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NHS Trust

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INFORMATION SHEET FOR A PATIENT - ADULT
Invitation to participate
(Version 2, 1st October 2016)
REC Reference: 16/SC/0346

Re: Clinical Registry for Endocrine and Metabolic Disorders

Name of Researcher: Professor R V Thakker

You are being invited to take part in a research registry. Before you decide, it is important for you to understand why the data is being collected, what will be done with it and what it will involve for you. Please read the following information carefully and discuss it with others if you wish. 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 this.

1. What is the purpose of the study?

The main purpose of the study is to establish a national database of patients with endocrine and metabolic disorders. This information can be used to try to identify dietary, environmental and therapeutic factors that can influence these problems. These conditions are due to over-production or under-production of hormones. Hormones are produced by glands, and can cause endocrine and metabolic conditions when they are not regulated normally. This is because disturbances in hormones can affect the body's metabolism, resulting in different disorders that include those of the digestion, bowels, weight, blood pressure, heart, kidneys, bone, sexual function, mood, thirst, and breathing.

Endocrine and metabolic disorders are common and may be caused by hormone excess, which may be associated with endocrine tumours, or hormone deficiency, that may be due to a birth abnormality or autoimmune destruction of the gland. These disorders usually occur as non-familial (i.e. sporadic) disorders but they may also run in families. The cause of these endocrine and metabolic disorders is poorly understood, but it seems likely that there is a genetic cause as over 10% of cases run in families. The aim of this study is establish a national database of patients with endocrine and metabolic disorders, as this will help to: 1) provide important clinical information that will help us to understand the epidemiology, natural history and genetic causes of these diseases; 2) understand the use of investigations and how effective certain treatments are; 3) formulate clinical practice guidelines that will improve patient care; and 4) further our understanding of the mechanisms underlying these disorders.

We wish to collect medical and other information about people who have endocrine and metabolic disorders, and their relatives. This information will be stored on the Endocrine Registry and made available for researchers to use where appropriate. This work is funded by the Medical Research Council (MRC), Wellcome Trust (WT), National Institute for Health Research (NIHR), Kidney Research UK (KRUK), European Union (EU) grants, NIHR Oxford Biomedical Research Centre (NIHR OxBRC), and Marshall Smith Syndrome Research Foundation.

2. Why have I been invited?

You have been invited because you have a metabolic or endocrine condition. It is important for us to have data from individuals who are affected with the condition as well as individuals from the family who are unaffected. It is by comparing the clinical and genetic data from affected and unaffected individuals in a family that enables us to understand the basis of the disorder, and environmental factors and treatments that may alter its course. We are contacting other families with this condition and inviting affected and unaffected members to help us in these studies.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form indicating your agreement for your information to be added to the registry. The Head of the Group (Professor R V Thakker) will then have day-to-day responsibility for managing and caring for your data, but the formal ("legal") custodian of the data will be the Academic Endocrine Unit (Oxford University) itself (i.e. an institution and not an individual). The University of Oxford Academic Endocrine Unit will have control over what happens to the data, how it is used, and all rights to any "inventions" (such as advances in drugs, treatments or tests) which may come out of the research performed using the data. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of medical care you receive.

4. What will happen to me if I take part?

Taking part in this study is very straightforward. If you decide to take part in this study, one of our research team will contact you to make arrangements to discuss the project in more detail and answer any questions you may have. If you then agree to take part in the registry, we will ask you to for written consent and then we will also ask if you would be happy to pass letters of invitation to your relatives to find out whether they want to take part in this study. There is a participant database website that can be accessed by those participating in the study from any computer. If you wish to use this then you will be granted access. You can use the participant database website to electronically give or withdraw consent, at any time. We can also arrange to give you a paper copy of the consent form if you would prefer not to use the website. Once you have given your informed written consent to participate in this study we will ask you, and your doctor, about your medical details and we may also need to consult your medical records, in order to confirm the results of tests (such as those from scans and genetic analysis), and other details (such as your medications and treatments). We would also ask for consent to keep the medical information up to date, by asking you or your doctors to send the information whenever you see them. You can provide your information either in person to one of our researchers, through completing a paper questionnaire, or electronically through the participant database website. If you choose to use the website then this you will have access to this up to date record of your medical details at any time.

5. What about my personal details and would my taking part in this study be kept confidential?

All the information relating to you will be treated in the strictest confidence – as with all medical records – and stored in line with the Data Protection Act (1988). To carry out our work we will need to maintain a computer record of your personal details (such as your name and hospital number) together with the details of your condition (such as how old you were when symptoms first developed and what year it started). The computer storing your personal details will not be connected to the "internet", so information held in the database cannot be accessed by unauthorised users. Your medical information and results of the tests will be anonymised and stored on a separate computer that is connected to the internet. The coding information linking your anonymised personal details and your test results is available to only a maximum of six individuals who are engaged in the research at any one time and may also need to be accessed by responsible members of the University for the purpose of monitoring the study. Researchers wishing to use this registry will be required to submit a formal request which will be reviewed by a team of senior academics from across the UK specialising in this field. They will only grant access to the data if they feel that the research proposal is worthwhile and will use the data appropriately. Names would not be disclosed to other researchers or third parties, and any results that are published will be in an anonymised form so that neither you, nor your family, can be identified.

