**Understanding osteogenesis in health, development and disease**

**PARENT/GUARDIAN INFORMATION SHEET**

**Collection of Tissues and blood from spine surgery**

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

Thank you for reading.

***1. What is the purpose of the study?***

We believe that certain cells of the immune system can influence the behaviour of a special type of cell called mesenchymal stem cells which are able to form new bone. This is important in the spine for healing of fractures and normal development. Alternatively, in some types of arthritic disease such as ankylosing spondylitis bone formation in the spine is abnormally accelerated, this can lead to individual bones of the spine fusing together causing loss of mobility and progressive disability. We would like to study the interaction between cells of the immune system and mesenchymal stem cells in the spine, in the hopes of understanding how we may influence bone formation.

***2. Why has my child been chosen?***

We would like to study the cells that are present in bone and tendons or ligaments. Your child has been chosen for this study because he/she will be having an operation on part of their spine. As part of the surgical procedure, a small portion of bone and ligament may be removed. This would usually be discarded, but with your permission we would like to keep this tissue and use it in our study. We would also like permission to take a small amount of bone marrow (up to 10ml or 2 teaspoons) and blood (up to 20ml or 4 teaspoons), although bone marrow will only be taken in certain circumstances as detailed in section 6.

***3. Does my child have to take part?***

No. It’s up to both you and your child to decide, only if you are **both** happy will your child be included in the study. If you and your child decide to take part, you are still free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care that you’re child receives. Please be aware that once any tissue or data has been collected and anonymised we will not be able to return it.

***4. What will happen to my child if he/she takes part?***

If you and your child decide to take part, you will be given this information sheet to keep and be asked to sign a consent form, If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to. Your child’s operation will proceed as normal however the collected tissues will be kept and sent to the laboratory. A blood sample may also be taken during the surgery, alternatively this may be taken either before or after the surgery. For children under 10 we will only take a blood sample if this can be done during surgery.

***5. What do I and my child have to do?***

There are no other requirements/tests needed beyond the surgical procedure and blood sample.

***6. What are the side effects of taking part?***

There are no side effects associated with donation of the bone and ligament tissues since these are normally thrown away after the operation. Also, there are no side effects associated with donation of bone marrow in this case, because this sample will only be taken if the surgeon plans to drill into the bone as an essential part of the operation (for example for implanting surgical screws). No drilling will take place just for the sake of collecting research samples, so if the surgeon does not need to drill into the bone, no bone marrow will be collected. Donating blood is very safe, although some people do experience some mild after effects, such as: **bruising** at the site where the blood was taken (which affects around one in four people) a **sore arm** (which affects around one in 10 people) **dizziness** and fainting (which affects around one in 15 people).

***7. What are the possible benefits of taking part?***

Neither you nor your child will benefit directly from taking part in this research and all other aspects of your child’s care will be the same as if he/she did not take part.

***8. What if something goes wrong?***

In the unlikely event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The University of Leeds but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

***9. Will my child’s taking part in this study be kept confidential?***

As soon as the sample(s) is taken and before being sent to The University of Leeds, all information that identifies your child will be removed so that he/she cannot be recognised. Only members of your child’s clinical care team will have access to your child’s medical notes. From these, only information about your child that is relevant to the study will be collected and passed to researchers at The University of Leeds This may include information on current medications and health status, but will not include personal information such as address or family details. This could continue for up to 3 years after recruitment of participants has ended. All information which is collected about your child during the course of the research will be kept strictly confidential. Any information passed to third parties will have all identifying information removed so that your child cannot be recognised from it. The only identifying information held by the University of Leeds will be that on the consent form that you will sign if you choose to take part, this will be stored securely so that only members of the research team will have access.

***10. What will happen to the tissue samples?***

Once sent to The University of Leeds, the samples will be processed for use in laboratory experiments. The samples may also be stored so that we can use them in current and future studies. We may pass anonymised samples to third parties including industrial partners on the understanding that The University of Leeds maintains exclusive control and that no direct commercial gain will be made. We may also hire outside agencies to perform certain specialised services involving anonymised donated tissue. Any additional studies will be subject to additional independent ethical committee review.

***11. Will there be any genetic testing involved?***

We may perform some genetic testing looking specifically at genes involved in growth, tissue repair and immunity. No information genetic or otherwise will be published or passed to third parties that could in any way identify your child, his/her involvement will be kept strictly confidential.

***12. What will happen to the results of the study?***

At the end of the study, the results will be written into a scientific paper for publication in a scientific journal.

***13. Who is organising the research?***

This project is being organized by Doctors of St. James Hospital and Leeds General Infirmary under the supervision and support of the University of Leeds.

***14. Who has reviewed this study?***

This study has been reviewed by the independent ethics committee called the North West - Greater Manchester West Research Ethics Committee. This committee is appointed to determine that research studies are ethical and do not impair the rights or well-being of patients. We have received approval by this committee to be able to do this research study.

***15. Contact for further information***

For further information on the study please contact:

Professor D McGonagle,

Wellcome Trust Brenner Building

St. James’s University Hospital

Leeds LS9 7TF

E. mail: D.G.McGonagle@leeds.ac.uk

Telephone: 0113 3924747