Human Research Ethics

Introduction

Completing the form

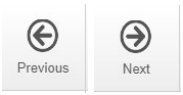
This application can be completed by any member of the research team but will require sign-off from the Principal Investigator if they are not submitting the form.

Before starting the application please complete the Risk Assessment and Pre-Application Acknowledgements which follow.

In completing the application, it is recommended researchers consult all relevant information or guidance built into this application, as well as the accompanying [user guide].

Saving the form

This form will save when you navigate through the sections using the 'Previous' and 'Next' buttons on the 'Actions' menu.



The form can be saved manually by clicking the 'Save' button on the 'Actions' menu. It is recommended that you save the form regularly to avoid changes being lost, as you will be logged out of the system after periods of inactivity.

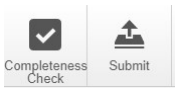
Please note: You will be logged out of the system after periods of inactivity, please ensure you save the form periodically using one of the methods described above to ensure you do not lose your work.

Submitting the form

Once the form is complete and you have uploaded all supporting documentation, you are ready to submit the form.

Prior to submission, you can check that all compulsory questions have been answered by clicking the 'Completeness Check' button on the 'Actions'menu.

Once all the questions have a valid response, click the 'Submit' button on the 'Actions' menu.



Additional assistance

If you require additional assistance, please consult the FAQ and user guide or contact humanethics@rmit.edu.au.

Acknowledgements

Before completing this form, the researchers acknowledge that:*

1. The information provided in this application, including any personal, sensitive or health information, will be handled responsibly and in accordance with applicable privacy laws and University policy. For more information refer to the RMIT Privacy Statement.
2. Research activities must not commence until ethics approval has been provided.

☑ I acknowledge the above statements

Application Type

The following Risk Assessment will assist researchers in determining the level of risk associated with the human research project or activities being undertaken.

The National Statement recognises three risk levels for human research:

Negligible risk – human research involving only a risk of inconvenience

Low risk - human research involving only a risk of discomfort

More than Low Risk – human research involving a risk of harm.

The risks that inform this assessment may apply to the research participants, the research topic, the research method or procedures, or other aspects of the research. Further guidance and tools can be found on the Researcher Portal [link to guidance and decision tree in Researcher Portal]

S1 Application Type *

- ☑ Standard Application
- ☐ Coursework Application
- ☐ Labwork Application

Risk Assessment

Item	Information
Human Biospecimens	This includes any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person (National Statement 3.2).
Human Embryos	Research involving the derivation of embryonic stem cell lines or other products from a human embryo must be considered by a Human Research Ethics Committee (HREC) as part of a licence application to the Embryo Research Licensing Committee (see Part C of the ART guidelines). (National Statement 3.2).
Exposure of Illegal Activity	National Statement 2.3.4 Only a Human Research Ethics Committee (HREC) can review and approve research that: a) involves active concealment or planned deception or b) aims to expose illegal activity.
Clinical trial	A research study designed to find out the effects of one or more health related interventions on health outcomes of human participants. This includes treatments or diagnostic procedures.
Concealment or limited disclosure	Not disclosing to research participants all of the aims and/or methods of the research. This covers a spectrum of practices from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants (see below).
Deception	Where relevant material is withheld from research participants and/or they are intentionally misled about procedures and/or purposes of research.
Genomic data	Raw data, processed data or information that has been subject to a process of critical analysis and/or interpretation to assign meaning in the context of genomic research.
Human genetics (genomic research)	Research generating, gathering, collecting, conveying or using genomic data or information that has hereditary implications and/or is predictive of future health in research involving participants, relatives and other family members.
Opt-out approach	An approach used in human research where information is provided to potential participants regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate.
Waiver of consent	A waiver of consent is a process by which the requirement to obtain individual and explicit consent from participants for the use of their data and/or biospecimens in human research is waived.

Will this research involve the following?

S2.1	Interventions and/or therapies, including clinical and non-clinical trials, and innovations *	○ Yes	◉ No
S2.2	Human Genetics *	○ Yes	◉ No
S2.3	Human biospecimens *	○ Yes	◉ No
S2.4	Human embryos and/or gametes, including the derivation of human embryonic stem cell lines *	○ Yes	◉ No
S2.5	Active concealment or planned deception *	○ Yes	◉ No
S2.6	Exposure of illegal activity *	○ Yes	◉ No
S2.7	An opt-out approach for collection and/or use of personal health information or personal information in health or medical research *	○ Yes	◉ No
S2.8	A waiver of consent for research where the research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research *	○ Yes	◉ No