6. Photographs

For some research and teaching purposes, it may sometimes be helpful to publish facial (or other) photographs as this may aid other doctors in recognizing the condition. We would disguise the photograph so that you cannot be identified from it. We would like to seek consent for this.

7. What if I change my mind and no longer wish to participate in the research?

If, for any reason, you change your mind and no longer wish to be involved in the study, you can withdraw your consent at any time. You can do this in two ways, either by informing your research doctor or electronically via the participant database website. If in the future you change your mind and would like to re-join the research study, this will be possible and you will be re-consented at

that stage. If we have already fully anonymised your data, i.e. removed any link of it to you, then we will not be able to withdraw this from the study.

8. What are the possible disadvantages and risks of taking part?

These are minimal. The information being recorded in the Registry will already be known to you. Some people may worry about their results becoming known to others. However, confidentiality is maintained at several levels (see "Question 5. What about my personal details and would my taking part in this study be kept confidential?").

9. What are the possible benefits of taking part?

Initially there are no intended clinical benefits or other benefits to the participants from taking part in this study. Of course it is our future aim that once we know more about the condition, then we may be able to devise better treatments, and possibly even to prevent the disease. Thus, it is possible that the research could produce findings of direct clinical significance for you. In this instance we will inform you and your usual clinician of these results, if you indicate that you would like to know on the consent form.

10. What would happen if I lost the capacity to consent in the future?

In the event that you lost capacity to consent (through a serious illness or accident), the research team would retain the personal data previously collected. It would continue to be used only for research into the causes of endocrine and metabolic conditions and confidentiality of the data would be maintained. We would not attempt to obtain any further data from you.

11. What about commercial exploitation?

This research does not aim to make patentable products or discoveries or otherwise seek any commercial benefit. However, in the event that such a product or discovery is made, you would not have any commercial rights to these benefits.

12. What would be the eventual outcome of the research?

We, and other researchers, would intend to publish important research findings in the specialist medical/scientific literature, probably about 2 years after the study has finished. In addition, if we undertook any studies, e.g. clinical trials or genetic investigations, on the information that you have provided, then we might share data on the results with other researchers and/or submit the data to curated databases, again on an anonymous basis. These data would be coded and no names or addresses recorded to ensure that the information remained confidential and safe.

13. Would I be told the results of this research?

If you are interested in learning about the progress in the research studies, then you can view the publications on our research website (www.ocdem.ox.ac.uk) which will be updated regularly.

14. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. However, the chances of something going wrong are very small, as the procedures being used e.g. taking a blood or urine sample, or a mouthwash, are not hazardous. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor RV Thakker (email rajesh.thakker@ndm.ox.ac.uk and phone 01865 857501) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk. The Patient Advisory Liaison Service (PALS) is a confidential

NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact **01865 235855** or PALSCH@ouh.nhs.uk.

15. Who is organizing and funding the research?

This study has been funded by the Medical Research Council, Wellcome Trust, National Institute for Health Research (NIHR), Kidney Research UK, EU grants, NIHR Oxford Biomedical Research Centre (NIHR OxBRC), and Marshall Smith Syndrome Foundation. The research is organised by Professor R V Thakker (May Professor of Medicine) at the Radcliffe Department of Medicine, University of Oxford, Churchill Hospital, Headington, Oxford.

16. Who has reviewed the study?

The study has been reviewed by the London Multi-Centre Research Ethics Committee (MREC) and also by the appropriate grant committee from funding organisations, which include the Medical Research Council, Wellcome Trust, National Institute for Health Research (NIHR), Kidney Research UK, EU grants, NIHR Oxford Biomedical Research Centre (NIHR OxBRC), and Marshall Smith Syndrome Research Foundation.

17. Contact for further information.

If you have any further questions about the study please contact Professor R V Thakker, Radcliffe Department of Medicine, University of Oxford, OCDEM, Churchill Hospital, Headington, Oxford, OX3 7LJ, Telephone No. 01865 857501, Fax No. 01865 857502, E-mail: rajesh.thakker@ndm.ox.ac.uk.

18. What do I have to do?

If you agree to take part in the study then please let us know by completing the enclosed form, and we can contact you to make the arrangements.

Thank you for taking the time to read this Invitation. Please keep it in a safe place so you can refer to it again.