PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study and registry of twins and their family members. We are currently recruiting expectant twin parents who have been referred to a special multiples clinic.

The aim of this study is to provide insights into the way differences between individuals are determined by hereditary and environmental influences. We would also like to investigate how life of parents of twins changes from a social point of view. In order to take this research forward we are asking parents expecting twins to join the Birmingham Registry for Twin and Heritability Studies (BIRTHS). With the help of registered twins and their families, the BIRTHS will examine the influence of genes and environment on the growth and development of children. We would be grateful if you would join the BIRTHS and fill in a questionnaire when you come to the hospital for your antenatal appointments and after delivery. We would like your permission to take cord blood from your twins to genetically determine whether your twins are identical or non-identical. We will feedback this information to you. We do not take blood from the twins themselves. In addition, we would like to investigate the afterbirth. Once registered, we will invite you and your twins to a special twin clinic for regular follow-up not only of growth and weight, but also to monitor
your babies’ development in detail. After each visit you will receive detailed feedback on the developmental status of your children. In addition, we will look through your and your twins’ medical records and will ask you to complete short and easy to fill in questionnaires.

Taking part is entirely voluntary. Before you decide whether you would like to join, it is important for you to understand why the research is being done and what it exactly will involve. Please take time to read the following detailed information carefully and discuss it with others if you wish. Please do not hesitate to contact me if there is anything not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Thank you for taking the time to read this information sheet. If you agree to take part in the BIRTHS, could you fill in the attached “patient consent form” and bring this along to your next appointment.

Yours truly
1. What is the purpose of the study?
In this study we investigate the influence of genes and environment on the development of children. We will also investigate how life of parents of twins changes from a social point of view. This will include research on the relation between maternal depression and child development. This has not been investigated in mums of twins so far.

2. Why have we been chosen?
You have been referred to a special multiples clinic as you are expecting twins. We are asking prospective parents of twins to join the Birmingham Registry for Twin and Heritability Studies. We intend to recruit at least 200 twins over the next two years.

3. Do we have to take part?
It is up to you to decide whether or not to join. You do not have to decide straight away. When you come to antenatal multiples clinic, you will be asked if you would like to join the registry and participate in the study. If you agree to take part you will be asked to sign a consent form. If you do decide to take part you are free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you and your twins receive or your or your twin’s relationship with your doctor.

4. What will happen to us/our twins if we take part?
Once you have agreed to take part and have signed a consent form, a scientific study will run alongside your and your twins’ standard care. When you come to antenatal clinic and to the follow-up appointments for your twins we will ask you to fill in a questionnaire. The questions will be on your background, medical history and lifestyle. We would need you to give us about 30 minutes of your time to fill in the questionnaires. We will also ask you to let the midwife take blood from the placental end of your twins’ cords. We do not take blood of your babies. In addition, we will ask you to give us permission to look through your and your twins’ medical records. After discharge, we will invite you to regular follow-up clinics at your local well baby clinic. These clinics will be held 3 monthly in the first year and 6 monthly in the
second year. At each visit your twins’ growth and weight will be measured and a detailed developmental screen of both twins will be carried out. After each visit you will receive detailed feedback on the developmental status of your children. We will also ask you to fill in a questionnaire at each visit. The questionnaire will contain questions about changes in your lifestyle after the birth of your twins. For your convenience and to avoid any double investigations we will ask for your permission to look through your twins’ personal child health records (“red booklets”). We will document our findings in the twins’ personal health record. Each follow-up appointment will take about two hours.

At the moment we have funding to run the study over a 2-year period. However, as we will collect data on growth and development there will be a much longer period of interest. This study could be considered a first approach to future studies, so we might come back to you and your twins later and ask for further follow-up appointments. Of course any subsequent study will have separate ethical approval and we will ask you and your twins for consent.

5. What do we have to do?
Other than your normal care we would need you to complete our questionnaires and to donate samples of your twins cord blood and the afterbirth. In addition, we would need you to visit the special twin clinics for further follow-up of your twins.