Item	Information
Cognitive impairment	When a person has difficulty remembering, learning new things, concentrating, or making decisions that affect everyday life. Cognitive impairments can range from mild to severe.
Highly dependant on medical care	Persons receiving medical care (interventions or treatment) at a time of serious risk to their life or wellbeing. For example, neonatal intensive care, terminal care, emergency care, intensive care and the care of unconscious people.
Intellectual disability	A disability which is characterized by significant limitations both in intellectual functioning (reasoning, learning, problem solving) and in adaptive behaviour (everyday social and practical skills). Intellectual disabilities develop before adulthood and can range from mild to profound.
Mental illness	A general term that refers to a group of illnesses or health problems that significantly affect how a person feels, thinks, behaves, and interacts with other people and which is diagnosed according to standardised criteria.

Will your research involve recruitment of the following groups?

S2.9	Women who are pregnant and the human foetus *	○ Yes	◉ No
S2.10	People highly dependent on medical care who may be unable to give consent *	○ Yes	◉ No
S2.11	People with a cognitive impairment, an intellectual disability, or a mental illness *	○ Yes	◉ No
S2.12	Aboriginal and Torres Strait Islander Peoples or Communities *	○ Yes	◉ No
S2.13	People who may be involved in illegal activities *	○ Yes	◉ No

Item	Information
Physical Harms	This includes any risk of physical injury, illness or pain.
Psychological harms	This includes feelings of worthlessness, distress, guilt, anger or fear related, for example, through disclosure or discussion of sensitive or embarrassing information, devaluation of personal worth through humiliation, manipulation or being treated disrespectfully or unjustly, or learning about genetic disorder or predisposition.
Social harms	This includes damage to people's social networks or relationships with others, discrimination in access to benefits, services, employment or insurance, social stigmatisation, and findings of previously unknown paternity or maternity status.
Economic harms	This includes the imposition of direct or indirect costs on participants.
Legal harms	This includes discovery and prosecution of criminal conduct.

Is there potential that this research has the potential to cause or lead to

S2.14	Physical harms? *	○ Yes	◉ No
S2.15	Psychological harms? *	○ Yes	◉ No
S2.16	Social harms? *	○ Yes	◉ No
S2.17	Economic harms? *	○ Yes	◉ No
S2.18	Legal harms? *	○ Yes	◉ No

Data Access and Use

S2.19 Will this research involve use of secondary non-identifiable data (no identifiable or re-identifiable data) only? * ○ Yes ◉ No

Based on your selections, this research is considered *Low Risk* and will be considered by the relevant College Human Advisory Network (CHEAN). Please select *Low Risk* in the pathway below

Pathway

Based on your responses to the Risk Assessment, please select the pathway below *

S3

- ☐ Negligible Risk
- ☑ Low Risk
- ☐ More than Low Risk / Other

1.1 Project Summary

1.1.1 Project Title *

Extending the Theory of Planned Behaviour via Positive and Negative Reinforcement to Better Understand Alcohol Use Disorder

1.1.2 Provide a brief plain language description of the proposed project or activity, including the overall aim *

This study extends the Theory of Planned Behaviour to better explain the use and misuse of alcohol consumption. There is support in the literature for positive and negative reinforcement to explain drinking behaviour and it is anticipated that adding these concepts will increase the explanatory power of the model to improve treatment outcomes.

The proposed study attempts to build an improved model to explain the transition of non-problematic to problematic alcohol consumption in the adult population (18+). Previous studies have examined intention, attitudes, societal norms, perceptions of control, past behaviour (Theory of Planned Behaviour; Ajzen, 1991) and positive (enhancement) and negative (drinking to cope) reinforcement (Operant Conditioning, Skinner, 1958; Copper et al., 1994) in separate studies with mixed results. This study combines these theories to build a model that may better explain the aetiology of alcohol use disorder (AUD) across low, medium, and high groups. Following the trends of Farber et al. (1980) and Cho et al. (2019), it is anticipated that negative reinforcement will become more pronounced in the high AUD group compared to the low and medium AUD groups.
On the basis of previous research, the following hypotheses were formulated:

Hypothesis 1.
It is hypothesized that the Theory of Planned Behaviour predicts a statistically significant linear relationship in binge-drinking behaviour in the low, medium and high AUD groups.
Hypothesis 2.
It is hypothesized that there is a statistically significant interaction effect between past behaviour and binge- drinking behaviour in the high AUD group.

Hypothesis 3.
It is hypothesized that negative reinforcement predicts a statistically significant linear relationship in binge- drinking behaviour in the high AUD group.
Hypothesis 4a.
It is hypothesized that there is a statistically significant difference in the negative reinforcement mean scores in the high versus low and medium AUD groups.
Hypothesis 4b.
It is hypothesized that there is a statistically significant difference in the positive reinforcement mean scores in the low versus medium and high AUD groups.

