To be printed on local headed paper

Infant **KI**dney **D**ialysis and Filtration

The **I-KID** Study

INFORMATION SHEET FOR PARENTS & GUARDIANS

Version 1.0

Invitation

We are doing some research called the I-KID study, which involves children who have received, or are receiving, kidney dialysis in a Paediatric Intensive Care Unit (PICU).

We would like to ask if you would give your consent for information about your child and the care that was given to be used in our research study.

We understand that this is a very difficult time for you and your family. We do though feel it is important to give you the opportunity to decide whether or not you would want your child's information to be included in this study which aims to improve the care of children in intensive care.

To help you decide, it is important for you to understand more about the study and why it is being done. This document will give you some key information, please take some time to read it carefully and you can talk about it with friends and family. Please ask us if there is anything that is not clear or if you have any questions.

What is the I-KID Study?

- Some children in PICU are so poorly that they need support for their kidney function by using a form of dialysis. There is more information about dialysis and what this is at the back of this information sheet. Dialysis is also sometimes called Renal Replacement Therapy (RRT).
- There are several existing methods of dialysis used in hospitals for very small babies. These have been adapted from those designed for use with adults and older children.
- There is a new NIDUS dialysis machine which has been developed in Newcastle upon Tyne. It is specially designed for babies who weigh less than 8 kg and is being used in clinical care at certain times in hospitals taking part in this study. The NIDUS is being used as part of a study so it can be monitored very closely and we can compare it to the other methods used.
- The I-KID study is looking to find out which method of dialysis gives the best support to very small babies. At the moment there is not enough information available to tell us this. 6 hospitals in England have agreed to take part in the I-KID Study. They will collect information on babies treated with existing dialysis methods and with the new NIDUS machine, to compare how well they work.

Why did my baby have dialysis /renal replacement therapy?

The clinical team in charge of your baby's care felt that your baby needed some extra kidney support and the decision to start dialysis was not related to the study. No extra blood tests were done for the study, but the dialysis fluid and waste bags were measured and some of the waste fluid was analysed in the laboratory.

Why was I not approached before about taking part?

Your baby's caring clinical team considered it medically urgent and in your baby's best interests to start dialysis. They did not want to delay starting treatment that your child needed. A treatment is often started straight away in routine care. This approach has been discussed with other parents, with the research ethics committee and has been used in other emergency care studies to make sure vital research can be done without delay to treatment.

Why am I being approached now?

We believe that the information already collected on your baby is very important and could help improve care for other babies.

What information do you want to use?

We are now asking for your permission to use the information collected about your child. The information we need for the study has already been collected by the hospital. The information that is additional for this study are:

1. The **weight of the fluid bags** that were collected to tell us how accurate the dialysis method was at removing the correct volume of fluid. The fluid bags were
2. The **results of the laboratory tests done on the waste fluid** that is normally thrown away. This fluid is destroyed once the chemistry tests have been done. We are not keeping any samples for this study.

What are the possible risks and benefits of taking part?

At the moment there are no fully approved machines for use in very small babies as they have been adapted using adult methods and the NIDUS uses a new design for small babies. The clinical and research teams carefully watched your baby closely as they would any child on dialysis. They gave all the treatments necessary to provide the best possible chance of recovery.

We hope that by looking closely at this information it will help us improve the care of sick babies in the future. We understand that this is a stressful time and we hope we do not add to your difficult time in any way.

Do I have to consent?

No, it is up to you to decide if you want information to be used in this study. We understand that this is a stressful time and we hope we do not add to your difficult time in any way. We are grateful to everyone who agrees for information on their baby to be used in this study, and value the contribution that the information will make. We also understand this some parents do not feel able to do this.

Optional Questionnaire

We also think it is important to hear your views and we will ask if you would be happy to answer a simple questionnaire. We want to know about your experience of having a baby on dialysis and how you found taking part in this study. Your baby's information can still be used even if you don't want to answer these questions, it is completely optional.

What will happen next?

There are 2 ways of letting us know whether or not we can use the information from your child in the I-KID study:

1. If you agree for your child's information to be used in this study, we would ask you to return a signed a consent form (enclosed with envelope). You can still change your mind and

withdraw your consent at any time

2. You can contact the I-KID site research team on <site to localise with phone number> to tell them that you consent or do not consent for the information collected to be used for the study. If you decide not to continue we will not use any information already specifically collected for this study. The information will be destroyed in a secure way.
3. If the hospital I-KID research team have not received a response from you within XX They will give you a call from <site to localise with phone number>. If you do not want to take part in the study, you do not need to pick up the phone. The research team will try a maximum of …. Times.

What if there is a problem?

If you are not happy with any part of this study, you should ask to speak to the study team first who will do their best to help you. **Their contact details are on page 5**. If you are still unhappy you may wish to raise your concerns with someone who was not directly involved in your baby's care. You can contact the Patient Advice Liaison Service (PALS) who provide a confidential service on <site to localise with phone number and email address>

Expenses and Payments

There is no payment for taking part in this study. Information will be used that has already been collected and there are no extra visits.

What will happen to the results of the study?

If you would like us to email you a summary of the study results, please give your email address to a member of the study team at your hospital. They will pass these on securely to the site team.

