Ensuring Consent and Revocation (EnCoRe): Mapping the Views of Patients, Researchers, and Clinicians in the Oxford Radcliffe Biobank (ORB), Nuffield Orthopaedic Centre (NOC) and Oxford BioBank (OBB)

Information Sheet

Patient Participants in an EnCoRe Focus Group

"Developing new technology to improve biobanking for patients and medical research"

We are inviting you to take part in a focus group relating to the above research study. We would like to stress that this is entirely voluntary. Before you decide whether to take part in the focus group, it is important that you understand the reason why this research is being carried out, and what your participation will involve. We would be grateful if you could take time to read the following information carefully, and discuss it with other people if you wish. Please feel free to contact us if anything is unclear, and to take as much time as you need to decide whether or not to take part. Our contact details are at the end of this information sheet.

What is the purpose of the focus groups?

We are a group of academics based at Oxford University and the London School of Economics working on a UK research project called the EnCoRe Project. As part of the EnCoRe Project, we are working with the Oxford Radcliffe Biobank (ORB), the Nuffield Orthopaedic Centre (NOC) and the Oxford BioBank (OBB), to investigate ways in which our research could benefit the operation of biobanks for patients who take part in biobank research but also interested patients from other studies within the Oxford University Hospitals NHS Trust, as well as the researchers and clinicians who work in these groups.

We are holding two types of focus groups: 1) one set with patients who are involved or interested in ORB, NOC, OBB and Oxford University Hospitals NHS Trust and interested in biobanking principles and practice; and 2) another set with professional researchers and clinicians who are involved or interested in personal data access practices in ORB, NOC and OBB. The purpose of the two sets of focus groups is to discover the thoughts on how information about patients' data and samples used in biobanking research could and should be communicated to patients.

What is the EnCoRe Project?

The EnCoRe Project is a multi-disciplinary UK research project, which began in mid-2008, involving both industrial and academic project partners, including HW Communications; the London School of Economics; and the HeLEX Centre at the University of Oxford.

The aim of the project is to make giving consent as reliable and easy as turning on a tap, and revoking that consent as reliable and easy as turning it off again. Consent in this context is the consent of an individual to allow someone else to use their personal data. Personal data are types of information that can identify an individual e.g. a medical record. In the context of this study in collaboration with ORB, NOC and OBB, we are interested in the consent of biobank patients to allow researchers/clinicians to use personal data in medical research.

Ultimately, EnCoRe aims to provide an easy to use piece of technology that will allow biobanking patients to achieve some levels of 'control' over how information and data relating to them are used by researchers and clinicians. By 'control' we mean methods that both inform biobanking patients as to the use of personal data by researchers/clinicians, and also permit them to make some kind of meaningful decisions that can affect such use in the future.

Why have I been chosen to take part?

You have been chosen to take part because you are a patient who has donated or are considering donating a sample to ORB, NOC or OBB, or you have taken part in non-related studies in the Oxford University Hospitals NHS Trust and are interested in biobanking. ORB, NOC and OBB are asking many patients already enrolled to such studies if they would like to take part in the focus groups run by the EnCoRe Project.

Who is running the focus groups?

Researchers at the HeLEX Centre for Health, Law, and Emerging Technologies at Oxford and at the London School of Economics have prepared the material for the focus groups. The focus groups will be run by a team of researchers based in those two academic departments and will be coordinated by an experienced facilitator.

Who has reviewed the study?

The EnCoRe project was given a favourable opinion for this study by the South Birmingham NHS Research Ethics Committee.

The scientific quality of this study has been assessed favourably by external independent review and by internal review from the project partners.

Do I have to take part?

Your participation is entirely voluntary. You are given this information sheet to keep, and if you do decide to take part, you will also be asked to sign a consent form. You will still be free to withdraw at any time: this includes the right to walk out of a focus group, or request to be removed from the study after the focus group has taken place. If you decide not to take part, you will not be required to tell us why.

What do you want me to do?

We would like you to take part in a focus group with no more than 10 other people. These will be other participants involved and/or interested in personal data access practices within ORB, NOC and OBB and Oxford University Hospitals NHS Trust studies. The focus groups will take place in Oxford in March 2013 and will last approximately two hours. Refreshments will be provided. The focus group will take the form of a structured group conversation. It will involve a discussion covering a variety of relevant topics relating to ORB, NOC and OBB, data access practices in biobanking, and the EnCoRe Project. We will ask for your written permission to make an audio recording of the focus group, to ensure that an accurate record of the information that you give is maintained. The interviewer will not seek information about any other identifiable individuals and any other named individuals will also be de-identified. If you do not agree to take part in the audio-recorded session of the focus group, you will not participate in the focus group. In such case, we may be able to offer you an alternative non-recorded, one-on-one interview.

