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The Fetal Medicine Research Institute

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Participant information sheet

**Study Title: FERN- Fertility Evaluation of ReNal disease**

**IRAS number: 285546**

We would like to invite you to take part in our research study. This study is for educational purposes. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and will answer any questions you may have. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

### **What is the purpose of the study?**

Kidney disease affects 3% of women of childbearing age. However, pregnancy rates in patients with kidney disease are very low at 1-10% of the general population.

We do not fully understand why kidney disease reduces fertility and how it affects female reproductive hormones. We would like to measure these hormones and look at ovarian function in women with kidney disease to get more information.

The aim of the study is to better understand how kidney disease affects fertility and what can be done to help women who want to become pregnant.

### **Why have I been invited?**

You have been invited to take part because you are female between the age of 18 and 50 years old and have kidney disease.

**Do I have to take part?**

1. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

### **What will happen to me if I take part?**

If you agree to take part in the study, you will be required to sign a consent form. You can withdraw your consent at any time and do not have to give an explanation. Withdrawal will not affect your ongoing care.

We will ask you to fill out a questionnaire about your health and feelings about your fertility. We would like to take some blood (approximately 2 teaspoons) from a vein on day 1-5 of your period if you are having regular periods. We may also ask you to do two more blood tests at 3 and 6 months.

We would also like to do a transvaginal ultrasound scan of your ovaries to assess how many follicles (early eggs) you have at King’s Fertility. The transvaginal ultrasound is an internal scan where a small lubricated probe will be placed about 2-3 inches inside your vaginal canal. The probe is larger than a tampon but is smaller than a speculum that would be used in a smear test. It should not be painful but may cause you to feel a light amount of pressure. There will be a chaperone and your dignity will be maintained throughout the procedure. If you do not feel comfortable with a transvaginal scan, we can do an abdominal scan but the views are less clear. We may ask you to come for an additional scan or blood test 3 and 6 months later.

You can still take part in the study if you do not want to have the scan.

If you wish, after the study is complete, a fertility specialist can contact you to discuss your results.

**What are the alternatives for treatment?**

Participation in this study is voluntary. The medical treatment that you require will not change based on your participation.

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

Your samples and information may help us to improve the care for women with kidney disease who have fertility problems. A fertility specialist will contact you to give your results, explain what they mean and how best to act on them if there is a problem. Your GP will be informed of any findings and if you need emotional support counsellors will be available to you as part of the study.

**What are the possible disadvantages and risks of taking part?**

There are no risks to you by taking part. The amount of extra blood that we take will not affect you. The blood test will be taken at the same time as any blood tests as part of your clinical care. There can be minimal pain and bruising with the blood tests. The transvaginal ultrasound scan is safe and has no significant risks associated with it. Occasionally there is minimal discomfort during the scan but your wellbeing will be the upmost priority during the scan.

**Who is organising and funding this study?**

The doctor in charge of this study is: Dr Kate Bramham. The study is funded by the Fetal Medicine Foundation and is being sponsored by King’s College Hospital.

**How have patients and the public been involved in this study?**

Patients helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.

**Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by \_\_\_\_\_\_\_Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

**Expenses and Payments**

Travel expenses are available for payments to those participating in this study (up to £42).

**What happens when the research study stops?**

You will continue with your medical care.

**This completes Part 1 of the Information Sheet.**

If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

### **PART 2**

### **What if new information becomes available?**

Sometimes we get new information about the treatment being studied. If this happens, your study doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study he/she may ask you to sign an agreement outlining the discussion.

This new information that becomes available might specifically affect you and your health. If this happens, your study doctor might consider that you should withdraw from the study. He/she will explain the reasons for withdrawing from the study and arrange for your care to continue*.*

You will be fully supported by the study doctor throughout the study and if any significant clinical findings are found we will refer you to the appropriate specialist and contact your GP.

If the study is stopped for any other reason, we will tell you and arrange for your continuing care.

1. **What will happen if I don’t want to carry on with the study?**

You are free to withdraw from the study at any time; and if you would like to do so; please speak to your study nurse or doctor. Your decision to withdraw from the study will not affect the care you receive.If you withdraw your consent; Information collected about you may be used if you are happy with this. You can withdraw consent for all information collected to be destroyed where this is possible. Wherever possible, any stored blood samples that are yours will be destroyed if you wish.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions ( Study doctor: Miss Mahua Bhaduri. Email: mahua.bhaduri@kingsfertility.co.uk). If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS choices website. <http://www.nhs.uk/pages/home/aspx>

Every care will be taken in the course of this study. However in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King’s College London but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

1. **Will my taking part be kept confidential?**

If you consent to take part in the research, any of the information collected about you may be inspected by the King’s College London. These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, your hospital doctor may tell your GP about your participation if you agree to enter the study.

1. Involvement of the General Practitioner/Family Doctor (GP)
2. With your consent, your GP will be informed of your involvement in the trial. Any other medical
3. practitioners who treat you, e.g. should you be admitted to hospital for any reason, will also be informed.
4. **What will happen to any samples that I give?**

Your samples will be stored here at the Fetal Medicine Research Institute for up to 25 years for later analysis. All samples stored will be pseudonymised.

1. Will any genetic tests be done?
2. No genetic testing will be carried out within this study.
	* 1. **What will happen to the results of the research study?**

We aim to publish the results of this study in a peer reviewed medical journal. Any published report will not contain any identifiable information from the participants involved. If a participant wishes to learn the results of the study, then they can contact the study doctor for further information. Should an individual health implication be found then with the patient’s permission, these details will be forwarded to the participant’s GP for further investigation.

**How we will use your data**

We will need to use information from you and from you medical records for this project. This will include your demographic and clinical data related to your treatment and the information we collect during the study. 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 your name or contact details. Your 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 your personal and research data so we can check the results for up to 5 years after the study has ended. 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 you 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 you. If you agree to take part in this study, you will have the option to take part in future research using your data and samples collected during this study.

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

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

* on the Health Research Authority website [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* in a leaflet called: HowWeWillUseYourData KCH V1 (21-11-19) – available from the study team
* at our website <https://www.kch.nhs.uk/about/corporate/data-protection>
* by emailing our Data Protection Officer on kch-tr.dpo@nhs.net
1. **Thank you**
2. Thank you for considering taking part and taking the time to read this information sheet.
3. If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

**Further information and contact details**

INVOLVE, Alpha House, University of Southampton Science Park, Chilworth, Southampton, SO16 7NS

Telephone: 023 8059 5628 Email: involve@nihr.ac.uk

Local Contacts:

Your Study doctor ..Miss Mahua Bhaduri Tel: 020 3957 7950