**Participant Information Sheet/Consent Form - Parent/Guardian**

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| **Title** | Electrical Impedance Tomography and Lung Ultrasound Measurements of Neonates with Congenital Diaphragmatic Hernia during positioning |
| **Short Title** | ETL Study in CDH Infants |
| **Principal Investigator** | Dr Judith Hough |
| **Associate Investigators** | Dr Luke Jardine, Miss Abby McCullagh, Ms Bronagh McAlinden |
| **Location** | Mater Mothers’ Hospital |

**Part 1 What does participation involve?**

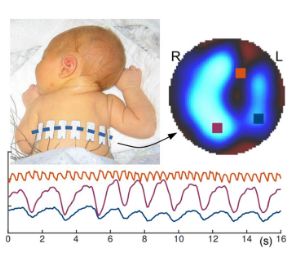
**1 Introduction**

You are invited to consent your baby to participate in this study because your baby was born, or is expected to be born, with Congenital Diaphragmatic Hernia (CDH) and is in the Neonatal Intensive Care Unit (NICU) at Mater Mothers’ Hospital receiving support to help them breath.

Babies born with CDH, have or are going to have a hard time breathing and will need support to help them breath. Their lungs are underdeveloped and smaller than most other babies’ lungs of their age. Your baby will need ongoing medical support to assist in their breathing, usually in the form of artificial ventilation. Artificial ventilation refers to the use of a machine to help your baby breathe and fill their lungs with air. This can be done through a mask over their mouth and nose or with a tube into the lungs for more supported breathing. This is standard procedure and is determined by the doctors in charge of your baby. Babies who need artificial ventilation are regularly placed in different positions to help assist their breathing.

The research project will use different pieces of equipment to see how the air moves to different parts of the lungs when the baby breaths, and how this pattern is changed when placed in different positions. This means that your baby will be placed in different positions including on their stomach, on their back or on their side. Regular position changes are part of usual care for a baby with CDH and your baby’s medical and nursing care will not be affected or changed by being involved in this research.

To measure what is happening within the lungs in a particular position, two pieces of equipment will be used to assess your baby’s breathing: Lung Ultrasound (LUS) and Electrical Impedance Tomography (EIT). Lung Ultrasound (LUS) will be used to scan your baby’s lung to look for any changes in your baby’s lungs. Electrical Impedance Tomography (EIT) uses a belt that is placed around your baby’s chest and will look at how their lungs fill with air (Picture 1.). The EIT belt does not put any extra pressure on your baby’s chest and normal breathing movements can still occur. Small electrical currents are produced from the belt at an extremely safe setting and the EIT machine will measure how easily these currents move through different parts of the lung (called "impedance”). The amount of impedance represents the amount of air in a specific part of your baby’s lung. The more impedance, the more air that has travelled to that section of the lung. Your baby should not feel any pain from either the LUS or EIT measurements.



Picture 1. Electrical impedance tomography belt on a baby

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want the baby to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not your baby can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for your baby to take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want your baby to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to your baby taking part in the research project

• Consent to your baby having the tests and research that are described

• Consent to the use of your baby’s personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

The research project will use different measuring tools to see the pattern of where air travels in the lungs, when placed in different positions. The results will help us improve both medical and multidisciplinary respiratory therapy and breathing treatment for future babies.

**3 Why has my baby been invited to participate in the study?**

Your baby has been diagnosed with CDH, a condition that effects the lungs in a very particular way. As such, babies will be monitored during each position and throughout the duration of study. If at any point, the doctor or medical staff decide your baby requires a change in their care, this will be done immediately and independently from the study.

**4 What does this study involve?**

If your baby is eligible to participate, a member of the study team will discuss the study with you and give you the chance to ask questions. If you consent to have your baby participate, you will be asked to sign this consent form. After you have signed the consent form, LUS and EIT will be performed to scan their lungs and measure their breathing. Your baby will then continue their normal clinical care while the EIT belt remains in place during a particular position. During the baby’s routine change, the EIT belt will be taken off and LUS will be performed and the belt place back on. During this time, all routine care and medical management will be undertaken. Your baby’s measurements taken by the LUS, EIT machine will be compared to other babies with the same condition.