1.1.3 **Provide a brief rationale for the proposed project or activity** *

Mewton et al. (2010) showed that 11.1 % of young adults (16-24 years) in Australia met the criteria for AUD in the Diagnostic and Statistical Manual of Mental Disorders (4th ed., DSM-4, American Psychiatric Association, 2007). This demographic is more at risk of AUD compared to older cohorts in Australia. AUD is associated with comorbid psychopathology (e.g. depression, anxiety) and presently, there is limited aetiology on AUD in Australia. This study attempts to address this gap in understanding.
AUD has a ripple effect on society. AUD affects family members, friends, the workplace, schools, and the community as a whole. AUD can lead to intoxicated driving, unsafe sex, anti-social behaviour, and domestic violence. Past studies have shown that while alcohol may not cause domestic violence, it appears to make the violence worse (Graham, 2011). One benefit of this study is that additional findings may bring the government closer to allocating funds to create more effective treatment programs to increase safety and to offer greater protection to vulnerable populations, e.g victims of domestic violence.
This research contributes to a larger body of empirical knowledge that may benefit society in the future. As this knowledge accumulates, it may create a mounting body of empirical evidence suggesting a different approach, which may help those who are most vulnerable and in need of more effective treatment programs.
The research design is an online cross-sectional survey, and it is anticipated that the accrual of knowledge from this research will far outweigh the potential distress that may arise during the course of the questionnaire.

1.1.4 **Category of Project or Activity** *

Tick all applicable

- ☐ Research (Staff)
- ☐ Research (HDR Candidate)
- ☐ Contract Research
- ☐ Masters by Coursework
- ☑ Honours
- ☐ Other

1.2 Institutions

1.2.1 **Is the project single-institution or multi-institution?** *

- ◉ Single-institution (RMIT only)
- ○ Multi-institution (RMIT and other sites)

1.3 Project Funding

1.3.1 **Does or will this project have funding?** *

- ○ Yes
- ◉ No

1.4 Research Review

1.4.1 **Has this research been reviewed or evaluated by people external to the project?** *

- ○ Yes
- ◉ No

1.5 Location

1.5.1 **Where will the research procedures be conducted?** *

☑ Australia ☐ Overseas ☑ Online

1.6 Project Duration

1.6.1 **Duration of project or activity (in months)** * 6

Anticipated Start Date *

1.6.2 ○ Specific Date ◉ Upon ethics approval

Anticipated End Date *

1.6.3 ◉ Specific Date ○ Three years from date of approval (Max)

1.6.3.1 Enter end date * 30/11/2020

Adding Investigators

In order to list an RMIT staff member or student as an investigator, they must have previously logged into the Research Ethics Platform. Once they have logged in, their account will be created and details updated from the staff and student systems **overnight**.

2.1 Principal Investigator

Principal Investigator Details *

2.1.1 Title * DR

2.1.2 First Name * Merv

2.1.3 Last Name * Jackson

2.1.4 School * School of Health and Biomedical Sciences

2.1.5 College: Science, Engineering and Health

2.1.6 Campus: B201

2.1.7 Position: Senior Lecturer

2.1.8 Staff ID *: E50587

2.1.9 Email *: merv.jackson@rmit.edu.au

2.1.10 **College** *: Science, Engineering & Health

2.1.11 **Research Activities** *: Supervisor responsible for this honours project

2.1.12 **Expertise and Experience** *: I have supervised 10 Ph D to completion and over nearly 100 honours theses to completion

2.1.13 **Education or Training** *: I have completed all of the required online research modules

2.2. Other Investigators

Does this project include other RMIT investigators? *

(•) Yes ( ) No

Other RMIT Investigators *

2.2.1 Title *

Mr

2.2.2 First Name *

Donald

2.2.3 Last Name *

Apted

2.2.4 School *

Health and Biomedical Sciences

2.2.5 College *

Science Engineering Health

2.2.6 Campus

Bundoora Campus

2.2.7 Position

Undergraduate

2.2.8 Email

S3427306@student.rmit.edu.au

2.2.9 Staff/Student ID *

S3427306

2.2.10 **Investigator Type** * Co-Investigator

2.2.12 **Research Activities** * Research design. the development of scales on The Theory of Planned Behaviour and Positive and Negative Reinforcement, statistical analyses, composing the manuscript, and submission of the manuscript to an academic peer-reviewed journal.

2.2.13 **Expertise and Experience** * Undergraduate courses in psychology and statistics.