6. What will happen to the blood samples taken as part of this study?
The blood samples will be stored centrally at a laboratory at The University of Birmingham. These blood samples will be used to genetically determine whether your twins are identical or non-identical. We will feedback this information to you. In addition, we would later use the samples donated as part of this study for future research. Such research projects have not yet been planned and could occur many years in the future. These future research projects may involve studies of your twins’ genes and DNA. By giving your consent for your twin’s blood to be stored you will be offering your twins samples as a gift.

The blood and DNA samples will be stored under strict confidentiality and security and are coded, so that researchers receiving the samples do not know your or your
twins names or any other personal details. Researchers who wish to use the samples that are stored will only be given access to the samples after their research has been approved by an independent Research Ethics Committee who makes sure that the research is in the interest of patients and is carried out safely.

7. What are the possible disadvantages and risks of taking part?
There are no risks of taking part. This study will run alongside your and your twin’s routine care and follow-up; it will not influence this process.

8. What are the possible benefits of taking part?
There is no intended immediate clinical benefit from taking part in this study. However, your twins’ growth and development will be closely monitored for the first two years of their life. After each visit you will receive an extensive report about your twins’ development. If we are concerned, we will inform you and your GP, and a specialist appointment will be arranged. Furthermore, we will be able to tell you whether your twins are identical (“monozygotic”) or non-identical (“dizygotic”). You will receive this information. The information obtained from this study may result in changes in the future care and follow-up of expecting mothers during twin pregnancy and care and follow-up of their twins.

9. What if new information becomes available?
This study does not influence your routine care and follow-up. However, any new discoveries or information relating to this will automatically be incorporated into the standard treatment provided by your doctors.

10. What happens when the research study stops?
When the study stops your and your twins’ routine care and follow-up will continue in the normal way, although it may incorporate new discoveries or information generated by this study.

11. What if something goes wrong?
As this study does not influence your and your twins’ routine care and follow-up, the normal National Health Service complaints mechanisms should be followed.
12. Will my/our taking part in this study be kept confidential?
All information that is collected about you and your twins during the course of the research will be kept strictly confidential. If you agree to take part in this study we will need you to sign a consent form. You will be given a copy of the consent form and this information sheet to keep.

Upon registration in the BIRTHS we would collect some contact details from you including your current address and telephone number. These details will be used to ask you again for future studies after the first research study is closed. You can of course reject this request. By registration in the BIRTHS you are not obliged to do anything! Your contact details will be kept strictly confidential and only members of the BiRTHS research team would be allowed access to them.

Information on all patients entered into this study will be sent to the BiRTHS Study Office. This is located at The University of Birmingham where it will be retained in secure storage and handled according to the 1998 Data Protection Act. No personally identifiable information will be released from the BiRTHS study office. Limited clinical information may be passed on to the researchers within the UK. It would not be possible to identify any patient from this information and any information provided will be handled according to the normal standard of medical confidentiality and data protection.

13. What will happen to the results of the research study?
Important results from the study will be published as they come available, which may be during the course of the study or after the study has finished, and this could possibly take several years. We intend that any results will be published in scientific journals or will be presented at meetings involved with this field of twin research. These publications will be available upon request from your GP. You and your twins will not be identified in any report or publication.

14. Who is organizing and funding the research?
The research is being organised by the Unit of genetic Epidemiology at the Department of Public Health and Epidemiology at The University of Birmingham in collaboration with the Neonatal Unit at the Birmingham Women's Hospital,
Birmingham. The Birmingham Children’s Hospital Research Foundation funds the research. The doctors conducting this study are not being paid for including and looking after you within this study.

15. Who has reviewed the study?
This study has been positively reviewed as a multi-centre study by the Solihull Research Ethics Committee and by scientific experts affiliated with The Birmingham Children’s Hospital Research Foundation and The University of Birmingham. The two major UK twin associations: The “Multiple Births Foundation” (MBF) and the “Twins and Multiple Birth Association” (TAMBA) have give written declarations to support the BiRTHS.

16. What if I have other concerns or would like further information?
If you have any concerns or other questions about this study or the way it has been carried out, you should contact the number listed below.

Contact details:

Name:

Telephone: