**PARTICIPANT INFORMATION LETTER (PICF)**

* ***NOTES. The information in black text is compulsory with the text in blue italics being for guidance only.  Please revise and delete text as necessary.***
* ***Specific guidance can be obtained from the NHMRC National Statement and the Research Ethics Webpage;***
* ***Your letter should be written in the first person (you are invited) and use non-technical/lay language suitable for your participant group.***
* ***Do NOT change the headings nor re-arrange the order.***
* ***This PICF should be used unless the approving HREC is external to ACU.***
* ***To assist with version control, 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: (202X-**add the ethics 4-digit number generated in ORION**)**

**PRINCIPAL INVESTIGATOR:
STUDENT RESEARCHER AND 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*]

**2.Who is involved in 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. )*

|  |
| --- |
| This research is funded by (*list the funder (including Honours projects)/funding organisation – if no funding, then delete this table.*)  |

|  |
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| This research is also being conducted by *(insert name of the collaborative research group, sponsor - insert name of commercial or other entity and state any* ***disclosure of interest*** *or financial benefits which one or more investigators, sponsors and institutions may have) - delete table if not applicable)* |

**3. Why have I been invited to participate?**

You are invited because (*insert the reason for the invitation in plain language)*

Findings of the study will provide *(Describe the general realistic benefits and value 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….’)*

**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 are able to take part if (*Outline the inclusion criteria e.g., age)*

You will not be able to take part if *(Outline the exclusion criteria e.g. 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 the data, including for those who don’t meet the criteria)***

**5. What will the researchers do and when?**

*Describe in lay terms and without jargon, what the project involves and what you expect the participant to do. e.g. interview, Focus Group etc)*

**\*\* If asking the participant to do multiple activities, *consider using dot points or if relevant, tables that explain the process and incorporate the below information. Ensure to break up the paragraphs for readability, rather than a huge amountof information lumped together.***

If you decide to take part in this research, you will be asked to complete the following activities (*procedures*.) (*Indicate the nature of the activities –what is involved, types of questions asked and examples, are there any follow up requirements* *–\*\* (*choose and adapt from the options below where relevant to your research, and delete what is not)

**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 medium 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 software 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 the information you have provided. 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 the information you have provided. 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.

**A Transcription review** *is preferred if the research is of a sensitive nature and* *for accuracy and transparency, as well as to allow for additional context, clarification, or removal of identifying information, transcription review is considered best practice.* (*delete the below text if not applicable)*

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)* *To protect your identity, and in line with best practice, your data will be coded. (explain the process, especially if the code will be generated by the participant.*

**Procedures/Activities:** The research will require you to (*insert relevant information \*\*).* 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 e.g. Complete 3 maximal sprints over a 40 m distance. Add the time it will take for each study activity/procedure to be completed. Where the study activity/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?**

If you do not wish to take part, you do not have to. If you decide to participate, you can pull out at any time, and it won’t change your relationship with the research team or anyone else. If you decide to pull out of the project, contact the researchers on the contact details below before this date (insert date) to have your information deleted*. for anonymous surveys, insert*, Once you have submitted the survey however, we will not be able to withdraw your responses, as the survey is anonymous.

*(For group discussion/ Focus Group/workshops – if applicable)*

As the group discussion (or Focus Group) will be recorded, the research team will not be able to withdraw or destroy individual responses after the group discussion has commenced *(state if otherwise).*

Please read the information carefully and feel free to ask questions, or to talk things over with a relative or friend. (*or where relevant, a medical professional)*

(*If the participant is in a dependent relationship or has an association with any of the researchers e.g. member of the organisation/community, then address this issue and add this statement – ‘Your decision to participate or not, or withdraw, will not affect your relationship with - insert with whom e.g., the community or organisation/ACU)*

**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 expected risks in this research, you may find *eg. some of the questions/procedures uncomfortable or distressing*

If you were to become upset by any of the questions (insert information if conducting an intervention etc) *(Insert what risks are applicable to your research and indicate how any risks will be mitigated or managed.)*- *eg., you can skip a question, take a break, or simply stop/close your browser)*.

*If your project intends to study or expose illegal activity, or is likely to discover illegal activity, then insert: Any information that you provide can be disclosed only if (1) it is to protect you or others from harm, (2) if specifically allowed by law, (3) you provide the researchers with written permission. Any identifying information obtained for the purpose of this research project and for the future research described will be treated as confidential and securely stored. In the event illegal activity is disclosed, the researchers cannot guarantee that a third party could not use a legal process to gain access to the data (e.g.: subpoena or search warrant);*

You can contact a member of the research team on (insert name and contact details). If you require support from someone not involved in this research, please contact this free service/s below: *provide the appropriate support contact details for whatever is relevant to this research and appropriate to the participants involved eg* ACU student counselling if ACU students are the participants, or WellMob or Beyond Blue if the research is about depression or anxiety.

