Date of Decision Notification: **20 Dec 2023**
Dear Professor Ju Lee Oei,
Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2023/ETH02217:**CUT umbilical cord milking to prevent Encephalopathy in infants with prenatal drug exposure – the CUTE project

This Application was reviewed as a **Greater than low risk review pathway**and was initially considered by the **South Western Sydney Local Health District Human Research Ethics Committee** at its meeting held on**ENTER INITIAL MEETING DATE**.
The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

**This email constitutes ethical and scientific approval only.**
**This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.**

**Please note the following conditions of approval:**

* The Histopathologists performing any non-Standard of Care histopathological analysis are listed as Associate Investigators and the NSW Health Pathology laboratories where this work is to be conducted are listed as study sites
* The membership of the DSMB is listed and are identified (when known).
* Please change references to “SEALS/SSWPS Phlebotomists” to instead state “NSW Health Pathology Phlebotomists at St George and Liverpool sites”.
* Please confirm that any non-Standard of Care blood draws, biochemical tests, assays, biospecimen archiving and clinical imaging related to the study will be paid for from research funds.
* In the Protocol, Page 2- 39, please change “NSW Pathology Services” to “NSW Health Pathology Services”. Please submit the updated Protocol via email to
* We note that the Visual Information Sheet document did not include a footer. Please update this document to include a footer that lists the document name, version number, and date (matching the table below) prior to using this document in this study.
* Please submit the updated documents via email to SWSLHD-Ethics@health.nsw.gov.au

This project has been Approved to be conducted at the following sites:

* **Royal Hospital for Women**
* **Bankstown Lidcombe Hospital**
* **Liverpool Hospital**
* **Fairfield Hospital**

The following documentation was reviewed and is included in this approval:

|  |  |  |
| --- | --- | --- |
| **Documentation Title** | **Version** | **Date** |
| Human Research Ethics Application | Version 2.0 | 27/11/2023 |
| Protocol | Version 4.0 | 01/12/2023 |
| MASTER Participant Information Sheet/Consent - exposed | Version 3.0 | 02/10/2023 |
| MASTER Participant Information Sheet/Consent – non-exposed | Version 3.0 | 02/10/2023 |
| MASTER Withdrawal of Participation | Version 3.0 | 02/10/2023 |
| MASTER Withdrawal of Participation – guardian | Version 3.0 | 02/10/2023 |
| Visual Information Sheet | Version 1.0 | 05/07/2023 |
| Infant Behaviour Questionnaire-Revised-Very Short Form | Version 1.0 | 01/03/2023 |
| Protein Targets of Cytokine Assay | Version 1.0 | 01/03/2023 |

The Human Research Ethics Application reviewed by the HREC was:
Version: 1.01
Date: 01 Dec 2023

The approval is for a period of 5 years from the date of this e-mail **(20 Dec 2023)**

Please note the following conditions of approval:
***\*\*Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted\*\****

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
5. The Principal Investigator must reassure participants about confidentiality of the data.
6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
7. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from:<https://www.swslhd.health.nsw.gov.au/ethics/policies.html>

**Interpreter use:** If this study will involve the use of interpreters, you are required to contact SWSLHD Interpreter Services on 8738 6088 and/or swslhd-interpretersbookings@health.nsw.gov.au. This is required even if you have access to interpreters for clinical purposes, as SWSLHD Interpreter Services are required to review and approve the use of interpreters for any research work. Once you have contacted SWSLHD Interpreter Services, please ensure that you include the provided quote/s (if any) with your SSA submissions for your project.

Should you have any queries about your project please contact **our office** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <https://www.swslhd.health.nsw.gov.au/ethics/>

Please quote the above Ethics number in all correspondence. The HREC wishes you every success in your research.

Yours faithfully,
**Dr Cameron Lutman**
*on behalf of*
**Professor Murray Killingsworth**
Chairperson, SWSLHD Human Research Ethics Committee

|  |
| --- |
| This HREC is constituted and operates in accordance with the National Health and Medical Research Council’s (NHMRC) *National Statement on Ethical Conduct in Human Research (2007).*The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council. |