**INVITATION TO TAKE PART IN RESEARCH INTO THE INHERITANCE OF HIGH BLOOD PRESSURE (HYPERTENSION)**

**You are being invited to take part in research investigating how high blood pressure runs in families. Before you decide, it is important that you understand why this research is being done and what this involves. Please take time to read the following information carefully and discuss it with a friend, relative and your GP, if you wish. Be sure to ask any questions you may have, especially if anything is unclear, or you would like to know more. Take time to decide, whether or not you wish to take part. Thank you for reading this information.**

## *What are we aiming to do?*

In co-operation with other doctors and scientists throughout the country we are studying the inherited factors (genes), which lead people to develop high blood pressure. By understanding which genes cause this problem, it may be possible to improve the treatment to prevent strokes and heart attacks. We aim to recruit 1000 families over a period of 18 months. These families will be comprised of two parents, who may or may not have high blood pressure, and one affected son or daughter. At the end of the study we aim to have a total of 3000 people involved.

## *Why are we seeking your help?*

Recently, you or one of your relatives returned a questionnaire on your family history of high blood pressure. Based upon this information and questions you have allowed us to ask your family doctor, about your blood pressure, we are now inviting you and other members of your immediate family, to help us further with this research. We will not ask you to take part if you have diabetes, kidney disease, anaemia or receive blood transfusions, or are under treatment for cancer. If you are uncertain if you should take part please ask us. Having read this information sheet and listened to one of our trained nurses explain the study, you are under no obligation to continue taking part. Your participation in any aspect of the study is completely up to you. You are under no obligation to provide us with any information you do not wish to divulge.

In your blood stream white cells which normally fight infection carry a complete set of your genes which we can study. We would like to store some of these white cells in the laboratory because we think it will take many years and a lot of experiments to understand the cause of high blood pressure. Please note;

- No information about you or your genes will be released to anyone at anytime in a form by which they could identify you. Personal details about you and your health record will be stored in a computer but not in a form by which anyone could identify you.

- Your genes will be used to investigate the inherited cause of high blood pressure and related diseases such as stroke. It is possible that this research will lead to the development of new treatments for high blood pressure. Neither you or the researchers involved in this study will benefit

financially from this research.

- We cannot guarantee to discover anything that will directly benefit you or your family.

- We will be happy to transmit any concerns or questions regarding your treatment to your GP but, we will not offer advice regarding treatment and will not adjust your treatment.

## *What will we be asking you to do?*

Following counselling, we will ask you to donate a 70 ml blood sample (less than half a tea cupful) which will be taken by needle and syringe from a blood vessel in your arm. This should only cause a brief discomfort. The sample will be used to obtain a set of your genes from the white cells and to make other routine tests which we would usually do as part of the investigation of a patient with high blood pressure. This will include a heart tracing (ECG) and measurement of your blood pressure over 24 hours which can be recorded automatically by a machine the size of a personal stereo which you wear attached to a belt. The machine does make a slight noise when it inflates the cuff and people who find the inflation of the cuff uncomfortable when they have their blood pressure taken at their surgery may notice slight discomfort. We will measure your height, weight, waist and hip size and measure the thickness of the skin on your arms. In addition we will ask you to collect all your urine for 24 hours in a special bottle which we will provide. Finally, if you are able to attend the hospital, we would like to organise an echocardiogram (this is a measure of heart muscle size using sound waves), which will give us useful information about how your blood pressure affects you. This information will help your own doctor decide if your blood pressure treatment is being effective, and is often part of the routine care of patients with high blood pressure.

We will provide your doctor with a copy of your 24 hour blood pressure record and any other information which may help in your care. In total you will receive 2-3 phone calls and be asked to meet with 1 of our trained nurses once or twice. Travel expenses will be reimbursed. Once we have identified enough families we will start to search for the genes which lead to high blood pressure. You are welcome to phone us on 0207 882 3422 (3425 / 3424) to check on our progress and we will be in touch to update you. If you have any questions please do ask at any stage. You are free not to participate and may withdraw from the study at any time. This will not affect your medical treatment

## *WRITTEN CONSENT FORM:*

**TITLE OF RESEARCH PROPOSAL: AN INVESTIGATION OF THE GENETIC BASIS OF HUMAN ESSENTIAL HYPERTENSION BY GENOME WIDE SEARCH.**

Name of patient:

Address:

I have read the attached information on the above research project and have been given a copy to keep.
I have had the opportunity to discuss the details and ask questions about this information and the Investigator has explained the nature and purpose of the

research and I understand what is proposed. I understand that this study is part of a research project designed to promote medical knowledge.

I have been informed that the proposed study involves monitoring and special examinations which have been explained to me, together with possible risk involved. I understand that my personal involvement and any results will remain strictly confidential.

I also understand that my General Practitioner will be informed that I have taken part in this study.

I hereby fully and freely consent to participate in this study.

PATIENT'S NAME:(BLOCK CAPITALS).....

PATIENT'S SIGNATURE .....

PATIENT'S WITNESS' NAME: .....

WITNESS' SIGNATURE: .....

INVESTIGATOR'S NAME: Dr Mark Caulfield

INVESTIGATOR'S SIGNATURE:…….

DATE:.....

As the Clinician/Investigator responsible for this research or a designated deputy, I confirm that I have explained to the patient named above the nature and purpose of the research to be undertaken.

CLINICIAN'S NAME: DR MARK CAULFIELD

CLINICIAN'S SIGNATURE:.....

DATE: .....

IF YOU ARE AT ALL CONCERNED ABOUT THIS TRIAL PLEASE CONTACT:
Dr Mark Caulfield Tel. No. work 0207 882 3403

DECLARATION BY THE CONSULTANT OR PRINCIPAL INVESTIGATOR IN CHARGE OF PROPOSED RESEARCH: E.C. NO.....

TITLE OF RESEARCH PROPOSAL: AN INVESTIGATION OF THE GENETIC BASIS OF HUMAN ESSENTIAL HYPERTENSION BY GENOME WIDE SEARCH.

Principal Investigator; Dr Mark Caulfield (Professor in Clinical Pharmacology at Barts)

I FULLY ACCEPT RESPONSIBILITY:

- To inform all medical and nursing staff (including GP with the subject's consent) at each location where a patient may be treated, that a subject is enrolled in a trial or experiment, what drugs (if any) or invasive procedures will be used (or not as may be) and what precautions they should take, if any.

- To ensure that details of each procedure to be done or drug to be given are entered in the clinical notes and that the date and time when the procedure was done and/or drug given are subsequently noted.

- To make three copies of the "Written Explanation to be Given to Potential Subjects" and the signed "Written Consent Form", including the signed "The Declaration by the Consultant or Principal Investigator in Charge of the Proposed Research". One copy of each should be kept by the patient/volunteer, one copy should be included in the patient's clinical notes and one copy should be kept by the Senior Consultant/Chief Investigator responsible for the Research
- To place a copy of the written explanation to the patient in the notes;

- To ensure that each subject is verbally warned not to take part in more than one study at any time.

- To inform the Committee of any adverse or unforeseen circumstances arising out of this research.

- For clinical research, to provide the Committee with one brief report of progress half way through the project and another at its completion.

PRINCIPAL INVESTIGATOR: Dr Mark Caulfield

SIGNATURE: .....