**PARTICIPANT INFORMATION LETTER**

***\*\*Guideline: The information in blue italics is for guidance only. Please revise as necessary for individual projects and delete all blue writing prior to submission.***

***Ensure to write to the participant in the first person. Eg “You are invited…” Do not change headings or re-arrange the order and ensure that the language is non-technical and relevant for the intended audience, as this information sheet will help the participants to decide whether to participate. Adherence to these instructions will expedite the approval process and the need for additional review. As necessary, this letter should be translated for the local language and may also be used as a verbal script to be read out to participants if required eg for literacy or cultural reasons.***

***NB Only this ACU Participant Information Letter (PIL) will be accepted. Please ensure the Version number and date in the Footer is completed.***

***\*\*DELETE all blue italic information or change to black text all writing that is relevant to your research PRIOR to submission. All black text is compulsory and can be adapted to suit your research.***

**PROJECT TITLE:**

**APPLICATION NUMBER: (2023-**add the ethics 4-digit number generated in ORION**)**

**PRINCIPAL INVESTIGATOR:
STUDENT RESEARCHER:**

**STUDENT’S DEGREE:**

Dear Participant,

You are invited to participate in the research project described below.

**1. What is the project about?**

The research project aims to (*describe the project in plain English, its aims and objectives, why it is/should be important to the participants and what you hope to achieve*] You are invited because (*insert reason for invitation) (delete if unknown)* and your contact details were obtained from (*if known and appropriate - insert how/where they were obtained)*

**2.Who is undertaking the project?**

This project is being conducted by [*insert names of all researchers*] and [*if appropriate*] will form the basis for the degree of [*insert degree*] at the Australian Catholic University under the supervision of [*insert name of supervisor if appropriate*]. The researchers are experienced in (Researcher qualifications and expertise relevant to the project should be included here.*)* *Xx* has a strong background in *(xx, along with several years of experience in xx. )*

**3.****Research Funding,** *Sponsors, and collaborators):*

This research is funded by (*list the funder/funding organisation – if no funding, sponsors or collaborators,* *then state ‘This research has no funding’*) ***add where appropriate****:* *This study is part of a national/international collaborative study coordinated by (Australian, Canadian etc – insert collaborators details)* This study is being sponsored by *(name of commercial or other entity and state any conflict of interest which one or more investigators may have)*

**4. Who can take part in this study?**

To participate in this research project, we need to ensure that it is ok for you to take part in this study.

You will need to meet the following to be **included**:

* (*Outline the inclusion criteria eg, age)*

If you meet the following, you will be **excluded**: *(delete if unnecessary)*

* *(Outline the exclusion criteria eg diseases/conditions)*

(*Delete if not required)* You will complete a screening questionnaire via an (*delete where necessary* *- online questionnaire, paper questionnaire, telephone or online interview.)* asking about (*insert details*). The screening questionnaire will determine if you are eligible to take part in this study. Completing the screening measures will take approximately (*insert expected time*). If you meet the criteria for inclusion, then you will *(insert as appropriate – be contacted by a researcher or be able to start the research project after providing informed consent).* If the screening questionnaire shows that you cannot participate in the research project, (*explain what will happen e.g. you will exit the survey* *and all data collected about you will be deleted*)

***(NB. If information from the screening will be used in the study, then the screening tool can only be used once consent has been obtained and information provided about what will happen to this data, including for those who don’t meet the criteria)***

**5. What will I need to do to participate in this study?**

*Describe in lay terms and without jargon, what the project involves and what you expect the participant to do.*

If you decide to take part in this research, you will be asked to complete the following procedures. (*Indicate the nature of the activities –what is involved, types of questions asked and examples, are there any follow up requirements – (*Complete and delete from the below options where relevant to your research)

**Interview:** A (*specify - face to face, online video, telephone*) interview where you will be asked questions about (*provide details, an interview guide or provide some example questions*). The interview will take place (*insert the location or note the type of video software being used)* and will take approximately (*specify the expected time).* With your consent, the research team would like to (*specify - audio or audio/video and the medium that will used eg Teams)* record the interview for transcription purposes. Transcription means we will type up what you have said so we don't miss anything, and so we can analyse your information alongside other people in the study. The researchers (*add who will have access to the data if using a Research Assistant or an external transcription service* will transcribe the interview (*add information about the security/confidentiality of the data*). If you do not wish to be recorded, but would like to participate, ask the research team if written notes can be taken. (*Delete if not applicable) You will be asked to complete a follow up interview, the research team will contact you via [insert method of contact] to organise the time. You will receive an initial reminder and one follow up reminder. (if applicable) The data will be coded to link the data (explain the process, especially if the code will be generated by the participant)*

