

## Information sheet: **PATIENT** interviews

**We are inviting you to take part in a research project called:** Electronic Risk Assessment for Cancer (ERICA) led by Professor Willie Hamilton at the University of Exeter Medical School.

**Please read this information to help you decide if you would like to take part in the study.**

### **What is this research about?**

The UK is not as good as other countries in diagnosing cancer early. A team led by researchers at the University of Exeter has developed new electronic risk assessment tools (otherwise known as eRATs) to help GPs identify possible cancer. The eRATs sit in GP's computer system; they go off when a patient reports a symptom with at least a 2% chance of a possible cancer. This means that the eRATs alert GPs to patients who may be at a very low risk. However, an eRAT prompt doesn't necessarily mean that the GP is concerned that a patient actually has cancer. It simply alerts the GP to think about the possibility. The GP will use their clinical knowledge to decide the best course of action for the patient. We are studying how good eRATs are in helping GPs to catch cancer sooner. In the ERICA study some GP surgeries will have the eRATs installed on their computer system; other GP surgeries won't.

We are contacting you because at a recent visit to your GP you reported some symptoms which either triggered an eRAT or would have triggered an eRAT if they were being used in your GP surgery. It is important to note that the symptoms you reported are likely to be explained by an illness other than cancer. Because you are receiving this letter does not mean that you have cancer.

As researchers, we do not know why you went to see your GP, or know how your GP has chosen to manage your care. If your GP has access to eRATs we do not know how much they used the tool. So, it is important for the research for us to learn about your recent experience of care and to obtain your views and opinions about your recent visit to your GP, including any further care you may be receiving.

### **What does taking part involve?**

We would like to interview you for up to an hour, at a time and place that suits you. We will ask you about your experience of your recent GP visit. We will tape record the interview; this will be typed up by a professional transcriber. We will keep all of your responses confidential. We may ask you to take part in two short follow-up interviews so that we can learn about your experiences of any continuing care from your GP or other parts of the NHS. You do not have to agree to take part in any interviews if you do not wish to. By taking part in the research you will not need to make any extra visits to your doctor over and above those needed for your normal care.

### **Do I have to take part?**

No. Participation is entirely voluntary. If you do take part in the study you will be asked to sign a consent form. You are always free to withdraw at any time. You do not have to give a reason for withdrawing. If you do withdraw any information that you have already given will remain part of the study.

### **What are the benefits or advantages of taking part?**

Although you would not receive any money for taking part, participating in research like this helps to improve future patient care. This research is exploring whether the eRATs are effective in catching cancers earlier, and therefore may potentially save lives. By taking part in this research you will help us understand whether the eRATs are a useful tool and help us understand how they are viewed by patients.

### **What are the risks or disadvantages of taking part?**

You will be asked to give up to three hours of your time in total. We do not envisage any serious risks in taking part in the study. However, given the subject matter, we recognise that some emotions may arise and you may have some concerns about possible cancer. Our interviewers are trained to help you with this process and will provide contact information for the patient advice and liaison service. You should also feel free to contact your GP to discuss any health concerns that you have. If you become especially troubled during the interview and the researcher perceives that there is a risk to your health the study team may be required to break confidentiality, to inform appropriate authorities who will need to provide essential care services.

### **What if there is a problem?**

If you are unhappy about any aspect of the study then please contact the researcher or trial manager (details given below) who will address your issues. You can also contact Ms Pam Baxter at Exeter University who specialises in making sure that research studies are run appropriately. Pam's contact details are:

Ms Pam Baxter  
Senior Research Governance Officer  
University of Exeter  
Research Ethics and Governance Office  
Lafrowda House  
St Germans Road  
Exeter  
EX4 6TL  
Tel: 01392 723588  
Email: [p.r.baxter2@exeter.ac.uk](mailto:p.r.baxter2@exeter.ac.uk)

### **Will my participation be kept confidential?**

Yes. Only researchers within the ERICA trial and selected staff at your GP surgery (e.g., your GP and a staff manager) will know of your participation in the study. Any data collected during interview will later be anonymised. Personal data will be stored securely at the University of Exeter Medical School where only members of the ERICA research team will have access to identifiable data.

For the purposes of this study we will also use consent to protect your confidentiality and provide you with choice in your participation. All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet at the University, which can only be accessed by the researcher (and research supervisors). You will be allocated a unique participant number, which will ensure the information from your interview(s) will be protected and cannot be identified by anyone else. Any personally identifiable information will be stored separately and securely from information obtained from the research.

### **How will my data be used?**

Your responses to our questions will be used to inform the main study question: how useful are risk assessment tools in the clinical setting? We may anonymously quote some of your answers for educational purposes, in research reports, research presentations or for publication. We will use a pseudonym (a false name) or a unique code when we present your findings. This means that people reading it will not be able to identify you.

### **Who will you share my data with?**

Access to personal data will be restricted to the ERICA research team. Names and participant details will not be passed to any third parties and no named individuals will be included in the write up of the results. We will share your audio-recording with a professional transcriber, who will type out the interview. This transcriber will have signed a confidentiality agreement with us.

### **How will you share my data?**

We will ensure that the interview data are passed securely to the transcription service. We will encrypt and password-protect the audio file, so only the individual responsible for transcribing your interview will be able to open it. The transcriber will keep your interview data confidential. They will permanently destroy the audio file after transcribing it. The transcript will then be securely passed back to the research team.

### **When will you share it?**

We will pass the audio file to the transcriber within 28 days of your interview.

### **What will happen to my data after the study?**

We will retain your anonymised interview transcripts for the purposes of future research or for educational purposes. Within the next five years, your anonymised data may be made available to third parties for research purposes only – providing those parties have received approvals from an independent ethical review committee. Your personal identifying data will be kept for 5 years under secure conditions on University of Exeter servers. Data will be collected and retained in accordance with the UK Data Protection Act 2018, and managed in accordance with the trial-specific standard operating procedure for data management.

You will be allocated a unique study ID or pseudonym and the information linking your ID to your personal information will be kept separately and securely at the University of Exeter. Audio recordings will be digitised, encrypted and stored on the University's secure server. Audio recordings will be retained until after anonymised transcripts have been finalised and analysed. At this stage they will be securely and permanently deleted.

### **How will the results of the research study be used?**

Once the study is complete, the results will be written up and published in scientific journals and presented at national and international academic conferences. If you would like a copy of any publication or a summary of the results, please let the researcher know.

### **Note on data processing**

Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing [dataprotection@exeter.ac.uk](mailto:dataprotection@exeter.ac.uk) or at [www.exeter.ac.uk/dataprotection](http://www.exeter.ac.uk/dataprotection).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you have any concerns about how the data is controlled and managed for this study then you can contact Pam Baxter, Senior Research Governance Officer, whose details are above.

### **Ethical approval and review**

This project has been granted ethical approval by London – City & East Research Ethics Committee.

**The Patient Advice and Liaison Service (PALS).** For your nearest PALS service please contact either your GP surgery for details or access them via this link:

[https://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-\(PALS\)/LocationSearch/363](https://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363)

***Thank you for reading this information***

If you would like to take part or have any further questions, please contact:

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