The results of this study will be published in medical journals to inform other doctors, nurses, parents and the public so we can all learn more about dialysis in small babies. Information from the study may also be presented at meetings and shared with other researchers. There will also be a report published by the study funder and this will be put on their website.

Will the information about my baby be kept confidential?

Yes and this how we will make sure:

- All babies who take part will be given an identification number. Only clinical staff at the hospital will be able to link this number back to each baby using the initials, date of birth and NHS hospital number.
- If you give us your email address, it will only be used to send you a study summary and not for any other purpose.
- All information for the trial will be entered on secure and password protected computers.
- Any information that may be shared with other hospitals and researchers will not identify you or your baby.

The study data in your baby's medical notes will be looked at by people directly involved in the study. This may include the Newcastle Clinical Trials Unit at Newcastle University as they are managing the study. It may also include regulatory authorities, the study sponsor or the NHS Trust to make sure the study is being run safely and correctly.

There is some additional information on the last page of this document about information transparency.

Who is organising and funding the research?

The main study doctor, also known as the Chief Investigator, is Dr Heather Lambert. Dr Lambert is a Consultant Children's Kidney specialist at the Great North Children's Hospital in Newcastle upon Tyne. The study team also includes senior doctors and nurses, university experts in research studies, and a parent who has experience of a similar study.

Study sponsor: The Newcastle upon Tyne Hospitals NHS Foundation Trust.
Study funder: The National Institute for Health Research, Efficacy and Mechanism Evaluation (EME) Programme.

There are 6 hospitals taking part and each hospital also has a study doctor, called an Investigator.

The Investigator in your hospital is _____

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the North East Tyne and Wear South Research Ethics Committee. It has been reviewed by the Medicines and Healthcare Products Regulatory Agency, who have approved the use of the NIDUS in this study. The study design has also been reviewed by the funder.

We have taken the advice of parents and a public research group when designing this study. A parent of a baby who had treatment using NIDUS has been involved from the start and will be part of regular reviews of how the study is going. Other parents have also looked at the study information to make sure it has been presented in a clear and understandable way.

What if I have any questions?
Please ask the doctor or nurse who has contacted you. They can put you in touch with the research team or the Investigator for this study at your hospital.

Thank you for taking the time to read this information sheet at this difficult time. You can find contact details for the study team on the next page.

Study team contact details for your hospital:

Principal Investigator:…….. Tel:

Research Nurse:…….. Tel:

You can find more information and the progress of the study on our website:
https://research.ncl.ac.uk/i-kid/

Additional Information:

Part 1:

What are the types of dialysis?

There are two different types of dialysis:

- **Peritoneal dialysis (PD)*:** runs fluid in and out of the abdomen.
- **Continuous Veno Venous Haemo Filtration/ Dialysis (CVVH/D):** filters and cleans the blood.

**Your doctors will have spoken to you about these different methods but if you want to find out more about how they work, please ask a member of the clinical team. We also have some information on our study website: www.research.ncl.ac.uk/i-kid*

Both PD and CVVH/D have been adapted from existing systems for adults and larger babies by using smaller tubing. Existing CVVH machines in the UK have been given what is called a CE mark only for treating children who weigh 8 kg or more. A CE mark means that it has been given approval to be sold and used in any country in Europe.

Current machines are not ideally suited for smaller babies because they need a large volume of blood for the circuits (50 to 70ml) and the fluid removal is not as accurate as we would like it to be. However, clinical teams do have a lot of experience using them in babies and have adapted them, for example by giving extra fluids and/or blood transfusions.

- **Newcastle Infant Dialysis Ultrafiltration System (NIDUS):** is designed especially to provide kidney support for babies who weigh less than 8 kg. So far it has been found to work well and has been used in Newcastle where it was developed. A submission has been made to get a CE mark for the NIDUS machine but this can take years to complete.

Having seen the results so far, some doctors across the UK have asked to use the NIDUS for small babies in their own hospital. As it is new, it is being used as part of a study so that detailed information can be collected and shared. Training and support is being provided to staff who use the NIDUS by the team at Newcastle who developed the NIDUS.

There is another new machine available in Europe (it is in use in a few centres in Italy and one in Belgium) which is a miniaturisation of an adult device, but it is not in use in the UK currently.

Additional Information:

Part 2:

Information Transparency
Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) is the sponsor for this study based in the United Kingdom and will act as the "data controller" for this study. They are responsible for looking after your information and using it properly.

This study is managed on behalf of the sponsor by the Newcastle Clinical Trials Unit who will act as the "data processor". As data processor, this means that we are responsible for processing personal data on behalf of a controller. We will be using information from you in order to undertake this study, and will keep identifiable information about you for 5 years.

Your rights to access, change, or move your information is limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Your child's data will be assigned a unique study identification number and this will be used to collate and analyse your data.

How will we use information about your child?
We will need to use information from your child's medical records for this research project.
The medical records will include your child's NHS number and name.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see you or your child's name or contact details. The data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- http://www.newcastle-hospitals.org.uk/about-us/freedom-of-information_how-we-use-information.aspx

The sponsor Data Protection Officer is Richard Oliver and you can contact him at nuth.dpo@nhs.net.
The data processor (Newcastle University) can be contacted at Rec-man@ncl.ac.uk