FUTUREInitiative

Warrington and Halton Hospitals NHS
NHS Foundation Trust

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PARTICIPANT INFORMATION LEAFLET

FUTURE INITIATIVE STUDY

PRINCIPAL INVESTIGATOR: DR RAHUL YADAV

You 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 time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. If there is anything that is not clear, or if you would like more information, please ask. This is a voluntary project, and if, when you have heard about the study, you would prefer not to take part; your decision will be accepted without question and will not affect the standard of care you receive.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to collect blood samples from 3000 healthy individuals over a period of five years. The blood sample will allow the researchers to

- Extract DNA from your blood which will be used to analyse the genes responsible for breaking down, and getting rid of, medicines in your body (this is called genotyping). We all vary in how we handle medicines which can result in differences in how well drugs work in different people. By understanding these differences, we may be able to develop better dosing for medicines to reduce this variability.
- Extract plasma from your blood which will be used for metabolomics analysis – a technique that determines what substances are circulating in the blood and how these relate to the variation in your genes.

The development of new and better medicines is vital for public health. When pharmaceutical companies or researchers are developing new medicines, or improving the use of existing medicines, a key step is the testing in phase I clinical trials (the testing of new and established medicines in humans). Researchers often face difficulties when recruiting volunteers who have specific genotypes (variation in the genes mentioned above). This study will help develop a panel of healthy volunteers who have been genotyped and are readily available to be recruited for early phase studies. By taking part in this study, your name will be entered onto a database and linked to your genotype, to facilitate phase I trials. The database will be secure and all the genetic information will only be accessible by the research team. Your information and contact details will never be passed on to any third parties without your explicit consent. *You should only take part in this study if you are willing to have your name included in the database, and are interested in taking part in phase I trials in the future.*

WHY HAVE I BEEN INVITED?

You have been invited to take part in the study because you are:

- Aged between 18 years and 45 years
- Body Mass Index (BMI) between 18.0 kg/m^2 and 32.0 kg/m^2
- Willing to donate a blood sample for DNA and other analysis
- In good health
- Happy to be re-contacted in the future for further clinical trials/healthy volunteer studies
- Happy to be re-contacted no more than twice per year by email, phone or social media, to confirm your contact details
- Registered with a GP in the UK
- Able to produce photographic identification (i.e. passport, visa, driver licence or other)
- Able to read and write English

In addition, you must <u>not</u>:

- Have any current medical history that may influence your ability to participate in the study (excluding mild eczema, mild asthma)
- Have a history of alcohol dependence or drug/chemical misuse
- Smoke more than 10 cigarettes, or equivalent in tobacco per day
- Have been taking any medication for more than 7 days prior to the day of screening (excluding oral contraceptive pills, hormone replacement therapy)
- Currently participating in another clinical study involving a new medication
- Have a history of allergy to multiple medications
- Have previously taken part in this study

The above information will be confirmed as part of a screening questionnaire.

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 asked to sign a consent form.

CAN I CHANGE MY MIND?

Yes, you can change your mind and have your details removed from our database. If you wish for your sample to be destroyed, this can also be possible. You are free to withdraw from the study at any time without giving a reason. However, once the study is complete and communication on further early phase trials come to an end, the links between your blood sample and identifiable information will be broken and it will not be possible to withdraw from the study. Withdrawal from the study will not affect the standard of care you receive in any way.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you are interested in taking part, a member of the research team will contact you to complete a screening questionnaire to obtain basic information to assess your suitability. If you are suitable to take part you will be invited to an appointment with a Research Nurse and you will have the opportunity to ask further questions. If you are happy to take part the Research Nurse will:

- Take some basic details such as medical history and ethnic background
- Take one blood sample – in total 18ml (about a single tablespoon) will be taken.

By signing the consent form you are consenting to have your details held on a database and give permission to be contacted in the future if there is a suitable research project that you may be eligible for.

Your sample will be analysed and the data stored securely on a database. If pharmaceutical companies or other researchers are looking for people to take part in early phase trials and you match their requirements, you may be contacted. If you are contacted in the future, it will be up to you to decide on whether to take part in the study or not. Any future early phase studies that you may wish to participate in, will have their own participant information leaflets and consent forms to read and complete. All studies will have been fully approved by the ethics committee and the Medicines and Healthcare products Regulatory Agency (MHRA), as these studies will involve development of new and better medicines. Your decision will be accepted without question.

You will be reimbursed £20 for your time and expenses for taking part in this study (future studies may also lead to reimbursement; the amount will be dependent on the nature of the study and will have to be approved by the ethics committee).

We will contact you no more frequently than twice per year to update your details and confirm the data we hold for you is still current. Contact may be by phone, email, letter or social media and will be entirely your preferred method of choice. You will be entered into prize draws for completing these short updates.

CAN I STILL TAKE PART IF I AM TAKING MEDICATION?

You may not be able to take part if you take some medications regularly. This will be assessed during the screening questionnaire and a decision will be made by a member of the research team.

WHAT WILL HAPPEN TO MY BLOOD SAMPLE?

Your blood sample will be assigned a random number and all identifiable information (such as name and contact details) will be removed before the sample leaves the research centre. Your blood sample will be sent to the University of Liverpool and stored securely. Only the research team will have access to the samples. Any residual sample may be used for future research and further tests – in particular, our ability to analyse genes is improving all the time, and we may need to analyse the whole genome at some stage in the future.

WHAT WILL HAPPEN TO MY INFORMATION?

Your clinical information will be assigned a random number matching that of your blood sample and all identifiable information (such as name and contact details) will be encrypted upon its storage within the database. All data collected as part of the study will be stored securely at the University of Liverpool.

WHO WILL HAVE ACCESS TO MY INFORMATION?

Healthcare professionals from the research centre will be the only people to have access to your identifiable information. We will not pass your information onto your GP or other doctors, unless specifically requested by you. We will not disclose all of your genetic information to anybody outside the research team – the only information that will be made available will be the relevant genotype if you are considering taking part in an early phase trial in the future. However, this information and

your contact details will never be passed to any company or another researcher wishing to conduct research without your explicit consent.

HOW WILL YOU USE MY INFORMATION?

When pharmaceutical companies or researchers are looking for people with a particular genotype, they will approach the research team to see if there are individuals on the database that may be eligible to take part in their research. If the research team identify that you may be suitable, you may be contacted to see if you would like to participant in an early phase study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

As stated above the research team at the research site will be the only people who have access to your identifiable information and contact details. All information collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the research centre will have your name and contact details removed so that you cannot be identified from it.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There may be some minor but short-lasting discomfort from donating blood. Taking part in the study will not affect your NHS care, nor will it affect your ability to obtain insurance for health purposes.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The study will not be of direct benefit to you; however you may be invited to take part in further research in the future if you would like to. Pharmaceutical companies or other researchers often offer incentives to encourage healthy volunteers to take part in phase 1 trials.

WHO HAS REVIEWED THE STUDY?

All research studies are 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 North West – Liverpool East Research Ethics Committee.

HOW DO I GAIN FURTHER INFORMATION?

If you need further information or are worried about any aspect of the study, please do not hesitate to contact the research nurse working on the study, Helen Whittle, on:

01925 662946 Mon-Fri **8am – 4pm** or

email us at: **Research@whh.nhs.uk** or

visit our website at: **www.liverpool.ac.uk/futureinitiative**

If you are unhappy and wish to complain formally, you can do this through the Complaints Procedure by contacting your local Patient Advice and Liaison Service (PALS) on 01925 275512.

THANK YOU FOR READING THIS INFORMATION LEAFLET