(*to be presented on headed paper*)
Parent Information Sheet **Version 3.0: 11.01.2016**

Title of the Study: When to give platelet transfusions to premature babies.

Short Title: **Pla**telets for **Ne**onatal **T**ransfusion - Study **2 (PlaNeT-2)**

1. We would like to invite you and your baby to take part in a research project.

We are asking you to consider including your baby in a research study. Before you decide whether to take part it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss with friends and relatives if you wish. Please ask us if there is anything that is not clear or if you would like more information.

2. What is the purpose of this study?

Platelets are the cells that help the blood to clot. Platelet counts may sometimes fall to low levels in about 5% (1 in 20) of babies on the neonatal unit, usually when babies are unwell. Platelet transfusions are like blood transfusions only the bag contains platelets and no red blood cells. Platelet transfusions are given to babies with low platelets and signs of bleeding, but we do not know when best to give platelet transfusions to babies with low platelets and no signs of bleeding. Platelet transfusions will help clotting but may also carry risks (please see point 6).

The aim of this study is to understand better when to give transfusions of platelets to babies with low platelet counts. There are no studies to tell us what is best for the babies. We would like to find out which platelet levels we should transfuse at in babies with low platelets and no evidence of bleeding. We will therefore compare outcomes at two different platelet levels

This study will take place in a number of hospitals and approximately 600 babies will participate.

3. Why has my baby been chosen?

You are being invited to consider allowing your baby to take part in this study because his/her platelet count is low (below 100). Your baby's medical team at the hospital has reviewed his/her medical details and they believe that he/she is suitable for taking part in the study.

4. Does my baby have to take part?

No, your baby does not have to participate in the study. It is entirely up to you. Whatever you decide it will not affect other aspects of your baby's care. We have approached you because your baby has a low platelet count (normal is above 150). If you do allow your baby to take part, you will be asked to sign a consent form and you will also be able to keep this information sheet. At any time, you can ask for your baby to be taken out of the study without giving a reason. This would not affect the standard of care your baby receives, and your baby would then be given platelet transfusions as needed and according to the existing guidelines in place in your neonatal unit.

5. What will happen if I agree my baby can take part?

We will continue to check your baby's platelet count to see whether your baby needs a platelet transfusion. If your baby's platelet count drops below the level of 50, then your baby will be placed at random into one of two groups:

- Group 1 babies will receive a platelet transfusion whenever their platelet count drops below 50.
- Group 2 babies will receive a platelet transfusion whenever their platelet count drops below 25.

This random allocation is not done by the doctors or the research team but by a computer programme. Randomly placing babies in the groups ensures that every baby has an equal chance of being in either group 1 or group 2.

Once your baby is enrolled in the study we will collect relevant information about your baby every day for 14 days. This will involve us checking your baby for any signs of bleeding. After 14 days information for the study will be collected once each week, until your baby is discharged home. This information will be collected by speaking to the nursing staff looking after your baby and from the case notes for your baby. If the care of your baby is provided in different hospitals, then the doctors and nurses in each hospital will continue to complete the weekly information collection until discharge home. Blood tests will be carried out as decided by your doctors to help with the care of your baby. No additional blood tests will be carried out solely for the purposes of the study. The study will not interfere with the medical or nursing care your baby will receive during this time. Being in this study will not stop the doctors giving platelets to your baby when it is considered appropriate for their care. Occasionally a baby will be discharged home before completing 28 days in the study. If this is the case we would like to contact you, your GP or Health Visitor to see how the baby is progressing around this time

6. What happens if my baby is transferred to another hospital whilst on the trial?

We would like to collect data up to at least Study Day 28. If your baby is transferred to another hospital before this day on the trial, we will ask the new unit to send us data up to this time

7. Will my baby be followed up after finishing the study?

All babies in the study will be followed up at 2 years of age (corrected) to assess their development by using a standard form. If you sign the consent form agreeing for your baby to take part in the study we will also ask if we can contact you or your GP / Health Visitor in 2 years' time so that we can collect this information.
At this time we would like to contact you with a follow up questionnaire to see how your baby is doing. At any time you can withdraw from the study by informing the research team

8. What are the possible risks or side effects of taking part?

Currently there is no clear evidence when to give platelet transfusions to babies who have a low platelet count but are not bleeding. It is possible that some babies who do not receive platelet transfusion when their platelet counts are low may have bleeding. On the other hand giving more transfusions of platelets also carries a small risk of causing harm, as for any blood transfusion. These risks include bacterial and viral infections, transfusion reactions and the need for more procedures for administering platelets (such as insertion of

intravenous cannula). All babies in the study will be carefully monitored by research and clinical staff.

