**PARTICIPANT INFORMATION SHEET - DATABASE**

|  |  |
| --- | --- |
| **Title** | **B**enefits of **A**nalysing **B**rain **Bi**omark**e**r**s** in perinatal care: a prospective observational cohort study  |
| **Short Title** | BABBies Trial  |
| **Protocol Number** | *[XXX-XXXX]* |
| **Project Sponsor** | SLHD |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr. David Zalcberg  |
| **Location**  | Royal Prince Alfred Hospital  |

**1. Introduction**

As a person presenting to Royal Prince Alfred Hospital to give birth, you are invited to voluntarily donate cord blood for a research project run through the Department of Anaesthetics.

The aim of this study is to optimise decisions made during labour and improve perinatal care through the examination of brain biomarkers in cord blood. In addition to the analysis of biomarkers in the cord blood we will also be collecting some data from your patient medical record related to the perinatal period.

Researchers will use the information collected in this database to assess the feasibility of a larger district-wide study, with the hope to develop additional investigations in the future to improve post-natal outcomes.

This project is being sponsored and supported by the Sydney Local Health District.

**2. Study Participation**

If you agree to participate in this study, you will not be required to do anything other than sign the Patient Consent Form. Relevant information will then be obtained from your medical record and stored in the database.

As per normal post-delivery care, a midwife will collect cord blood for standard rhesus testing and blood gas analysis. An additional 3 mL of blood will be collected during this time for this research project. The prioritisation of standard cord blood testing will be ensured by the midwife and cord blood will only be collected for the study if possible.

The blood sample will be transferred to the laboratory in the Department of Anaesthetics at Royal Prince Alfred Hospital and stored securely. All samples are de-identified and allocated into barcoded tubes. The samples will be sent overseas for analyses at the University of Gothenberg in Sweden. All biological samples will be destroyed as per lab policy after analysis. Currently Royal Prince Alfred Hospital and the University of Sydney do not have the equipment to analyse the samples.

In the database your health information will be identified with a number to protect your privacy. Your name will be recorded in connection with this number, but information about you will only be linked to your number.

Your information will always be treated confidentially, and only authorised research staff will have access to it. All data will be de-identified before being analysed.

All data will be stored on a secure server hosted by the Sydney Local Health District called RedCAP. Only the investigators of this study will be able to assess this data.

**3. Benefits**

While we intend this database to be used to further medical knowledge and to improve perinatal care and labour outcomes in the future, it may not be of direct benefit to you.

**4. Costs**

Participating in this study will not cost you anything, nor will you be paid.

**5. Voluntary Participation**

Consenting to this study is entirely voluntary. You do not have to do so. If you do, you can withdraw your health information at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

**6. Withdrawal Process**

If you decide to withdraw from this research project, you will need to notify a member of the research team (details listed under further information section below) and you will need to complete a Withdrawal Form.

If you decide to leave the research project, the research team will not collect additional health information about you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. If you do not want your data to be included, you must tell the researchers when you withdraw from the project.

**7. Confidentiality and length of data storage/data destruction**

All the information collected from you for the study will be treated confidentially and will be stored on a research database called RedCAP, which is maintained by the Sydney Local Health District.

In order to maintain confidentiality, you will be assigned a study ID during recruitment and all data/samples will be labelled with this study ID. A Master Code sheet with any personal data associated to the study ID will be kept in a locked facility or server in the Department of Anaesthetics and will only be accessible by authorised research staff.

As per policy all paper documents must be stored securely for 15 years post study and will be destroyed in a confidential manner.

**8. Future use of Data**

The data collected in this project may also be used in future research studies. The results of this study and de-identified data may be shared in the future with national and international collaborators, however the use of the data will be subject to ethics approval.

 **9. Further Information**

When you have read this information, a midwife will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact the Principal Investigator, Dr. Dave Zalcberg, on 02 95157150

This information sheet is for you to keep.

**10. Ethics Approval and Complaints**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor, Dr David Zalcberg on 02 9515 7150.

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Kaitlin Kramer |
| Position | Research Coordinator |
| Telephone | 02 9515 8789  |
| Email | Kaitlin.Kramer@health.nsw.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Sydney Local Health District (RPAH Zone) |
| HREC Executive Officer |  |
| Telephone | 02 9515 6766 |
| Email | SLHD-RPAEthics@health.nsw.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | Maree Larkin |
| Position | **Research Governance Officer**  |
| Telephone | 02 9515 7899 |
| Email | SLHD-RPAEthics@health.nsw.gov.au  |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title**  | Benefits of Analyzing Brain Biomarkers – in perinatal care: a pilot study |
| **Short Title** | BABBIES Trial  |
| **Consent Version**  | V.1 dated 29.05.2022 |
| **Coordinating Principal** **Principal Investigator** | Dr. David Zalcberg |
| **Location**  | Royal Prince Alfred Hospital  |

**Declaration by Participant**

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purposes, procedures and risks of the research described in the project.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Royal Prince Alfred Hospital concerning my health purposes of this project. I understand that such information will remain confidential.
* I understand that my participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my medical record, and I agree to this.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
* I understand that, during the course of this study, my medical records may be accessed by by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
* I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
* I understand that I will be given a signed copy of this document to keep.
* I acknowledge that my de-identified data may be shared with other local or international collaborators and used for future research purposes, and I agree to this: □Yes □No

I would like to receive a copy of the study results when they become available. My email address is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project

• Other research that is closely related to this research project

• Any future research.

By signing this consent section, I agree to the use of my blood samples for this research project.

Name of Participant (please print)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Study Doctor/

Senior Researcher† (please print)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title**  | **B**enefits of **A**nalysing **B**rain **Bi**omark**e**r**s** in perinatal care: a prospective observational cohort study  |
|  |  |
| **Short Title** | BABBIES Trial  |
| **Consent Version**  | V.1 29/05/2022 |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr. David Zalczberg |
| **Location**  | Royal Prince Alfred Hospital  |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal Prince Alfred Hospital.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.