|  |
| --- |
| **[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 - organisation] |
| **Research funder** | **[INSERT/DELETE - projects with funding]**This research is being funded by [INSERT - list of name/s of funding organisations].**[INSERT/DELETE - projects WITHOUT funding]**This research is supported by in kind support by La Trobe University. |

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

This is an invitation for your child to take part in a study. The study is about [INSERT - lay description of your study]. We hope to learn [INSERT - aims of the study].

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

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

1. **Does my child have to participate?**

Being part of this study is voluntary. We ask that you discuss the study with your child when you are deciding if you want your child to take part. If you decide together for your child to be part of the study we ask that you read this information carefully and ask us any questions.

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

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

Your child has been asked to participate because:

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

If your child wants to take part in this study, we will ask your child 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 child’s time to be part of this study. We [INSERT - do/ do not] require you to be present at the same time.

[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 your child 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 your child experiences something that you or your child 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 your child should 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 we be paid to be part of this study?**

There will be no cost incurred for your child 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 child’s time.

1. **What will happen to information about my child?**

We will collect and store information about your child in ways that only we will know who your child is. Any information that reveals your child’s identity will be kept confidential, and will only be disclosed with your permission, unless we are required by law to reveal this information. The Human Research Ethics Committee, monitors and regulatory bodies may also access information about your child, if possible, these people will not know who your child is.

The way we store and find out the results of the study means your child cannot be identified in any type of publication from this study.

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

We will collect, store and destroy your child’s data in accordance with La Trobe Universities Research Data Management Policy which can be viewed online using the following link: <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The information you and your child provide is personal information for the purposes of the Privacy and Date Protection Act 2014 (Vic). You and your child have the right to access personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the Information Privacy Act.

1. **Will we 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 we change our minds?**

At any time you or your child can choose to no longer be part of the study. You can let us know by:

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

Your or your child’s 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 your child;
* The treatment you are receiving doesn’t give you any benefits
1. **What happens if my child suffers an injury or complications because of this study?**

If your child suffers an injury or if you or your child 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 child’s 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 and your child should know about. If this happens we will contact you and discuss what it means for your child. New information may mean that we recommend your child withdraw from the study, or that you and your child may choose to withdraw.

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

If you or your child 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 we have a complaint?**

If you or your child 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 Parent/Guardian**

I (the parent/guardian) have read (or, where appropriate, have had read to me) and understood the parent/guardian information statement, and any questions have been answered to my satisfaction. I understand I am being asked to provide consent for my child to be part of this study. I agree for my child to participate in the study, I know either myself or my child can withdraw at any time. I agree information provided by my child or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that my child cannot be identified.

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

**I would like my child’s information collected for this research study to be:**

[ ]  Only used for this specific study (up until my child turns 18, and then they will be asked for their own consent);

[ ]  Used for future related studies (up until my child turns 18, and then they will be asked for their own consent);

[ ]  Used for any future studies (up until my child turns 18, and then they will be asked for their own consent)

**Parent/Guardian Signature**

**[ ]** I have received a signed copy of the Parent/Guardian Information Statement to keep

**[ ]** If appropriate - I have discussed the study with my child and through these discussions they have shown to me they want to be part of the study.

|  |  |
| --- | --- |
| Parent/Guardian printed name |  |
| Parent/Guardian 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 for my child to participate in this study. I understand withdrawal will not affect my or my child’s relationship with La Trobe University of any other organisation or professionals listed in the Participant Information Statement. I understand my child’s information will be withdrawn as outlined below:

 I understand my information will be withdrawn as outlined below:

* Any identifiable information about my child will be withdrawn from the study
* **[INSERT/DELETE - Option which isn't applicable]**The researchers will withdraw my contact details and my child’s contact details so we 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 my child I understand the research team will keep my contact and my child’s contact details so they can provide me or my child 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 child’s already collected and unanalysed data

[ ]  Destroyed and not used for any analysis

[ ]  Used for analysis

**Parent/Guardian Signature**

|  |  |
| --- | --- |
| Parent/Guardian printed name |  |
| Parent/Guardian 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] |