**8. What costs or benefits are involved?**

There are no costs to participating in this study beyond your time. *(if applicable, add costs or delete where necessary)* However, we will provide (provide details e.g. a voucher, or what is deemed culturally appropriate to this research) 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 e.g., a new screen will open at the end of the survey where you can leave your contact details separate from the survey results)*

Although there may be no direct benefits to your involvement in this research, the benefits from this research may (*Describe the general realistic benefits of the project to the participant. Be careful not to overstate the benefits or provide unrealistic expectations.*

**9. What will anyone happen to my information?**

The results of the study will be used to create a (insert e.g a report, education program, video etc) and published *or reported (insert if applicable and where).* If you would like to receive a copy of the results, *or a plain English summary,* 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.

Any information or personal details gathered during this study are confidential and will not be shared with third parties (or anyone else) without your consent, unless as required by law. The data from this research project will be shared and stored by the researchers on the ACU secure server OneDrive or file servers for 15 years *(20 years for clinical Trial* after last action or when participants 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*.

*ACU will manage your personal information and share data in accordance with its Privacy Policy and, where applicable, international regulations, such as the EU/UK’s General Data Protection Regulation (GDPR).* In limited cases, your data may also be viewable to ACU systems/software staff and administrators to address IT issues. *(including, in some cases, third party software providers - if applicable, Insert who the third-party provider is e.g. app providers etc, outline who can access the data, if the data will be identifiable, and how it will be managed/deleted etc)*

*(optional text below – add as applicable to your research and ensure to include an optional consent option in the consent form. Delete where not applicable. E.g. if not using a data repository)*

With *your consent, data may also be used for future research or shared with collaborators or others [insert specific details] for the purposes of [insert specific details] and made available in a deidentified (identifiable) format, through a research data repository or open access arrangement [insert specific details] or could be reassessed by the researchers named on this study for future studies relating to [insert specific details].*

You will retain any Intellectual Property from your own personal interview recordings.

Copyright will be (*outline who owns copyright of the material being produced and whether it will be shared with the participants)*

**9. Culturally restrictive information**

*State whether any culturally restricted information will be collected or not, and if so, indicate the permissions that will be sought from the relevant communities, traditional owners, etc.*

**10. 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.

|  |  |
| --- | --- |
| **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 The cultural aspects of this research has been reviewed by the ACU Indigenous Research Ethics Advisory Panel (IREAP). (Review number 202X- insert 4-digit application number from ORION).

If you have any complaints or concerns about the conduct of the project, you may email the Manager of Research Ethics and Integrity, the Office of the Deputy Vice Chancellor (Research and Enterprise) at [Resethics.manager@acu.edu.au](file:///%5C%5Cisilon-cluster.acustaff.acu.edu.au%5Cdepartment%24%5CResearch%5CETHICS%5CADMINISTRATION%5CWebsite%20documents%20and%20material%5CResethics.manager%40acu.edu.au)

Any complaint or concern will be treated in confidence and reviewed and acted upon, as appropriate.

**11. 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**

***When using e-consent, a copy of the full Participant Information Letter and Consent Form (PICF) must be presented to the potential participants within the platform (e.g. Qualtrics) prior to the eligibility and e-consent process, and a downloadable PICF provided, or by another means, e.g. via email or Hard copy. If any of the data from the screening questionnaires will be utilised in the research, then the participants must consent first.***

*Delete or modify where applicable to your research project.*

* 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.
* (for projects where participants are asked to complete procedures or many activities - delete if not applicable) I understand I am agreeing to participate in all procedures or activities as outlined in section 4 of the PICF. (If any of the activities are optional, then list them with a separate tick box to be consented individually)
* I understand that if I withdraw from the study before (*insert date*) or prior to data aggregation or use of data in presentations and publications, then my data will be deleted from the dataset. (*delete and add as applicable and ensure consistency with what you have stated in the PICF,* *for example for focus groups if the data has already been collected and individual responses cannot be identified, or if the research group will keep the data if a participant withdraws).*
* 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).***

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

* *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 from me, or as required by law.*
* *If GDPR applies to me, I consent to transferring and storing my personal information in Australia.*
* *I acknowledge and I am aware of the risks associated with disclosing illegal activity, as stated in the PICF.*
* *I consent to my research data, as described at section 10 of this document, being used for future research, and being shared by the research team and its collaborators. 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 health data and samples (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 or a summary via email or post, and I have provided my personal details below for this purpose only.*
* *I consent to being identifed in publications relating to this research,* *and acknowledge the risks associated with identification.*
* *I* *agree to my name and contact details to be retained in a register , so that the researchers can contact me about pariticpating in future research projects* ***(\* Please note, a new application in Orion will need to be submitted for a database for this option)***

I agree to participate in this research:

* Yes
* No

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

|  |
| --- |
| **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:** |