**Participant Information and Consent Form (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: (2023-***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*] You are invited because (*insert reason for invitation) (delete if not applicable)* 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. ) \*\* With research involving a lot of researchers,* *add “Please reference table below” and add a detailed table at the end of the PICF.*

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

|  |
| --- |
| 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. Who can take part in this study?**

Participation in this study is subject to certain eligibility criteria:

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)***

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

*Describe in lay terms and without jargon, what the project involves and what will be expected of the participant.*

**\*\* *If asking the participant to perform 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 having large amounts of 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 – (*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 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 e.g. 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)* *If there is a need for 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)* *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.*

**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.*

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**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 i.e. lab address etc or note the type of software being used)* and will take approximately *(specify the expected time frame/s and how many visits).*  With your consent, the research team would like to (*specify –e.g.* outline the procedure/activity). (if relevant or explain the reason for the use of video *or device/s etc)*

(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 activity/ procedure to be completed. Where the study activities/procedures will take place****.*** *It should be made clear what information will be collected e.g. age, gender, medical history, body measurement etc. The location of any sample collection, e.g., blood, saliva, biopsy, etc, should be mentioned, along with who will perform collection and the sample size to be collected. Add a statement on how samples will be used (related to this study or other research and whether the sample/s will be destroyed after analysis or retained for future use and how long specimens will be stored)*

**5. 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 explanation at any stage. Your decision to participate or not, or to take part and withdraw, will in no way affect your relationship with ACU or any parties involved in this research. (*If the participant is in a dependent relationship with any of the researchers e.g. students, then address this issue and add this statement to the last sentence above ‘or have any effects on your* *grades/employment/organisation’*

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 where relevant, a medical professional).* If you agree to participate in this study, you will be asked to complete a Consent Form at the end of this document and to keep a copy of this form. *(If consent is conducted online or via another mechanism, adjust text accordingly).*

**6. 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, such as loss of time, to confidentiality etc*

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

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

*If your study includes* ***illegal activity*** *or potential illegal activity, then insert the following statement: Any identifying information obtained for the purpose of this research project and for the future research described will be treated as confidential and stored securely. However, any information that you provide may be disclosed to an appropriate third party if (1) it is to protect you or others from harm, (2) it is specifically required by law, (3) you provide the researchers with written permission. In addition, in the event that you disclose illegal activity, you should be aware that a third party may be able to gain access to this information via a legal process (e.g.: subpoena or search warrant).*

*Insert For MRI incidental findings only (delete if not applicable):*

*As part of this study, you will be asked to undergo [procedure/s], which will be conducted by [service provider], a third-party service provider, on behalf of ACU. In agreeing to undergo this/these [procedure/s], it is important to note the following:*

*The/These [procedure/s] (and any subsequent results or reports) are being conducted solely for the purposes of research. As such, they should not be relied upon for clinical or diagnostic purposes. If you have a clinical or diagnostic need for [procedure/s], you should consult the appropriate medical professionals and have the/these [procedure/s] conducted independently of this study.*

*Following The/These [procedure/s], a [service provider] [employee title] [will/may] review your [scans/results]. Typically, this review is conducted within [x] days of your [procedure/s] (or, as appropriate; Typically, noting that the/these [procedure/s] is/are conducted for research rather than clinical or diagnostic purposes, this review may take some time [provide a time frame where possible], and neither ACU nor [service provider] can guarantee review within a set timeframe. In the event that the [employee title]’s review identifies any anomalies or incidental findings (i.e., findings that may be of clinical consequence) in your results, they will contact [you/your nominated medical practitioner] and may recommend that you seek medical advice and/or undergo further testing/procedures. [Include details of who will be notified and how they will be notified. Nominate timeframes, as appropriate].*

*In the event that any anomalies are identified, the principal investigator/s and (where relevant) medical supervisor on the study will also be notified. They in turn will be required to provide a report to the ACU Human Research Ethics Committee, for its review and feedback. Depending on the circumstances, the principal investigator/s may also choose to withdraw you from the study.*

*Noting that this is a research study, and that any anomalies identified as a result of the procedure/s likely fall outside the researchers’ scope of expertise, the research team will not be in a position to provide medical advice or ongoing support. Accordingly, while the researchers may be in touch to check in with, you should also seek independent medical advice or support.*

*(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 a service that is relevant to this research and appropriate to the country of research e.g., 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 )*

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

**7. Are there any costs or reimbursements 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) 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)*

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

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. 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. You can withdraw any of your data from the project up to the point we start data analyses (provide date). Then it will have had identifiers removed and combined with other people’s data and we cannot take out your specific data. *or before and during the review of the transcript up until this date (insert date or timeframe e.g.., 2 weeks after the interviews) (delete as applicable)* and your data will be deleted from the dataset.

*In circumstances where data cannot be withdrawn, then, a justification needs to be provided.*

**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 may not be able to withdraw or destroy individual participant responses after the focus group has commenced.

**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. (*In circumstances where data that has not been submitted is used, then a justification needs to be provided)* Once you have submitted the survey however, we will not be able to withdraw your responses, as the survey is anonymous. *If using codes, then you will need to advise participants they will need to quote their unique ID to withdraw (which will then identify them).*

**10. 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. *(Add if your research involves illegal activity – “unless meeting the specific requirements outlined under Point 6 above when research involves illegal activity”).* The data from this research project will only be accessible to the research team and will be shared and stored on the ACU secure servers (e.g. SharePoint, 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].*

**11. 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, *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.

*(The option to provide a copy and explanation to the participants about their assessment/outcome should be offered where applicable, and information about how/where this will take place provided)*

**12. 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 (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](Resethics.manager%40acu.edu.au)

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

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

Please sign the Consent Form below *(or online via e.g. 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,

***Add 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 before (*insert date*) or prior to data aggregation or use in 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. (provide infr
* (*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. (*In circumstances where data that has not been submitted is used, then a justification needs to be provided)*

***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*

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:** |