|  |
| --- |
| **[INSERT/DELETE - projects without students]**The research is being carried out by the following researchers:**[INSERT/DELETE - student wording]**The research is being carried out in partial fulfilment of [INSERT - course name e.g., Honours, Masters, PhD] under the supervision of [INSERT - supervisor's full name]. The following researchers will be conducting the study: |
| **Role** | **Name** | **Organisation** |
| [INSERT - role e.g., CI/Student etc.] | [INSERT - First Name + Last Name] | [INSERT - school/department/organisation] |
| **Research funder** | **[INSERT/DELETE - projects with funding]**This research has received [INSERT - list funding amount and source].**[INSERT/DELETE - projects WITHOUT funding]**This research receives in kind support from La Trobe University. |

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

You are invited to participate in a study of [INSERT - lay description of your study]. We hope to learn [INSERT - aims of the study]. There will be [INSERT - number of people to be enrolled in the study] people who will be part of this study.

**[INSERT/DELETE - how contact details were obtained]**

Your contact details were obtained from [INSERT - how contact details were obtained].

1. **Do I have to participate?**

Being part of this study is voluntary. If you want to be part of the study we ask that you read the information below carefully and ask us any questions.

If you decide you do not want to participate, this won’t affect the treatment you are currently receiving, or your relationship with La Trobe University or any other listed organisation. You can read the information below and decide at the end if you want to participate.

1. **Who is being asked to participate?**

You have been asked to participate because:

* [INSERT - reason for invitation/ inclusion & exclusion criteria].
1. **What will I be asked to do?**

If you want to take part in this study, we will ask you to [INSERT - description e.g., questionnaires / interviews / study procedures]. It will take [INSERT - time e.g., 4 hours per week for one year etc..] of your time to be part of this study.

[INSERT - description if partipants will be randomised to groups, of if a control group or placebo will be used]

**[INSERT/DELETE – Study Procedure Table]**

| Example procedures | Assessment/task | Screening Time: 2 hours | Visit 1Time: 3 hours | Visit 2Time: 4 hours | Follow-upTime: 30 mins |
| --- | --- | --- | --- | --- | --- |
| Informed consent | x |  |  |  |
| Demographic information | x |  |  |  |
| Weight  | x | x | x | x |
| MRI | x | x | x |  |
| Questionnaire | x |  | x |  |
| Blood Collection | x | x | x | x |

**[INSERT/DELETE – Standard Care Vs Additional to Standard Care study procedure table]**

| Standard Care |  | Additional to standard care |
| --- | --- | --- |
| Procedure | Time/visit | Dosage/volume | Procedure | Time/visit | Dosage/volume |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **What are the benefits?**

The benefit of you taking part in this study is that [INSERT - benefits to participants \*\*Benefits must be realistic and not overstated. If there are no benefits, please explain this]. The expected benefits to society in general are [INSERT - benefits to society].

1. **What are the risks?**

With any medical treatment there are (1) risks we know about, (2) risks we don’t know about and (3) risks we don’t expect. If you experience something that you aren’t sure about, please contact us immediately so we can discuss the best way to manage your concerns.

We have listed the risks we know about below. This will help you decide if you want to be part of the study.

|  |  |  |  |
| --- | --- | --- | --- |
| Side Effect | How often is it likely to occur? | How severe might it be? | How long might it last? |
| [INSERT - Risk/Side Effect] |  | [INSERT - Mild, moderate. severe] |  |
| [INSERT - Risk/Side Effect] |  | [INSERT - Mild, moderate. severe] |  |

1. **Will I be paid to be part of this study?**

It will not cost you to be part of this study. We will reimburse you for reasonable travel and food expenses. We [INSERT - will / will not] pay you for your time.

1. **What will happen to information about me?**

We will **collect** information about you in ways that [INSERT - will or will not] reveal who you are.

We will **store** information about you in ways that [INSERT - will or will not] reveal who you are.

We will **publish** information about you in ways that [INSERT - will or will not] be identified in any type of publication from this study.

We will **keep** your information for [INSERT/DELETE 5/7/15 years] after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the [Research Data Management Policy](https://policies.latrobe.edu.au/document/view.php?id=106/) <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

1. **Will I hear about the results of the study?**

We will let you know about the results of the study by [INSERT - how you give them the results & if results will be indivdual and/or group results].