**Focus Group:** A Focus group that will take approximately *(specify the expected time).* During the focus group you will be asked questions about (*provide some sample questions, especially If sensitive).* All focus group sessions will take place (*insert the location and/or note the type of video software being used).* With your consent, the research team would like to (*specify – audio only or audio/video)* record your comments along with other participants, for transcription purposes. Transcription means we will type up what you have said so we don't miss anything, and so we can analyse your information alongside other people in the study. The researchers (*add who will have access to the data if using a Research Assistant or an external transcription service* will transcribe the Focus Group (*add information about the security/confidentiality of the data*). Each Focus Group will have (insert approximate number) and be grouped with (insert whether they’ll be “like” participants e.g., students in one group and staff in a separate group) Focus group discussions are confidential and should not be discussed outside of the group.

**Transcription review:** (*delete if not an option – NB; is preferred if the research is of a sensitive nature or with vulnerable groups)* Your interview *(or Focus Group themes)* transcript will be sent to you for review. The review allows you to add any further information, or to change or remove anything you said during the interview. Please return the transcript within *(insert time period eg.,2 weeks)* . If we do not receive a response from you within this period, (insert if appropriate – we will contact you to…) your data will (will not) be used in this study.

**Questionnaire/Survey:** An [(insert - online/email/paper/verbal) survey asking you to answer questions about (*provide details or give some examples*). You will be asked to complete this survey on (*insert number)* occasion/s. The survey should take approximately (*specify time)* to complete, (*delete if not applicable) You will be asked to complete additional rounds of questionnaires/surveys, and the research team will contact you via (insert method of contact) to remind you when to complete the next round. You will receive an initial reminder and one follow up reminder. (if applicable) The data will be coded to link the data (explain the process, especially if the code will be generated by the participant)*

**Procedures:** The research will require you to (*insert relevant information \*\* Consider using dot points or if relevant, tables that explain the process).* During the *(insert activity/procedure/s etc)* you will be asked to *(insert details) (and/or questions about provide details).* All sessions will take place (*insert the location or note the type of video software being used)* and will take approximately *(specify the expected time).*  With your consent, the research team would like to (*specify – audio only or audio/video)* record your (insert what is relevant eg. comments along with other participants, for transcription purposes, or outline the procedure/activity). (if relevant or explain the reason for the use of video) Transcription means we will type up what you have said so we don't miss anything, and so we can analyse your information alongside other people in the study. The researchers (*add who will have access to the data if using a Research Assistant or an external transcription service and add information about the security/confidentiality of the data*) will transcribe the interview.

(if appropriate) Each Group will have (*insert approximate number)* and be grouped with (insert whether they’ll be “like” participants e.g., bringing professionals from the same industry together or different industries into the one group).

 *\*\* outline the exact nature of the procedures eg. Complete 3 maximal sprints over a 40 min distance. Add the time it will take for each study procedure to be completed. Where the study procedures will take place****.*** *It should be made clear what information will be collected e.g. age, gender, medical history. The location of where the samples will be collected and by whom should be mentioned. The blood volumes (mL) should be specified. Add a statement on how the blood samples will be used (related to this study or other research and whether the blood sample/s will be destroyed after analysis or retained for future use and how long specimens will be stored)*

**6. Do I have to take part in this research?**

There is no obligation to participate in this research and if you do not wish to take part, you do not have to. Your participation is completely voluntary, and you may withdraw without consequence and reason at any stage. Your decision to participate or not, or to take part and withdraw, will in no way affect your relationship with the ACU (*If the participant is in a dependent relationship with any of the researchers eg. students, then address this issue and add this statement – ‘Your decision to participate or not, or to take part and withdraw, will in no way affect your relationship with the ACU or have any effects on your* *(grades/employment/organisation’ – delete and insert where necessary)*

Before deciding to take part in this research study, please read the information carefully and feel free to ask questions, or to talk things over with a relative or friend (or doctor). If you agree to participate in this study, you will be asked to sign a *(an online)* Consent Form at the end of this document and to keep a copy of this form.

**7. Are there any risks associated with participating in this project?**

*Describe any risks associated with the project. If there are no foreseeable risks, you should state this rather than saying there are ‘no risks’. Every project contains some risk.*

Whilst there are no foreseeable risks in this research, you may find *eg. some of the questions/procedures uncomfortable or distressing. (Insert what risks are applicable to your research and indicate how any risks will be mitigated or managed.)*

If you were to become distressed or upset by any of the (insert and delete as appropriate - *procedures, questions, you can skip a question, take a break, or simply stop/close your browser)* as this research is completely voluntary.

