Other

Please complete the Clinical Trial Detail (CTD) form and attach below.

G2 Please specify the number of participants anticipated for this trial.

70

G3 Please specify the number of sites at which this trial will be conducted.

1

G4 Is this clinical trial to be conducted in Australia?

- (•) Yes
- ( ) No

Please specify the states in which this trial will be conducted.

Victoria

Sponsor and Agreements

G5 Is Monash University the sponsor of this clinical trial?

- ○ Yes
- ◉ No

G6 Is Monash University named on the Clinical Trial Agreement (CTA)?

- ◉ Yes
- ○ No

Please upload a copy of the CTA.

G7 Is Monash University indemnified by the Sponsor in the CTA?

- ◉ Yes
- ○ No

G8 Does the project have separate Clinical Trial Insurance?

- ○ Yes
- ◉ No

G9 Is Monash University named on the Clinical Trial Notification (CTN) / Clinical Trial Exemption (CTX)?

- ○ Yes
- ○ No
- ◉ Not Applicable

Drug Details

G10 Please complete the questions below for each drug. Include investigational and non-investigational drugs.

(i) Name of the drug.

(ii) Is the drug included on the Australian Register of Therapeutic Goods (ARTG)? If Yes, under what name is the drug registered?

(iii) Is the application of the drug proposed in this project different from the application(s) of the drug included on the ARTG? If Yes, provide justification, including a summary of the most up-to-date information, to support the unregistered use in this project.

(iv) Has the drug been registered/licensed/approved for marketing for this application by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)? If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the drug.

(v) Has the drug been registered, licensed or approved for marketing for other applications by an accepted international regulatory authority (other than the Australian Therapeutic Goods Administration)? If Yes, identify countries and/or regulatory authorities that have registered, licensed or approved the drug and give details of the other application(s) for which the drug is registered, licensed or approved.

(vi) Has the drug been reviewed for investigational or research uses by an international regulatory authority? If Yes, provide evidence of the review (including country and, if applicable, the regulator's identification number).

(vii) Did the international regulatory authority raise any objections? If Yes, give details

(viii) Have all the issues raised by the international regulatory authority been satisfied? If Yes, please provide details.

To add another drug, click the "Add Another" button.

Privacy and confidentiality

H1 The research involves:

- [x] Identifiable personal information (e.g. consent forms with names etc..)
- [ ] Re-identifiable / CODED personal information
- [ ] Observation of participants
- [ ] None of the above

H2 Will the personal information or observations be used without the consent or knowledge of the individuals?

- ( ) Yes
- (•) No

Data access and security

I1 Describe the security arrangements for the storage of the data. Include details of where the data will be stored and who will have access to the information?

All paper and pencil tests will be stored in a locked filing cabinet. Tests on the tablet will be de-identified and data will be stored on a secured USB. The USB will remain in the locked filing cabinet at all times (except when it is being used for other participants). Only the student research and chief investigator will have access to the information.

I2 Will a non-Monash third party have access to the data during this research?

e.g. using online survey tools such as Survey Monkey, translators or external data analysis/processing.

- ( ) Yes
- (•) No

I3 Will the research findings be made accessible or publicly available?

- (•) Yes
- ( ) No

Please explain how and what will be shared.

Research findings will be made available in the form of future publications. All information will be de-identified.

I4 Are the data access and security arrangements detailed in the Explanatory Statement and Consent Form?

- (•) Yes
- ( ) No

I5 How will the data be disposed of if it is no longer required?

After 5 years paper and pencil data will shredded and disposed of. Tablet information will be securely deleted.

Research outcomes

J1 Please indicate the format(s) in which the research will be published and/or communicated to participants or organisations.

- [x] Thesis
- [ ] Book / Book chapter
- [ ] Dataset
- [ ] Report to organisation
- [ ] Other
- [x] Journal article
- [ ] Conference
- [ ] Report to participants
- [ ] Report to community or group

J2 Please describe how participants and organisations will be able to access to the results.

Results will be published in the form of journal articles and a thesis (by publication).

J3 In what format will others be provided with the results?

- [x] In totally deidentified summary form, in which no individual can be identified.
- [ ] In deidentified summary form, but in a manner which may allow some individuals to be identified.
- [ ] In identified form, or in a manner which may allow some participants to be identified.
- [ ] Other

Documents

K1 Please attach other relevant supporting documents e.g. interview questions or topics, focus group topics, advertising flyers, permission letter, OHS risk assessment, etc..

Type	Name	File Name	Date	Version	Size
Supporting Documentation	Demographic Questionnaire	Demographic Questionnaire.docx	17/04/2017 12:00:00 AM	1	574.7 KB
Supporting Documentation	GBA Flyer	GBA Flyer.pdf	17/04/2017 12:00:00 AM	1	285.3 KB

K2 For projects from the School of Public Health

Please upload a copy of the protocol with this application. Please note that any amendments to this protocol should include the new version numbers and should be submitted using track changes.

Declarations

By submitting this project, I/We, declare that I/We:

Signatures are no longer required for human ethics applications. Please ensure that you check all the boxes below.

- ☑ accept responsibility for the ethical conduct of the research detailed above in accordance with the principles outlined in the National Statement and the Australian Code for the Responsible Conduct of Research.
- ☑ undertake to conduct this research project in accordance with the protocols and procedures outlined in this proposal as approved by MUHREC.
- ☑ inform MUHREC of any changes to the protocol after the approval of the Committee has been obtained by submitting an Amendment.
- ☑ have read and agree to comply with the Monash Research Data Management Policy and have a plan for managing and/or sharing Research Data securely.
- ☑ understand and agree that study files and documents and research records and data may be subject to inspection by MUHREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.