1. **What if I change my mind?**

You can choose to no longer be part of the study at any time until [four weeks] following the collection of your data. You can let us know by:

1. Completing the ‘Withdrawal of Consent Form’ (provided at the end of this document);
2. Calling us; or
3. Emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

1. **What happens if the study needs to be stopped?**

The study may be stopped if we find out:

* The risks from side effects outweigh any benefits to you;
* The treatment you are receiving doesn’t give you any benefits
1. **What happens if I suffer an injury or complications because being part of this study?**

If you suffer an injury or have any concerns, please contact us immediately so we can help you.

In the event of an injury, we have the following compensation arrangements in place:

* [INSERT - Description of compensation arrangements]
1. **What happens when the study ends?**

When the study ends you will [INSERT - description of what participants will have access to after the study ends].

1. **What happens if you find out new information about the study?**

To ensure your safety we will make sure we look at the information we collect about this study. This may mean that we find out new information that you should know about. If this happens we will contact you and discuss what it means for you. New information may mean that we recommend you withdraw from the study, or that you may choose to withdraw.

1. **Who can I contact for questions or want more information?**

If you would like to speak to us, please use the contact details below:

| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| --- | --- | --- | --- |
| [INSERT - name/organisation] | [INSERT - Position Title] | [INSERT - work number] | [INSERT - work email] |

1. **What if I have a complaint?**

If you have a complaint about any part of this study, please contact:

| **Ethics Reference Number** | **Position** | **Telephone** | **Email** |
| --- | --- | --- | --- |
| [INSERT - Ethics Number] | Senior Research Ethics Officer | +61 3 9479 1443 | humanethics@latrobe.edu.au  |

**Consent Form – Declaration by Participant**

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study, I know I can withdraw at any time until [four weeks] following the collection of my data. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

[ ]  I give permission for my doctors, health professionals, hospitals and/or laboratories to release information concerning my health and treatment for the purposes of this study. I understand this information will remain confidential.

**[DELETE - Option/s that are irrelevant to the study]**

I would like my information collected for this research study to be:

[ ]  Only used for this specific study;

[ ]  Used for future related studies;

[ ]  Used for any future studies

**Participant Signature**

**[ ]** I have received a signed copy of the Participant Information Statement to keep

|  |  |
| --- | --- |
| Participant’s printed name |  |
| Participant’s signature |  |
| Date |  |

**[INSERT/DELETE – Witness section, if you anticipate the participant won't be able to read the PICF]**

**Witness Signature**

[ ]  I have been present for the entire discussion about this study

[ ]  I confirm all written information was accurately explained, and apparently understood by the participant or their legal representative and informed consent was given freely and without coercion.

|  |  |
| --- | --- |
| Witness’ printed name |  |
| Witness’ signature |  |
| Date |  |

**Declaration by Researcher**

[ ]  I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;

[ ]  I am a person qualified to explain the study, the risks and answer questions

|  |  |
| --- | --- |
| Researcher’s printed name |  |
| Researcher’s signature |  |
| Date |  |

\* All parties must sign and date their own signature

**Withdrawal of Consent**

I wish to withdraw my consent to participate in this study. I understand withdrawal will not affect my relationship with La Trobe University of any other organisation or professionals listed in the Participant Information Statement. I understand the researchers cannot withdraw my information once it has been analysed, **[INSERT/DELETE - focus group]** and/or collected as part of a focus group.

I understand my information will be withdrawn as outlined below:

* Any identifiable information about me will be withdrawn from the study
* **[INSERT/DELETE - Option which isn't applicable]**The researchers will withdraw my contact details so I cannot be contacted by them in the future. **[INSERT/DELETE - Option which isn't applicable]** If new safety information about the drug/device is available after I have withdrawn I understand the research team will keep my contact details so they can provide me with new safety information.

*\*\*if you have consented for your contact details to be included in a participant registry you will need to contact the registry staff directly to withdraw your details.*

I would like my already collected and unanalysed data

[ ]  Destroyed and not used for any analysis

[ ]  Used for analysis

**Participant Signature**

|  |  |
| --- | --- |
| Participant’s printed name |  |
| Participant’s signature |  |
| Date |  |

**Please forward this form to:**

|  |  |
| --- | --- |
| CI Name | [INSERT - CI Name] |
| Email | [INSERT - work email address] |
| Phone | [INSERT - work phone] |
| Postal Address | [INSERT - work postal address] |