(Delete if not applicable) If you require support from someone not involved in this research, please contact the free service/s below: *provide support contact details for whatever is relevant to this research and appropriate to the country of research eg* ACU student counselling if ACU students are the participants, or Beyond Blue if the research is about depression or anxiety, or an autism specific research contact such as Amaze.org.au etc

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| --- | --- |
| E.g., ACU student counselling (ACU students only) | 1300 638 485 or text 0488 884 191 |
|  |  |

**8. Are there any costs or reimbursements involved?**

There are no costs to participating in this study. (if applicable or delete where necessary)However, we will provide (provide details eg a voucher) to reimburse you for your time *and any reasonable travel, parking, meals and other expenses while completing the* (provide details). *(*Include information about how they can claim the reimbursement and provide details on how their contact details will be securely stored and managed.)

*(For anonymous surveys, explain how the process for reimbursement eg, a new screen will open at the end of the survey where you can leave your contact details separate from the survey results)*

***9*. What are the benefits of the research project?**

It is anticipated findings of this study will provide *Describe the general realistic benefits of the project to the participant. Be careful not to overstate the benefits or provide unrealistic expectations. If there are no immediate benefits to the participant, this should be stated such as – ‘Although there are no direct benefits to your involvement in this research, the benefits from this research may….’*

**10. Can I withdraw from the study?**

*Delete whichever option below is not applicable to your research project.*

**Identifiable surveys/ Interviews/Procedures**

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time prior to and during the study, without adverse consequences. You can withdraw by contacting the researchers on the contact details below before this date (insert date) or prior to data aggregation (insert date) or before and during the review of the transcript up until this date (insert date) (delete as applicable) and your data will be deleted from the dataset. Your decision not to participate or to withdraw from the study, will not affect your relationship with ACU *or (list the names of organisations/funders if applicable).*

**Focus Groups**

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time prior to and during the focus group session, without adverse consequences. You can withdraw by contacting the researchers on the contact details below. However, because of the way in which focus group discussions are recorded, the research team will not be able to withdraw or destroy individual participant responses after the focus group has commenced. Your decision not to participate or to withdraw from the study, will not affect your relationship with ACU *or (list the names of organisations/funders if applicable)*

**Surveys (if non-identifiable)**

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences by closing the browser before submission. Once you have submitted the survey however, we will not be able to withdraw your responses, as the survey is anonymous. Your decision not to participate or to withdraw from the study, will not affect your relationship with ACU *or (list the names of organisations/funders if applicable). If using codes, then you will need to advise they will need to quote their unique ID to withdraw.*

**11. Will anyone else know the results of the project or have access to my information?**

Any information or personal details gathered during this study are confidential, and will not be shared with third parties without your consent or unless authorised by law e.g. a subpoena or search warrant. The data from this research project will be stored by the researchers on the ACU secure server OneDrive (or state other) for 15 years *(20 years for clinical Trial* after last action or when subjects have reached 25 years of age, whichever is longer*)* in a *(choose the applicable option below and delete where necessary)*

* *Identifiable format, where your identity will be known,*
* *Re-identifiable format where a unique identifying code will replace details such as your name, contact details, DOB,*
* *Non-identifiable format where your identity will remain unknown*.

 Data will only be accessible to the research team, and will be shared securely via *(insert method eg Teams/Onedrive/ACU server/Sharepoint). Data will also be shared (insert other source if applicable)*

ACU will manage your personal information in accordance with its Privacy Policy (link: www.acu.edu.au/privacy) and in line with our privacy obligations under the Privacy Act, 1988, the Australian Privacy Principles (APPs) and, where applicable, international regulations, such as the EU/UK’s General Data Protection Regulation (GDPR*).* *(See further information regarding GDPR on our website, or contact* *privacy@acu.edu.au* *for guidance)*

Please contact XXX@acu.edu.au *(add contact person’s details)* to withdraw consent, access or correct. If you have a privacy enquiry or complaint or, if GDPR applies to you, and you wish to erase, request portability or restrict/object to processing, please contact privacy@acu.edu.au

*If you intend to use the data for future research or share* ***with Third Parties,*** *then include the below statement (suggest using as you cannot add retrospectively – delete if not applicable)*

The data from this research may be used for future research and may be shared by the research team if you choose this option in the consent form. Only data that is specific to the aims of this research, an extension of, or closely related to, will be shared. All information will be shared in a format that will not identify you in any way. *if research will be shared with Third Parties, say it will be shared with X, but that any further disclosure will not occur without consent or authorisation by law.*

**12. Will I be able to find out the results of the project?**

The results of the study will be published *or reported (insert if applicable and where).* All information about you will be published in a way that will not identify you (or will identify you) in an aggregated format *(or other method). (if applicable, for identifiable surveys/procedures - provide information about individual results and feedback)* If you would like to receive a copy of the results, please contact a member of the research team listed below, *or you can provide an email address on the Consent Form.* We will only use these details to send you the results of the research.