2.2.14 **Education or Training** * I have completed course units for the psychology honours program and I intend to complete the online modules on research and ethics this semester.

2.3 External Investigators

Does this project include Investigators external to RMIT? *

○ Yes ◉ No

3.1 Research Methodology

3.1.1 Will the research project or activity be conducted with: *

- ☑ Human beings (via active participation), including their associated data and/or bio-specimens
- ☐ Existing data associated with human beings only
- ☐ Existing human bio specimens only

3.1.2 Which Research methods will be used in the project or activity? *

View table of definitions by clicking question 'information' icon

- ☐ Action research
- ☐ Biospecimen analysis research
- ☐ Clinical research
- ☐ Creative practice research
- ☐ Epidemiological research
- ☐ Ethnographic research
- ☐ Experimental (non-clinical) research
- ☐ Genomic research
- ☐ Indigenous research methods
- ☐ Interview/Focus Group research
- ☐ Observational (non-ethnographic) research
- ☐ Social media (or internet) research
- ☑ Survey research
- ☐ Textual analysis research
- ☐ Other

3.1.3 **Thinking of the project aims and objectives, what is the rationale for your choice of method/s?** *

The Theory of Planned Behaviour studies used multiple regression, whereas the studies on positive reinforcement (mood enhancement) and negative reinforcement (drinking to cope) applied structural equation models. However, structural equation modelling does not measure the effect size and unique variance of each construct in the model and it is difficult for researchers to apportion the effects of each factor to drinking behaviour.

This research project will use a variety of statistical analyses to answer the research questions. Firstly, multiple regression and ANOVAs will be used to separate the different factors and give researchers additional insight into problematic drinking behaviour. Multiple regression/ANOVAs measures effect sizes, change in effect sizes and unique variance. Secondly, ANCOVAs will measure the moderating effect of past behaviour on intention across low, medium, and high AUD groups. Finally, ANOVAs will measure the change in means of positive and negative reinforcement in the low, medium, and high AUD groups.

3.13 Survey Research

3.13.1 Is the data collected in your survey qualitative, quantitative or both qualitative and quantitative? *

- ☐ Qualitative
- ☑ Quantitative

3.13.2 How will you engage with your participants to conduct the survey? *

- ☐ Face to face
- ☐ Via telephone, text message, email, or online collaboration tools
- ☑ Indirectly, via an online provider

3.13.3 **Will personal information be associated with survey responses, or will the data be anonymous (non-identifiable)?** *

- ☐ Collecting personal data
- ☑ Anonymous

3.13.4 **Is it foreseeable that your survey will explore topics that may cause distress for participants?** *

No, the survey does not involve any sensitive topics that may distress participants

4.1 Participant Numbers

4.1.1 **How many participant groups are involved in this research project?** *

Three groups shall be formed from the participants. These groups will be divided into low, medium and high alcohol use disorder groups according to the AUDIT output measure.

4.1.2 Provide the selection criteria for participants or participant groups that you will include or exclude from your research. *

The participants must be 18+ years of age and they must have consumed an alcoholic beverage in the last 12 months.

4.1.3 What are the characteristics (including age range) of each participant group? *

All the participants must be 18 + year of age. The groups shall be created according to the AUDIT scores. The low group = 0-7, medium = 8-19, and high = 20 and above. These scores reflect the AUD continuum of use to misuse of alcohol.

4.1.4 Where possible, provide participant numbers for each group. *

Each group should consist of 53 or more participants. Based on an ANCOVA G*Power 3.1 analysis, where there three groups and there is moderate effect size, power = .80, and alpha = .05, N= 158 participants will be required.

4.1.5 **What is the expected number (or range) of participants involved in this project (across all sites/groups)?** *

N = 158 - see above for justification

4.1.6 **Provide a justification for the chosen sample size.** *

According to a G*Power 3.1 analysis, an ANCOVA with three groups, α = .05, β - 1 = .80, and medium effect size (.25), requires N = 158 participants (Cooke et al., 2016; Faul et al., 2009).

4.1.7 **What will each participant group be required to do?** *

Each participant will be required to complete an online anonymous survey. The questions include age, gender, employment status etc, and questions on drinking behaviour. The survey consists of 72 items and takes approximately 10 minutes to complete.

4.1.8 **How will confidentiality of participants and their data be maintained?** *

The survey will not collect any identifiable data.

