The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Horizon 2020

Participant Information Sheet

(Final version 1.0: 23/09/2015)

Title of Study: Big Medical Data Use in Primary Care: an ethnographic, socio-technical, investigation of challenges and opportunities

Name of Researcher: Dr Paraskevas Vezyridis

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The purpose of the study is to identify the challenges and opportunities from the analysis of Big Medical Data in Primary Care.

We want to explore General Practitioners' experiences and perceptions from their involvement in the collection and analysis of data from electronic patient records as well as in the process of patients opting out from uploading their record to big healthcare databases, such as the care.data initiative by NHS England.

Why have I been invited?

You are being invited to take part because you are a GP who is uploading electronic patient records to big healthcare databases and you had to respect your patients' wish to opt out from, for example, the care.data initiative by NHS England. We are inviting 10 participants like you to take part.

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. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you choose to take part in this research you will be interviewed once about your views regarding big data in primary care, national initiatives such care.data by NHS England and the opt out process. This interview will last up to one hour and will be arranged in an appropriate to you time and place.

You will be asked to sign the consent form. The researcher will then get in touch with you to arrange a suitable time to meet. Feel free to make notes to remind yourself of certain details if you wish, but please don't write a word-for-word script as the information is usually more useful if it is more spontaneous and relaxed.

With your consent, the interview will be digitally audio-recorded. Once the researcher has transcribed the digital audio file, it will then be destroyed.

Expenses and payments

Participants will not be paid to participate in the study. Travel expenses will be offered for any visits incurred as a result of participation.

What are the possible disadvantages and risks of taking part?

Possible disadvantages of taking part are that you will need to set aside the time to talk to the researcher. There is also the possibility that when describing your experience and views you might directly refer to management practices and/or comment about colleagues.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help in achieving a better understanding of the technical, social and ethical challenges as well as opportunities from analysing electronic patient records for research and policy-making purposes, in identifying best practices and in helping NHS users make an informed choice before they decide to opt out.

What happens when the research study stops?

We will analyse the interview data collected from all participants and we will send you a web link to the report and any other scientific publications about our findings if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do his best to answer your questions. The researcher's contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Research Ethics Officer Mr Adam Golberg, Nottingham University Business School, Jubilee Campus, Nottingham NG8 1BB, Phone: 0115 846 6604, Email: adam.golberg@nottingham.ac.uk.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address) will be kept for 3 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the European Commission Research Executive Agency.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham University Business School Research Ethics Committee.

Further information and contact details

Chief Investigator: Dr Paraskevas Vezyridis, email: lizpv@nottingham.ac.uk, tel: 0115 846 6370, address: North Building, Jubilee Campus, Wollaton Road, Nottingham NG8 1BB