**13. Who do I contact if I have questions about the project?**

If you have any questions or concerns about the project, please contact a member/s of the research team below.

**Research Team Contact/s**

|  |  |
| --- | --- |
| **Name** | [INSERT full name] |
| **Position** | [INSERT position title] |
| **Telephone** | [INSERT work telephone number] |
| **Email** | [INSERT work email address] |
| **Name** | [INSERT full name] |
| **Position** | [INSERT position title] |
| **Telephone** | [INSERT work telephone number] |
| **Email** | [INSERT work email address] |

***What if I have a complaint or any concerns about the research study?***

The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (review number 20XX- insert 4 digit application number from ORION). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of Research Ethics and Integrity, the Office of the Deputy Vice Chancellor (Research and Enterprise).

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| **Name** | Manager, Ethics and Integrity |
| **Address** | c/o Office of the Deputy Vice Chancellor (Research and Enterprise)Australian Catholic UniversityNorth Sydney Campus PO Box 968, North Sydney, NSW 2059 |
| **Telephone** | 02 9739 2519 |
| **Email** | Resethics.manager@acu.edu.au |

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

**14. I want to participate, what do I have to do?**

Please sign the Consent Form below *(or online via eg Qualtrics)* and return to the researcher (*Describe how participants will contact you to agree to participate (i.e. how do they return a consent form, instruct on how to consent online if applicable).*

Yours sincerely,

**RESEARCHER NAME/S AND SIGNATURE/**

* ***Please retain a copy of this information letter insert weblink or PDF***

**Consent Form – Participant Consent**

* I *(participant’s name)* have read the Participant Information Sheet, or someone has read it to me in a language that I understand. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I understand the purposes, study tasks and risks of the research described in the study, and understand I am free to withdraw at any time during the study, and withdrawal will not affect my relationship with any of the *insert named organisations and/or* research team members.
* I understand that if I withdraw from the study by contacting the researchers on the contact details in the Participant Information Letter before this date *(insert date),* or prior to data aggregation or used in presentations and publications, (delete as applicable and ensure consistency with the PIL) then my data will be deleted from the dataset *(except for focus groups if the data has already been collected and individual responses cannot be identified).*
* For surveys (delete if not appropriate to your research) I understand I may exit the survey at any time by closing the survey "window" on my device and there is no obligation to answer all questions or finish the survey.  If I exit the survey before submitting my responses, my responses will not be included in the research.
* (*if anonymous data – delete if not)* I understand my responses to this survey/*or study* are anonymous, and responses cannot be withdrawn *after submission* because they are not individually identifiable.

***\*\* The above information is compulsory (except where not applicable).***

 ***Include as required from the below options or add as necessary to reflect what you have advised in the PIL. You may add extra options if mentioned in the PIL, ensuring to delete what is not relevant.***

**Personal Information and Privacy/ GDPR**

*Privacy Consent for personal information (name, address, email addresses, phone numbers DOB etc) (delete from below what is not applicable to your research)*

* *By ticking this form, I consent to ACU collecting, using, and storing my personal information for the purpose of conducting research into (XXXX explain what the research is about).*
* *I consent to my personal information being shared with Third Party researchers (insert name) for the purpose outlined, but any further disclosure will not occur without consent or authorisation by law.*
* *If GDPR applies to me, I consent to transferring and storing my personal information in Australia.*
* *I agree for my data from this research, as described at section 11 of this document, may be used for future research, and may be shared by the research team. Only data that is specific to the aims of this research, an extension of, or closely related to, will be used. All information will be shared in a format that will not identify me in any way.*
* *I agree to the Collection of (insert type e.g., specific Biospecimens, blood pressure, diet diary information etc).*
* *I agree to this interview/focus group/ research activity being audio/recorded (delete what doesn’t apply)*
* *I would like to use a pseudonym, rather than my name, in any publications and presentations related to this project.*
* *I would like to receive a copy of the study results via email or post, and I have provided my personal details below for this purpose only.*
* *I provide my consent to be identifed in publications relating to this research*
* *I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future*

I agree to participate in this research:

* Yes
* No

**Participant Signature/*Can be online.***

|  |
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| **Name of participant:** |
| **Signature:** |
| **Date:** |
| **Contact details:** |

**Researcher Declaration**

* I have provided a verbal explanation (as necessary) of the research study, its activities and risks and believe that the participant has understood that explanation.

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| **Name of researcher:** |
| **Signature:** |
| **Date:** |

**Student researcher Signature (if applicable) \*Please ensure an appropriately qualified member of the research team provide the explanation of, and information concerning the research study.**

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| **Name of student researcher:** |
| **Signature:** |
| **Date:** |