4.1.9 Will you be researching with Aboriginal and/or Torres Strait Islander Peoples or Communities? *

○ Yes ◉ No

4.1.10 Will you be recruiting any of the following groups when recruiting participants for this study? (Please select all that apply) *

- ☐ Children and young people (under 18 years of age)
- ☐ Culturally and Linguistically Diverse (CALD) participants
- ☐ People in dependant or unequal relationship with researchers or others involved in facilitating the research
- ☐ People in other countries
- ☐ People in over-researched population
- ☐ People who may be involved in illegal activities
- ☐ People with a cognitive impairment
- ☐ People with an intellectual disability
- ☐ People with a mental illness
- ☐ RMIT Staff
- ☑ RMIT Students
- ☐ People highly dependent on medical care and unable to provide informed consent
- ☐ Pregnant women/human foetus (where the research may pose a health risk to the pregnant woman or human foetus)
- ☐ Other

4.12 RMIT Students

4.12.1 Provide details of the researchers' relationship to student participants. *

The website will be advertised widely in the community and this will include students who may be enrolled in RMIT University courses at the city or Bundoora campuses.

4.12.2 Is there an existing student/teacher relationship between student participants and researchers? Or the potential for a future relationship? *

○ Yes ◉ No

4.12.3 How do you plan to manage the relationship to ensure voluntary consent and participation without compromising the relationship, or exposing the student participant/s to risk? *

The plain language statement outlines that consent is voluntary and that it can be revoked at any time without prejudice. The online survey contains no pressure to complete the survey and if the participant feels distressed during the questionnaire, there are the websites provides counselling and support services. Please see the plain language statement.

4.12.4 Please address whether research will be conducted during class time or involve coursework activities. *

The research will be conducted as part of my psychology honours coursework.

5.1 Recruitment

5.1.1 How will participants be identified for potential recruitment? *

- ☐ Involvement of other organisation
- ☑ Public website search
- ☐ Researchers' professional networks
- ☑ Other
- ☐ Public records
- ☐ Researchers' personal networks
- ☐ Self-selection

5.1.1.1 **Please detail other method/s for identifying potential participants** *

The researcher will recruit the participants through a series of media platforms (e.g radio interviews and newspaper feature articles) outlining the merits of the research.

5.1.2 Describe how potential participants will be identified. *

Potential participants will not be personally identified but will be classified according to age, interest in the subject matter and previous drinking experience.

5.1.3 How will participants be recruited? *

- ☑ Advertisements
- ☑ Face-to-face interaction
- ☐ Phone call
- ☑ Website
- ☑ Other
- ☐ Emails
- ☐ Letter
- ☐ Snowball sampling
- ☑ Word-of-mouth

5.1.3.1 **Please detail other recruitment method(s)** *

The other methods of recruitment include radio interviews with the researcher promoting the research and inviting outpatient clinics to participate e.g. Turning Point, ReGen and other alcohol and drug treatment service providers

5.1.4 Describe how potential participants will be contacted, informed of research, and recruited. *

Participants will be invited to join via newspaper articles and radio interviews. Clients at the outpatient clinics will be invited to join via the clinicians/counsellors who wish to be involved in the project.

5.1.5 **Where will recruitment take place?** *

Recruitment will take place via the website psychologyresearch.com.au, radio, newspaper advertising, and a possible TV interview on the Project with Dr Mervyn Jackson

5.1.6 Who will make the initial contact and how will this be done? *

The initial contact will be made through a radio interview that will involve the researcher talking to the presenter and inviting 18 + years of age listeners to take part in novel research.

5.1.7 **Will potential participants be screened?** *

☐ Yes ☑ No ☐ Not Applicable

5.1.8 What information will be provided to potential participants during recruitment? *

The participants will be provided with a plain language statement outlining the aims and potential benefits of the research.

5.1.9 **How will recruitment strategy account for ethical considerations relevant to participants?** *

If the participants feel distressed during the survey, the web portal will provide counselling and support services. In addition, it is clear that consent is voluntary, consent can be revoked at any time, and there is no pressure to continue the survey.

5.1.10 Inclusion or exclusion criteria have potential to risk exposure of sensitive information. Explain how you will manage this. *

The website provides online counselling services to help manage the risk of exposure to sensitive information.

5.2 Consent for Self

Consent for self describes a consent process by which each individual participant has capacity to consent and provides individual consent for their participation in the research.

5.2.1 **Consent for some or all participants?** *

☑ Yes ☐ No ☐ Not Applicable

5.2.2 **What is the scope of consent that you will be seeking?** *

Specific consent: consent limited to this research only.

Extended consent: consent applies to this research and to future related research.

Unspecified consent: consent applies to this research and to future related or unrelated research.

☑ Specific ☐ Extended ☐ Unspecified

5.2.3 **How will consent be obtained?** *

Implied in this context means conduct implying consent for example, completion and returning of a survey.