Will I be reimbursed for participating in a focus group?

You will not receive any payment for taking part in a focus group. We will reimburse your reasonable travel expenses and any child-care arrangements that you may need to incur. We will provide refreshments including water, tea and coffee.

What will happen to any information I give in a focus group?

The goal of the focus groups is to develop a better understanding of how a new technological system could benefit biobanking patients, researchers and clinicians. The information that you provide is primarily for use within the EnCoRe Project to aid the development of the new technology and will be confidential. The findings will be put into a report that will be used by the researchers in the EnCoRe Project, all of whom are bound by obligations of confidentiality.

Data from the focus groups may be used in future publications, reports and research. However, in all outputs, publications and reports derived from the focus groups, you will not be identifiable as all quotations will be anonymised and not directly attributable to individuals. We will publish regular updates of our research findings and research publications from this study on the HeLEX centre (www.publichealth.ox.ac.uk/helex/).

Will my taking part be kept confidential? How will you protect my confidentiality and anonymity?

The focus groups are being carried out in accordance with the Data Protection Act 1998 and approved research protocols. The focus groups will be recorded, transcribed and analysed for key themes that emerge from the discussion. These data will be available to all researchers working on the EnCoRe Project, but the transcripts will be kept anonymous. We will exercise all possible care to ensure that you cannot be identified in any of our research outputs, either directly or indirectly by implication or deduction.

Only members of the EnCoRe Project and an experienced transcriber – all of whom are bound by obligations of confidentiality – will handle the sound files and transcripts. Hard copies of research notes are kept in locked cabinets, and electronic files are kept on password-protected computers, accessible only to the EnCoRe researchers. We will destroy audio files at the end of the EnCoRe Project.

Responsible members of the University of Oxford or the Oxford University Hospitals NHS Trust may be given access to data for monitoring and/or audit of the study to ensure compliance with regulations.

What are the possible disadvantages and risks in taking part?

The main burden to you will be the time necessary to take part in the focus group. We are confident that the arrangements described above will prevent any of the information that you provide being shared, either intentionally or unintentionally, with anyone outside the EnCoRe Project. For this reason, we believe that the risk of harm to those who participate in the focus groups is low.

What will happen if I do not want to carry on?

If you decide to withdraw at any stage, you will not be required to tell us why. In such case, no further data will be collected in relation to you, and any identifiable data already collected with your consent will be retained and used in the study. The same will apply if you were to lose capacity to consent during this study; in such case, you would be withdrawn from the study.

Who is responsible if anything goes wrong?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr. Jane Kaye on 01865 287898, email jane.kaye@dph.ox.ac.uk or you may contact the University of Oxford Clinical Trials and

Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email heather.house@admin.ox.ac.uk.

The Patient Advice and Liaison Service (PALS) can also be contacted if you have any questions concerning your rights as a patient. The PALS website for the Oxford University Hospitals NHS Trust is www.ouh.nhs.uk/patient-guide/pals.aspx.

PALS at the John Radcliffe Hospital	PALSJR@ouh.nhs.uk	01865 221473 / 740868
PALS at the NOC	PALSNOC@ouh.nhs.uk	01865 738126

Given the nature of this study, it is highly unlikely that you will suffer harm by taking part. However, the University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor.

How can I find out more about the focus groups and the EnCoRe Project?

The EnCoRe Project website has general information about our research: www.encore-project.info

The HeLEX centre website has more information about our research: www.publichealth.ox.ac.uk/helex/

How do I register my interest in taking part? Where can I get further information on the focus groups?

Please address all queries to **Dr. Harriet Teare at harriet.teare@dph.ox.ac.uk or** 01865 287879.

Contacts

The researchers in our team are:

Dr. Jane Kaye	jane.kaye@dph.ox.ac.uk	01865 287898
Dr. Harriet Teare	harriet.teare@dph.ox.ac.uk	01865 287879
Dr. Michael Morrison	michael.morrison@dph.ox.ac.uk	01865 287847

HeLEX Centre for Health, Law and Emerging Technologies at Oxford
Department of Public Health, University of Oxford, Old Road Campus, Oxford OX3 7LF

Dr. Edgar Whitley	e.a.whitley@lse.ac.uk	020 7955 7410

ISIG Information Systems Management and Innovation Group
London School of Economics and Political Science, Houghton Street, London WC2A 2AE