9. What are the potential benefits of your baby taking part?

We do not know if your baby will benefit from taking part in the study and some babies may benefit from receiving fewer or more transfusions, but we do not know. We hope that the information from this study will help improve the future care of very premature babies. The information we get from this study will help us to improve the way we use platelet transfusion and guide us to recommend to others which platelet count level should be used to give platelet transfusions to very premature babies.

10. What if new information becomes available during the study?

Your doctor will discuss with you any important new information that may become available during the study which could affect your baby taking part.

11. Will taking part in this study be kept confidential?

Yes. At the beginning of the study your baby will be given a study number. This number (and not their name) will be used when studying the data, and information that is collected on your baby for the study will be stored electronically in an anonymised, password protected, computer database, accessible by the researchers only. It is a requirement that your baby's involvement in this study be noted in your baby's medical records. At all times the details will be handled only by fully trained staff and will remain confidential. Clinicians and research staff directly involved in the study will have direct access to your baby's medical records. In addition, employees of the sponsor (NHS Blood and Transplant) and/or the hospital research and development department may require access to your baby's records as part of the monitoring procedures that are in place to oversee the conduct of the study.

We value parent feedback and so we may ask you to give permission to be interviewed for our newsletter or website to help tell your story and find out how we can improve things for other parents or guardians who wish to participate in the trial. Your agreement to do this is entirely voluntary.

12. Will my own doctor know?

Yes. Unless you specify otherwise we will inform your G.P. with a short letter explaining the study to them.

13. What will happen to the results of the research study?

The results of this study will be shared with other doctors all around the world who look after premature babies, so that they will be able to learn from the new information and improve their practice. To do this a report containing the results of this study will be written, presented at scientific meetings and published in medical journals. Your baby's identity will not be made known in any circumstances.

14. What if I change my mind about the study?

If you decide to take part you are still free to withdraw your baby from the study at any time and without giving a reason. If you chose to withdraw your baby from the study, we hope that you will continue to allow us to collect some data about your baby until discharge home, as it

is important for the study that some results, for example use of platelet transfusions, are collected for all babies in the study.

However should you wish us to stop collecting any further data, we will stop collecting any additional information about your baby. In this case, we would use only data that has already been collected.

15. Who has reviewed the study?

All research that involves NHS patients, staff, medical records, premises or facilities must be approved by a NHS Research Ethics Committee before it goes ahead.
This study has been reviewed and approved by a national research ethics committee (Cambridgeshire 3 Research Ethics Committee) and by the local research and development committee at your hospital. Although approval does not guarantee that your baby will not come to any harm it does mean that the committees are satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information to make an informed decision whether to take part. This study was also reviewed by the Neonatal Clinical Studies Group of the UK Medicines for Children Research Network (MCRN).

16. Expenses and Payments

There are no financial costs nor benefits to you from participating in this study.

17. Who is organising and funding the study?

The study is being sponsored and funded by NHS Blood and Transplant. The study is being organised and run by the NHS Blood and Transplant (NHSBT) Clinical Trials Unit (CTU).

18. What if something goes wrong?

Research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm occurs as a result of taking part in this study. If by taking part in this trial your baby suffers any harm due to the study itself, you have a right to complain or take legal action against the NHS Blood and Transplant service unless that harm results from a negligent act or omission by the hospital, in which case it is the hospital's responsibility. Should the harm result from the giving of a platelet transfusion, you have statutory rights under the Consumer Protection Act.

19. What if I have any concerns?

If you have any concerns or other questions about this study or the way it has been carried out, you should contact your local study doctor and team whose contact details are shown below. They will do their best to answer your questions.

Local Principal Investigator:

If you remain unhappy, you may contact your local Patient Advice and Liaison Service (PALS) for advice:

PALS:

You will be given a copy of the information sheet and a signed consent form to keep.

For more information, please go to the Planet-2 website: www.planet-2.com

We would like to thank you for considering taking part in this study and helping us learn how to improve the care of babies