☐ Written ☐ Verbal ☑ Implied

5.2.4 **How will you ensure that consent is informed and voluntary?** *

The plain language statement states that consent is voluntary and can be revoked at any time and at the discretion of the participant. Participants must be at least 18 years of age to give informed consent. In addition, a three-minute video on informed consent shall be available on psychologyresearch.com.au prior to the commencement of the survey.

5.2.5 **Who will make the determination about capacity to give consent?** *

The participants (18 +) will make the decision to give informed consent.

5.4 Opt-Out Consent

National Statement 2.3.5 states that "an opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent if neither practical nor feasible."

5.4.1 **Will an opt-out approach be used?** *

○ Yes ◉ No

5.5 Limited Disclosure

Item	Information
Concealment or Limited Disclosure	Not disclosing to research participants all of the aims and/or methods of the research. This covers a spectrum of practices from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants (see below).
Deception	Where relevant material is withheld from research participants and/or they are intentionally misled about procedures and/or purposes of research.

5.5.1 **Are you proposing to obtain consent using limited disclosure?** *

○ Yes ◉ No

5.6 Waiver Consent

A waiver of consent is a process by which the requirement to obtain individual and explicit consent from participants for the use of their data and/or biospecimens in human research is waived.

5.6.1 **Are you seeking a waiver of consent?** *

Please be aware that if you are using personal information in medical research or personal health information, a wavier of consent may only be approved by an HREC (National Statement 2.3.9).

○ Yes ◉ No

6.1 Risks

6.1.1 Describe the risks of the research project or activity, referencing the research methods and methodologies, as described in Section 3. *

The research methodology requires the recruitment of participants to complete an online survey. The survey is completed in the privacy of their own home and in their own time via the internet. The survey takes approximately 10 minutes to complete and the participant can withdraw consent at any time.

6.1.2 **Describe how these risks will be mitigated and managed.** *

If a participant feels distressed during the survey, online support services are provided on the website psychologyresearch.com.au and in the plain language statement.

6.2 Benefits

6.2.1 **Describe the benefits of the research project or activity, including whether these benefits are actual, potential or perceived and who they will accrue to (i.e. research participants, the wider community, or others).** *

Mewton et al. (2010) showed that 11.1 % of young adults (16-24 years) in Australia met the criteria for AUD in the Diagnostic and Statistical Manual of Mental Disorders (4th ed., DSM-4, American Psychiatric Association, 2007). This demographic is more at risk of AUD compared to older age groups in Australia. AUD is associated with comorbid psychopathology (e.g. depression, anxiety) and presently, there is limited aetiology of the AUD trajectory in Australia. This study attempts to address this gap in understanding.
AUD has a ripple effect in society. AUD affects family members, friends, the workplace, schools, and the community as a whole. AUD can lead to intoxicated driving, unsafe sex, anti-social behaviour, and domestic violence. Past studies have shown that while alcohol may not cause domestic violence, it appears to make the violence worse (Graham, 2011). One benefit of this study is that additional findings may bring the government closer to allocating funds to create more effective treatment programs to offer greater protection to vulnerable populations.
This research contributes to a larger body of empirical knowledge that may benefit society in the future. As this knowledge accumulates, it may create a mounting body of empirical evidence suggesting a different approach, which may help those who are most vulnerable and in need of more effective treatment programs.

6.3 Statement

6.3.1 **Provide the overall justification for this research project or activity, addressing the National Statement criteria in Chapters 1.1 and 2.1.** *

Merit
Mewton et al. (2010) showed that 11.1 % of young adults (16-24 years) in Australia met the criteria for AUD in the Diagnostic and Statistical Manual of Mental Disorders (4th ed., DSM-4, American Psychiatric Association, 2007). This demographic is more at risk of AUD compared to older age groups in Australia. AUD is associated with comorbid psychopathology (e.g. depression, anxiety) and presently, there is limited aetiology of the AUD trajectory in Australia. This study attempts to address this gap in understanding.
AUD has a ripple effect in society. AUD affects family members, friends, the workplace, schools, and the community as a whole. AUD can lead to intoxicated driving, unsafe sex, anti-social behaviour, and domestic violence. Past studies have shown that while alcohol may not cause domestic violence, it appears to make the violence worse (Graham, 2011). One benefit of this study is that additional findings may bring the government closer to allocating funds to create more effective treatment programs and provide support to vulnerable populations.

Integrity

The researcher is committed to publishing the results of the study in a timely fashion irrespective of statistical significance. In this way, positive publication bias is not upheld and the results will incrementally add to the body of scientific knowledge on drinking behaviours. In addition to peer-reviewed academic journals, a short video summarizing the results will be published online at psychologyresearch.com.au. The video will summarize the statistically significant predictors of drinking behaviour and provide a list of treatment options available.

