CONSENT BY SUBJECT FOR PARTICIPATION IN RESEARCH STUDY

Study of stroke prevention through structured AF atrial fibrillation (AF), blood pressure (BP) and smoking risk detection in Cork Kerry Community Healthcare.

Name of Chief Investigator: Dr Claire Buckley Contact Number for Chief Investigator: 021-4205505

You are being asked to participate in a research study. The doctors at University College Cork study the nature of disease and attempt to develop improved methods of diagnosis and treatment. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form gives detailed information about the research study. Your general practitioner will also discuss the study with you. When you are sure you understand the study and what will be expected of you, you will be asked to sign this form if you wish to participate.

NATURE AND DURATION OF PROCEDURE(S):

You are invited to participate in a stroke prevention consultation with your general practitioner (GP). This will involve screening for atrial fibrillation (AF) using a handheld electronic device, blood pressure check and smoking detection risk. It will be conducted at the practice of your GP, where all Public Health clinical and risk guidance will be followed. Should AF be detected you may be invited to attend for up to 3 further consultations with your GP and have a 12 lead ECG test to confirm the diagnosis. Each of these consultations will take 10-15 minutes and may be with your GP, another GP at the practice or a practice nurse. After 7/10 days you may be invited to have a blood test. You may be started on anti-coagulation medication and be referred on to see a consultant cardiologist as deemed appropriate by your GP. Following screening you may be asked to participate in an interview with researchers to discuss your experience of the screening programme. This interview will take approximately 30-45 minutes. Upon completion of the screening and follow up visits a small sample of patients may be approached by their GP to participate in some evaluation interviews. If the patient is approached and agreed and gives their consent only then will their identifying information be shared with a researcher who will then make contact. The researcher interviewing them will not have any access to their anonymised data regarding any diagnoses made or investigation or treatment offered or received.

POTENTIAL RISKS AND BENEFITS:

Early diagnosis can help to prevent stroke and stokes due to AF are usually severe. Your participation in this study will pilot this method of screening for stroke risk in primary care to help inform future policy on AF screening and stroke prevention. We do not anticipate any negative outcomes from participating in this study.

POSSIBLE ALTERNATIVES:

Participation on this study is voluntary and you may withdraw at any time. There is no obligation to participate, and should you choose to do so you can withdraw from the study at any time.

Callanan A, *et al. Open Heart* 2024; 11:e002563. doi: 10.1136/openhrt-2023-002563

HOW WE WILL USE YOUR PERSONAL DATA

By participating in the study and performing the study exams, information from you (also called "personal data") will be collected for the study purposes mentioned above. This personal data includes, for example:

- information that directly identifies you (such as your name, and your year of birth);
- your gender, ethnic and racial background;
- information on your health and medical condition including your medical history;
- your treatments and your response to treatments;
- information contained in your blood samples and the results after analysis.

Personal data collected at any time during the study will be kept strictly confidential. To ensure confidentiality, the data generated during the study is **coded** with a number that will identify you in the study. Any information that leaves the general practice will be labelled with your code instead of your name. Every person that has access to your uncoded data (that is kept at your practice) is subject to professional secrecy and confidentiality.

Data that directly identifies you (uncoded data) is stored in your medical files at the practice in which the data have been obtained. A list or 'key' linking your study number to your name will also be kept securely (locked cupboard in a room with restricted access) by the investigator.

WHO WILL ACCESS MY PERSONAL DATA?

Your uncoded data will only be accessible to your general practitioner and general practice staff. Results of the study will be provided to the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) in compliance with national and international regulations on clinical studies.

THE PURPOSE AND LEGAL BASIS FOR COLLECTING YOUR DATA

Any personal data you provide to us during the course of this study will be processed fairly and lawfully. Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in this information and consent form.

Personal data collected during this study and the results of the study may be presented for scientific purposes. However, you will never be identified individually during these presentations. Your identity will not be revealed in any reports or publications.

The general practice and the investigator will only use your personal data within the scope defined above.

The General Data Protection Regulation allows us to process your data because you have provided your consent. You are entitled to withdraw your consent at any time.

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YOUR RIGHTS

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- to have inaccurate/incomplete information corrected and updated;
- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data by UCC;
- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form;
- to withdraw your consent to the processing of your data at any time without giving a reason by notifying your decision to the investigator. This will not affect the lawfulness of processing data about you based on your consent before the withdrawal. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study physician will present you the options you have concerning your personal data.
- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing. If you wish to exercise any of these rights, please address your request to the study physician or the Information Compliance Manager, University College Cork (details below).

QUESTIONS OR COMPLAINTS

If you have any queries in relation to this study, please contact Dr Claire Buckley 021-4205505.

If you have any complaints in connection with our processing of your personal data, you can contact UCC's Information Compliance Manager: **Information Compliance Manager, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: foi@ucc.ie Tel: +353 21 4903949**

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning all aspects of the project and any procedures

involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. Information about my stroke risk and investigations and treatment offered me by my GP will be shared with the researchers but without identifying me personally i.e. my GP will only pass on information in an anonymous form. As this consent form also identifies me, this will also be retained by my GP who will only pass on anonymous data to the researchers - subject to my consent. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I understand that my GP and investigators have such insurance as is required by law.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at University College Cork. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the Chief Investigator listed above. I understand that the study has been approved by the Cork Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact CREC at Lancaster Hall, 6 Little Hanover Street, Cork, 021 4901901.

Answer yes or no

I have read and understand the study: Yes/No

I agree to participate in this research: Yes/No

I grant permission for the data collected to be used in this research only: Yes/No

I understand that my anonymised data will be stored at the University College Cork OneDrive system and subsequently on the UCC server for 10 years: Yes/No

GP (or nominated delegate) Signature: _____

Signature of Study Participant: _____

Witness Signature (if applicable): _____

Legal Representative Signature (if applicable) _____

Date: _____