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|  | Dr Claire Meek  Consultant Chemical Pathologist & Metabolic Physician  GIFT PIL  Version 2  Date 9/4/2018 |
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**Participant Information Leaflet - GIFT study**

**Full Title: GIFT study: Semen glucose concentrations and sperm motility in fertility testing**

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

**Part 1** tells you the purpose of this study and what will happen to you if you take part.

**Part 2** gives you more detailed information about the conduct of the study.

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. The patient advice and liaison service (PALS) in Peterborough City Hospital can be approached for independent advice about the research information that you have been given. Thank you for reading this information sheet.

**PART 1**

**What is the purpose of this study?** Fertility issues affect around 1 in 7 couples in the UK. Around a third of cases are likely to be caused by male factors and these can be assessed using analysis of semen. During semen analysis, the ability of the sperm to move forward is assessed – this is called motility. It has been recognised that sperm motility is declining worldwide and this may be related to diet, inactivity, weight and blood sugar (glucose) levels within the population as a whole. Although the high blood glucose levels seen in diabetic patients are known to be very damaging for male fertility, there is currently no clinical recommendation to assess blood glucose concentrations in male patients under investigation for infertility. The aim of the current study is to assess whether blood and semen glucose is related to sperm motility.

**Why have I been invited?** You personally have been invited because you have been referred for a semen analysis test. We would like to recruit around 60 volunteers to help us carry out this research project. This is an educational project and will help NHS staff develop new skills.

We recognise that this is a difficult time for men and their partners, both in addressing fertility issues and in overcoming discomfort during fertility tests. The study team are experienced in caring for men undergoing fertility investigations and have received particular training in this field.

**Do I have to take part?** You are under no obligation to take part in this study. If you are interested, we will describe the study, give you this information sheet and answer any questions you might have. If you decide to take part in the study, we will then ask you to sign a consent form to show you have agreed to take part. Even after you sign the consent form, you are free to withdraw at any time, without giving a reason. This would not affect the standard of medical care you receive.

**Will the study affect my normal medical care?** Your normal medical care will not be affected by this study.

**What do I have to do?** You have been invited to take part in this study because you have been referred for a semen analysis test. The semen sample will be analysed as normal. However, we will ask you if you are willing for us to use the sample for research purposes once standard clinical testing is finished.

If you would like to participate in this study, you will also be asked to have a blood test. We will take around 10 ml (around 2 teaspoons’ full) of blood to look at your short-term and long-term blood glucose concentrations. This will be performed by a phlebotomist in the outpatient department.

If you are willing, we will also access any previous test results held on the laboratory computer system. This might include for example, your blood sugar levels if these have ever been measured before.

To overcome any discomfort you might experience attending for fertility investigations or discussing this study, we will provide the study information before the visit, to enable you to think about whether or not you would like to participate in the study. You will also have the opportunity to discuss the study with a member of the study team in confidence and to ask any questions you might have. If you would like independent advice about participating in the study, you can discuss this with the PALS service (details above). If you would like to talk to us about accessing more support during your fertility investigations or as part of the study, we would be happy to discuss this with you confidentially.

**What are the possible disadvantages or risks of taking part?** The risks of taking part in this study are low and the volume of extra blood required should not pose a risk to your health.

**Are any devices or drugs involved?** There are no devices or drugs involved in the study.

**What are the possible benefits of taking part?** We cannot promise the study will help you, but the information we obtain from our experiments will help us improve care for infertile couples in the future.

There is also a small possibility that while analysing your blood tests, we will detect abnormalities which you were not aware of before. This might include evidence about your blood glucose levels and long-term risk of diabetes. If we find out information relevant to your future health, we will send you a letter and can discuss the matter with you in confidence. We would also inform your GP. While this is a risk of participation in the study, it offers you the possibility of having important conditions diagnosed early, which may be of benefit to your long-term health.

For example, if we discovered high blood sugar levels, consistent with diabetes, we would invite you to return to the metabolic clinic to see a metabolic consultant who is experienced in the care and treatment of people with diabetes. At that appointment, we would discuss the diagnosis and to talk about how best to treat the condition. We would normally also inform your GP, unless you specifically tell us not to.

**Will I be paid for my participation in the study?** Volunteers will not be paid for their participation. As the study is funded by a charity, this helps us keep research costs down. We thank you for your understanding on this matter.

**What happens when the research study stops?** During the study, the samples will be stored securely in Peterborough City Hospital while the preliminary tests are performed. However, after preliminary testing is complete, anonymised samples may be sent to other hospitals in the UK or around the world for storage or further testing. This might include sending blood samples to a laboratory overseas for a specialist test which cannot be performed in the UK. At the end of the study, all samples will be discarded. If you wish, after the study has been completed, the investigators will send you a report explaining the results of the research.

**Is there any support available to me at the end of the research study?** After the study, your healthcare provider (GP or another clinician who referred you for fertility testing) will be sent the results of the semen analysis. You may then be asked to see them to discuss if you need any further tests or referral to fertility services. The study team will not arrange a referral as we do not have access to all the relevant information about you and your partner.