Justice
This research contributes to a larger body of empirical knowledge that may benefit society in the future. As this knowledge accumulates, it creates a mounting body of empirical evidence which may suggest an improved treatment approach. The participants with severe AUD are often vulnerable populations with associated homelessness and mental health issues and so this research may potentially help those who are most in need of support and services.

Beneficence
The potential psychological harm of completing an online drinking survey is assessed as low risk, and this low risk is outweighed by the potential benefits of the additional findings of the research, and improved treatment options that may flow from this research.

7.1 Data Direct from Participants

Data and Privacy

While there is no agreed definition of, or right to, 'privacy' in an Australian context there are laws which speak to the 'privacy' of certain types of data or information, and which also regulate the ways in which it may be collected, used, shared, stored, re-used and destroyed.

In a human research context, the following types of data or information are protected:

Personal information: Any information or opinion recorded in any form and whether true or not, about an identifiable individual or from which their identity can be reasonably ascertained (for example, name, address, mobile phone number, email address, photo, voice recording, employment record, student record, medical record etc.).

Sensitive information: A special category of personal information (see above) that might be used to discriminate against an individual and therefore requiring more protection (for example, racial or ethnic origin, sexual preferences or practices, political opinions, membership of a political association, religious beliefs or associations, philosophical beliefs, union membership or criminal record).

Health information: Defined broadly as information or opinion about, physical, mental or psychological health, disability, expressed wishes about health care provision, a health care service provided, of an identifiable individual (living or dead).

Where the terms identifiable, re-identifiable and non-identifiable are used in relation to kind of data being collected, used or stored the meanings are as follows:

Identifiable: Identity of an individual can be reasonably ascertained.

Re-identifiable: Possible to re-identify an individual. For example, identifiers removed from main dataset and replaced by Code (stored separately) which enables identification.

Non-identifiable: Any identifiers permanently removed and no specific individual can be identified.

Over the lifecycle of a research project or activity the identifiability of data may change. For example, it may be collected in an identifiable format, made re-identifiable (coded) for the purposes of use and analysis and then stored in a non-identifiable format (separate file containing codes destroyed and all identifiers permanently removed).

7.1.1 What type of information will be collected from participants for this research? *

- ☐ Personal
- ☐ Sensitive
- ☑ Health
- ☐ Other

7.1.2 What is the identifiability of the data that has been or will be collected? *

- ☐ Individually identifiable
- ☐ Re-identifiable (coded)
- ☑ Non-identifiable

7.1.3 What type of information will be used in this research? *

- ☐ Personal
- ☐ Sensitive
- ☑ Health
- ☐ Other

7.1.4 What is the identifiability of the data used? *

- ☐ Individually identifiable
- ☐ Re-identifiable (coded)
- ☑ Non-identifiable

7.1.5 Describe ethical considerations for the collection/use of this data direct from participants. *

The data is non-identifiable.

7.1.6 Describe ethical considerations for the storage of data, include details of the location, retention period, and where applicable, protocol for secure destruction. *

The data will be stored in a secure room on a computer disk that is password protected - access only by researchers.

7.1.7 Do researchers intend to 'bank' the data for re-use or sharing? *

○ Yes ◉ No

7.4 Supporting Documentation

7.4.1 **Please upload the Research Data Management Plan** *

Type	Document Name	File Name	Version Date	Version	Size
Research Data Management Plan	data management plan - revised	data management plan - revised.docx			17.4 KB