Information on your baby’s health in relation to their breathing, lung health and other conditions related to their cardiorespiratory system will be taken from their medical records. In conjunction, information about their gestation (pregnancy), demographic information will also be recorded. This information will allow doctors to interpret and understand the results of the study.

While the observation using the LUS, EIT will be undertaken over a few hours, we will continue to collect routine medical data on your baby’s health until they are discharged from the hospital.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid to participate.

**5 Does my baby have to take part in this study?**

Participation in any research project is voluntary. If you do not wish for your baby to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide that your baby can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether your baby can or cannot take part, or take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with Mater Misericordiae Limited.

**6 What are the possible benefits of my baby taking part in this study?**

There will be no clear benefit to the participant from their participation in this research.

Possible benefits may include helping improve respiratory support for CDH babies in the future.

**7 What are the possible risks and disadvantages of my baby taking part?**

Taking part in this research will not change your baby’s care beyond their usual, routine clinical care. It is not expected that the use of LUS or EIT will result in any significant changes to your baby’s clinical progress and both LUS and EIT can be used on your baby without interfering with their breathing support or medical treatment.

LUS is routinely used in the Neonatal Intensive Care Unit (NICU) and has been shown to be safe and not associated with any pain or discomfort. EIT has been approved by the European regulatory authorities as a research tool and has not been found to cause harm to the patient, or affect their disease progression or treatment. Any potential risk of tissue damage caused by the EIT electrical current will been eliminated by keeping it to a very low level (5milliamps). This amount of electrical current is well below the threshold of tissue damage and will cause no harm or danger to your baby. The EIT belt will be positioned on your baby’s chest in a way that will not interfere with their usual cares or assessments. The investigators who will apply the EIT to your baby in this study have significant experience (over 15 years) using this equipment with over 100 sick infants. Like any equipment put onto your baby’s skin, there is a possible risk of skin irritation caused by the EIT belt and/ or the gel used beneath the belt. There have not been any documented cases of this happening, however, meaning the chance of this happening is extremely unlikely.

Staff will examine your baby to ensure he/she is comfortable and stable before beginning EIT. The EIT measurements will be taken for research purposes only and are not intended to be used for clinical examination. If any unusual feature is identified on your baby using the EIT, the investigators will notify the on-duty neonatologist immediately.

**8 What happens if my baby suffers injury or complications as a result of the study?**

If your baby suffers any injuries or complications as a result of this study, you should contact the principal study doctor, Dr Judith Hough on 0422 404 369 as soon as possible, who will assist you in arranging appropriate medical treatment.

**9 What if I withdraw my baby from this study?**

If you decide to withdraw your baby from this research project, please notify a member of the research team. If you do withdraw consent during the research project, the study doctor and relevant study staff will not collect additional personal information from your baby, although personal information already collected will be retained to ensure that the results of the research project can be measured properly.

**10 What happens when the study ends?**

After the study has been completed, your baby will continue with usual patient care. Data collected from each baby will be de-identified (all identifiers will be removed but can be re-identified for future studies) and will be analysed. After the results are analysed, if you have ticked the box on the consent form requesting a copy of the results, you will be sent a summary of the findings of the study. The results will be posted in the hospital and a manuscript prepared for publication. Your baby’s identity will be protected at all times so no one will be able to guess which baby was yours.

Depending on the results of the study, we may wish to follow up your baby further. If so, you may be contacted to check on your baby. You may be invited to join a follow up study, which is completely voluntary, and we may wish to use the data we already collected in future research projects relating to infants with CDH. Please refer to Page 1 of Consent Form.

**11 Will it cost anything for my baby to take part in this study, and will I be paid?**

Participation of your baby in this study will not cost you anything and you will not be paid.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about my baby?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your baby for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential. Your baby’s information will only be used for the purpose of this research project, or with your permission, used in future research projects. For this reason, all information collected from your baby will be re-identifiable. This means that only the investigators listed on this study will be able to identify your baby and their study results, and only if you agree to your baby’s information being used in future studies. Any future research would be similar work relating to infants with CDH, such as respiratory distress in babies, how babies breathe, and devices that assess babies breathing. Your baby’s information will only be disclosed with your permission, except as required by law. Your baby’s information will be held securely by Mater and will be held for the sole use of Mater.