However, if you would like specific support related to the study, we can offer help in some circumstances, for example, if you wish to discuss any findings from your blood tests or any new diagnoses. If this occurred, we would make an appointment for you in a clinic to discuss the findings on your blood tests and to talk about what to do next. You would also have the opportunity to discuss any concerns with the PALS service. If you would like information about counselling services or charities providing support groups or events, we will provide information about services which could help you.

**What if there is a problem?** Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information of this is given in part 2.

**Will my taking part in the study be kept confidential?** Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

**PART 2**

**What if new information becomes available?** We continuously review the latest scientific reports in order to plan useful and worthwhile experiments. If new evidence came to light, we might consider amending our study design. However, if this occurred, we would explain the changes to you and give you the opportunity to withdraw if you wish.

**Will video/audio tapes be used?** No

**What if there is a problem?** If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions (<insert contact details>). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure, details of which can be obtained from the hospital.

**Are there any compensation arrangements if something goes wrong?** If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism may be available to you. In the event that something does go wrong and you are harmed during the research and that is due to someone’s negligence then you may have grounds for legal action for compensation against North West Anglia NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

**Will my taking part in this study be kept confidential?** We believe that the confidentiality of your personal data is vital. The study will meet the requirements of the Data Protection Act and will adhere to the NHS Code of Confidentiality. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised (anonymised).

**Who will have access to my personal information?** Dr Claire Meek, Alison Nolan and the study team will have access to your personal data. Dr Claire Meek is the consultant chemical pathologist with responsibility for the semen analysis clinic. Ms Alison Nolan is a senior biomedical scientist and works in the hospital laboratory. She leads the semen analysis service for North West Anglia NHS Foundation Trust. Although these healthcare professionals will have access to your details for the research project, they also have responsibilities for your NHS clinical care.

Both Claire Meek and Alison Nolan have either NHS hospital contracts or honorary hospital contracts which have the appropriate confidentially clauses inserted. We sometimes supervise students in healthcare disciplines who need to learn about clinical research, who also have strict obligations to maintain confidentiality. It is also possible that representatives of the North West Anglia NHS Foundation Trust may ask to see the study files, to confirm that the research is being performed to the required high standards. All staff are aware of the requirement for strict confidentiality and work to appropriate confidentiality standards.

After the study, any identifiable data will be stored for 3 months and then disposed of securely in line with the appropriate regulations. The anonymised data from the research will be stored for 15 years.

**What will happen to the samples I give?** Once the samples have been obtained by the researchers, they will be coded for identification and storage. Samples will be stored securely inside an NHS laboratory. We envisage that all laboratory testing will be performed within the chemistry laboratory at Peterborough City Hospital. However, if our study finds interesting or unexpected findings, we would consider sending blood samples away to more specialist laboratories in the UK or around the world for further analysis. For example, if we found that high sugar levels were associated with reduced sperm motility, we might look at new tests to assess long-term blood sugar levels, or for metabolomics to identify if the raised sugar levels are accompanied by other biochemical changes. These tests are not offered in Peterborough City Hospital and samples would be sent to specialist laboratories for these tests. Your sample would be anonymised if it leaves the laboratories of North West Anglia NHS Foundation Trust.

After the study has been completed, semen and blood will be disposed of in accordance with the best practice for research samples. This will occur inside the NHS laboratory. Samples which are sent to other laboratories will be returned to Peterborough City Hospital for disposal in line with the Human Tissue Act. After the research study, samples will be disposed of after 3 months. If there is any need to delay disposal of your samples, for example, if specialist testing was arranged in a different laboratory which might take longer than 3 months, we would seek approval from the research ethics committee and send you a letter to inform you of this change. If you had any concerns about this, you would also be given contact details for the research team who could provide more information about any proposed changes to the disposal time of your samples.

**Will any genetic tests be done?** No genetic tests will be performed.

**What will happen to the results of the research study?** We plan to write scientific papers in medical journals explaining to others what we have learnt from doing these studies. We may also present our findings to groups of scientists or healthcare professionals at conferences. Personal identities will not be revealed in any publications or presentations. As this is an educational study, a report will be written for a University degree submission process. This will not include any identifiable information.

**Withdrawal clause.** You will be free to withdraw from this study at any stage without explanation and without affecting your current or future treatment. Any samples taken up to the time of withdrawal will be kept and used in the study for the purposes they were taken for, unless you specifically request otherwise.

**Who is organising and funding the research?** This study is funded by the European Foundation for the Study of Diabetes. The doctors and healthcare professionals conducting the research do not receive any personal financial gain from including patients in the study.

**Who has reviewed the study?** All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the <insert name> Research Ethics Committee.

**Local contact for information.** Should you wish to discuss any issues related to this study, please contact the study team using the details below. Thank you for reading this leaflet.

Chief Investigator: Dr Claire Meek Lead Research Midwife: <insert name>

<insert contact details> <insert contact details>