Other Supporting Documentation

Type	Document Name	File Name	Version Date	Version	Size
Other - Research Data Management	methodology flow chart	methodology flow chart.pdf			55.7 KB
Other - Research Data Management	generic letter to newspapers - revised 18th July 2020	generic letter to newspapers - revised 18th July 2020.docx			14.3 KB
Other - Research Data Management	generic letter to outpatient clinics for the misue of alcohol - revised 18th July 2020	generic letter to outpatient clinics for the misue of alcohol - revised 18th July 2020.docx			14.2 KB
Other - Research Data Management	generic letter to radio stations - revised 18th July 2020	generic letter to radio stations - revised 18th July 2020.docx			14.4 KB
Other - Research Data Management	letter to the Australian Institute of Health and Welfare (AIHW) - 18th July 2020	letter to the Australian Institute of Health and Welfare (AIHW) - 18th July 2020.docx			14.4 KB
Other - Research Data Management	letter to the Adelaide state government Health Minister - 18th July 2020	letter to the Adelaide state government Health Minister - 18th July 2020.docx			14.5 KB
Other - Research Data Management	letter to the Australian Bureau of Statistics (ABS) - 18th July 2020	letter to the Australian Bureau of Statistics (ABS) - 18th July 2020.docx			14.4 KB
Other - Research Data Management	letter to the Federal state government Health Minister - 18th July 2020	letter to the Federal state government Health Minister - 18th July 2020.docx			14.5 KB
Other - Research Data Management	letter to the NSW state government - 18th July 2020	letter to the NSW state government - 18th July 2020.docx			14.5 KB
Other - Research Data Management	letter to the NT state government Health Minister - 18th July 2020	letter to the NT state government Health Minister - 18th July 2020.docx			14.6 KB
Other - Research Data Management	letter to the Project - TV show - 18th July 2020	letter to the Project - TV show - 18th July 2020.docx			14.4 KB
Other - Research Data Management	letter to the Queensland state government Health Minister - 18th July 2020	letter to the Queensland state government Health Minister - 18th July 2020.docx			14.5 KB
Other - Research Data Management	letter to the Tasmanian state government - 18th July 2020	letter to the Tasmanian state government - 18th July 2020.docx			14.4 KB
Other - Research Data Management	letter to the Victorian state government - 18th July 2020	letter to the Victorian state government - 18th July 2020.docx			14.5 KB
Other - Research Data Management	letter to the WA state government Health Minister - 18th July 2020	letter to the WA state government Health Minister - 18th July 2020.docx			14.5 KB
Other - Research Data Management	participation information statement - revised 18th Juky 2020	participation information statement - revised 18th Juky 2020.docx			27.9 KB
Other - Research Data Management	questionniare revised 18th July 2020 - changes in boldface	questionniare revised 18th July 2020 - changes in boldface.docx			35.4 KB

8.1 Conflicts of Interests

8.1.1 **Do any members of the research team (including persons not listed in this application), have any potential or actual conflicts of interest (financial or non-financial) related to this research?** *

○ Yes ◉ No

8.2 Restrictions

8.2.1 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project? *

○ Yes ◉ No

8.3 Evaluations

8.3.1 Has this research project had prior ethics review? *

○ Yes ◉ No

8.3.2 Will any further or additional specialised review of this application be sought? *

○ Yes ◉ No

9.1 Additional Supporting Documentation

Type	Document Name	File Name	Version Date	Version	Size
Other Project Related Documentation	data management plan - revised	data management plan - revised.docx			17.2 KB
Other Project Related Documentation	generic letter to newspapers - revised	generic letter to newspapers - revised.docx			13.9 KB
Other Project Related Documentation	generic letter to outpatient clinics - revised	generic letter to outpatient clinics - revised.docx			13.5 KB
Other Project Related Documentation	generic letter to radio stations - revised	generic letter to radio stations - revised.docx			13.6 KB
Other Project Related Documentation	participation information statement	participation information statement.docx			29.6 KB
Other Project Related Documentation	questionniare FINAL - revised	questionniare FINAL - revised.docx			32.3 KB
Other Project Related Documentation	radio stations	radio stations.docx			13.6 KB
Other Project Related Documentation	newspapers	newspapers.docx			12.6 KB

9.2 Declaration

In submitting this application, all named researchers (Principal Investigator, Co-Investigators and Student Investigators), certify that * :

9.2.1 All information in this application and supporting documentation is accurate and as complete as possible. ☑

9.2.2 We are familiar with and have addressed in this application the requirements of the National Statement and any other relevant guidelines. ☑

9.2.3 We are familiar with, and have considered and addressed in this application any relevant legislation, regulations, research guidelines and RMIT policies. ☑

9.2.4 We will ensure that the qualifications and/or experience of all researchers involved in the project are appropriate to their role and/or to the procedures performed and provide appropriate supervision to any student researchers (as applicable). ☑

9.2.5 We have disclosed and will appropriately manage all relevant conflicts of interests of the project team in keeping the National Statement and RMIT Policy. ☑

9.2.6 We understand that the information contained in this application will be managed in accordance with relevant RMIT Policy and legislation. ☑

9.2.7 **My role on the research project is as a * :**

☑ Principal Investigator ☐ Co-Investigator ☐ Student

In submitting this application, as Principal Investigator, I certify that *:

9.2.7.3 I accept overall oversight for the ethical conduct of this research project and activity and will ensure responsibilities relating to annual and final reporting and reporting of adverse events or non-compliance are met. ☑

9.2.7.4 I have the support of the Head of School or another appropriate approval authority at RMIT to conduct this research project or activity and their agreement that there are appropriate resources and facilities available to complete this research. ☑