You may be contacted by a member of the research team to request your consent to use your baby’s information for a future research project. You will be given the details of future research projects so that you may decide if you wish your baby’s information to be used for this purpose.

You may also be contacted to request your consent to collect additional information about your baby for future follow-up studies on your baby. If this occurs, you will be given the opportunity to consider your baby’s involvement in future follow-up studies, which is completely voluntary. If you don’t want your baby to participate in future research, you can still participate in this research.

Information about your baby may be obtained from their health records held at this and other health services (for example, the hospital where your baby was born, if not born at the Mater Mother’s Hospital). By signing the consent form you agree to the research team accessing your baby’s health records through a secure Mater information applications if they are relevant to participation in this research project.

The baby’s health records, and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of Mater Misericordiae Limited, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission.

Information about participation in this research project may be recorded in the participant’s health records as this is standard policy at Mater Misericordiae Limited.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about the participant. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access the participant’s information.

Any information obtained for the purpose of this or future research projects which can identify your baby will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**13 Who is organising and funding the research?**

This research project is being conducted by medical research personnel in the Neonatal Intensive Care Unit at Mater Mothers’ Hospital lead by Dr Judith Hough and Dr Luke Jardine.

No member of the research team will receive a personal financial benefit from the participant’s involvement in this research project (other than their ordinary wages).

**14 Who has reviewed the research study?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Mater Misericordiae Limited. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**15 Further information and who to contact**

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 issues with the care of your baby which may be related to involvement in the project, you can contact the principal study doctor, Dr Judith Hough on 0422 404 369 or any of the following people:

**Clinical contact person**

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| Name | Dr Judith Hough |
| Position | Physiotherapist Consultant, Neonatal Intensive Care Unit |
| Telephone | 0422 404 369 |
| Email | [Judith.hough@mater.org.au](mailto:Judith.hough@mater.org.au) |

This study has been reviewed and approved by the Mater Misericordiae Ltd Human Research Ethics Committee (EC00332). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the HREC Liaison Officer or HREC Chairperson, Human Research Ethics Committee, Mater Misericordiae Ltd, Level 2 Aubigny Place, Raymond Terrace South Brisbane 4101, or telephone (07) 3163 1585, email: research.ethics@mater.uq.edu.au.

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:

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| HREC name | Mater Misericordiae Limited |
| Telephone | 07 3163 1585 |
| Email | research.ethics@mater.uq.edu.au |

**Reviewing HREC Executive Officer details**

**Research Governance Officer details**

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| --- | --- |
| RGO Name | Mater Research Governance |
| Telephone | 07 3163 3769 |
| Email | research.governance@mater.uq.edu.au |

**Consent Form – Parent/Guardian**

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| **Location** | Mater Mothers’ Hospital |

**Declaration by Parent/Guardian**

⬜ 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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

⬜ I freely agree to the baby participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

⬜ I understand that I will be given a signed copy of this document to keep.

⬜ I give permission for the baby’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Mater Misericordiae Limited concerning the baby’s condition and treatment for the purposes of this project. I understand that such information will remain confidential.

⬜ I am aware that I may be contacted regarding a future follow-up study on the baby.

⬜ I am aware that data already collected may be used in future research projects relating to infants with CDH.

I wish to be provided with a summary of the results of the study when available

I consent to future use of data collected from my baby

I wish to be contacted for future studies that may involve myself or my baby

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|  | Name of Child (please print) |  | | | | |  |
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|  |  | |  | |  |  |  |
|  | Name of Parent/Guardian (please print) | | |  | | |  |
|  |  | | |  | | |  |
|  | Signature of Parent/Guardian | |  | | Date |  |  |
|  | | | | | | | |

**Declaration by Study Doctor or Delegate**

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

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|  | Name of Study Doctor or  Delegate† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member or delegate 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.

A copy of the signed consent form has been given to the participant

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Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_