



NUFFIELD DEPARTMENT OF **PRIMARY CARE** HEALTH SCIENCES

Nuffield Department of Primary Care Health Sciences
Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG
Tel: +44(0)1865 617869
Email: cancer@phc.ox.ac.uk
Web: <https://www.phc.ox.ac.uk/research/research-themes/cancer/>

PARTICIPANT INFORMATION SHEET

Study Title: Optimising Primary Care Risk Stratification for Clinically Significant Prostate Cancer: ProsDetect II

We are writing to invite you to take part in an interview for a research study based at the University of Oxford. This information sheet explains the purpose of the study and what we are inviting you to do. Please take time to read this information. If there is anything that is not clear, or you would like more information, please ask us.

What is this study about?

Most prostate cancers are diagnosed after a blood test measures too much prostate specific antigen (PSA) in the patient's blood. Despite the number of prostate cancers it finds, there is some debate around how the PSA test should be used and with which patients. This is because PSA can be high when there is no prostate cancer, and many of the prostate cancers it finds are slow growing and would not cause symptoms or threaten the life of the patient. This puts the patient at risk of complications from the investigations needed to find out if there is actually a prostate cancer, and at risk of going through unnecessary treatment which can be unpleasant and debilitating but without improving their life expectancy.

For these reasons, the PSA test is not recommended for patients aged ≥ 80 years old unless they are experiencing the symptoms of advanced cancer, but we know many PSA tests are still given to older patients and GPs value guidance on how to speak to older patients about stopping testing. This study is about how older patients make decisions about having the PSA test and what information they would like to make those decisions.

What is the purpose of the study?

The aim of the study is to understand how older patients think about prostate cancer in the context of their health, what information they would like to be able to make decisions around getting a PSA test, and how they would like their GP to speak to them about whether they would benefit from having a PSA test.

We want to interview 50 people with a prostate aged 80 or older about their experiences and views on PSA testing as an older adult, whether they have spoken to their GP about prostate cancer or PSA testing in the past, and what information they would find helpful if they did talk to their GP about prostate cancer or PSA testing. Individuals do not need to have experience of a PSA test or prostate cancer to take part.

Optimising Primary Care Risk Stratification for Clinically Significant Prostate Cancer: ProsDetect II.
Participant information sheet. V1.0 20.10.2025. Chief Investigator: Dr Claire Friedemann Smith.
REC ref: 25/NW/0341 IRAS ID: 360965

Why have I been invited?

You have been invited because:

- Your GP has identified you as a patient aged 80 or older with a prostate.
- You have identified yourself as having a prostate and being aged 80 years and older.
- We hope to interview 50 people aged 80 years and older with a prostate.

Do I have to take part?

No. It is entirely up to you to decide whether or not you want to take part. If you decide to take part, you are still free to stop at any time without giving a reason. Deciding to not take part in the study, or deciding to take part and then withdrawing will not affect your legal rights or any medical care you may be receiving.

What will happen if I decide to take part?

If you decide to take part, please visit this website

(<https://app.onlinesurveys.jisc.ac.uk/s/oxford/prosdetect>) and complete the form, or if you have been given a paper copy of this information, please complete the paper consent form and return it to us in the pre-paid envelope. You will be asked to give us your details so that a researcher can contact you to arrange a time for your interview and answer any questions that you might have. We will also ask you to tell us your age, gender identity, ethnicity, and past occupation and we will use this information to describe the people taking part in the study. You may also contact us by email (cancer@ox.ac.uk) or by telephone on 01865 617869 if you prefer.

You will be able to choose whether to have the interview online or in-person. If we hold the interview in person you may choose to have it at your home or at the researcher's offices. If you choose to come to the researcher's offices, you will be paid for the cost of your travel.

You can choose to be sent a copy of the interview questions before your interview. You do not have to read them but if you do it might help you to think about how you will answer them. At the interview, the researcher will make sure that you understand what the study is about, and you will be invited to ask any questions you may have. All interviews will be audio recorded so that we can transcribe them and the researcher will ask you to confirm verbally on the recording that you are willing to be interviewed and audio recorded.

During the interview, the researcher will first ask you to read three scenarios where someone aged >80 years has to make a decision about whether they should have a PSA test. These scenarios will differ in how healthy the person is, what their risk for prostate cancer is, and whether they are likely to benefit from having a prostate cancer diagnosed. The researcher will ask you to talk to them about how you would make the decision whether to be tested if you were in each person's position. The researcher will then ask you questions about your experiences and thoughts on PSA tests for prostate cancer in older patients.

Once your interview is finished, the researcher will not contact you again unless you tell us that you would like to receive a copy of the study results.

How long would the interview take?

The time it takes for an interview varies, depending on how much you have to say, but most interviews are finished in one hour. Remember, if you want to stop the interview at any point you can do so without giving a reason.

What should I consider?

We would like to talk to people who still have their prostate, so if your prostate has been removed for any reason then unfortunately you cannot take part. This is because prostate cancer is much more of a concern for people with a prostate.

You do not need to have personal experience of PSA testing or prostate cancer to take part.

If you are already taking part in another research project, you may still take part in this one.

While people sometimes find it helpful to talk about their experiences to researchers, research is not the same thing as counselling. If you find you would like support following your interview, we can suggest the following organisations who offer support services:

- Prostate Cancer UK <https://prostatecanceruk.org/>
- Macmillan Cancer Support <https://www.macmillan.org.uk/>
- Age UK <https://www.ageuk.org.uk/>

Are there any possible disadvantages or risks from taking part?

We do not think that there will be any disadvantages or risks to you from taking part. However, it is possible that while talking about being tested for or having prostate cancer, you may feel distressed. If this happens you are able to stop the interview and take a break, or not continue with it any further if you wish.

What are the possible benefits of taking part?

- There are no direct benefits to you in taking part.
- You will have the opportunity to talk about testing for prostate cancer for older patients and what information would make decisions around testing easier.
- Although we do not know what the outcome of this research will be, we hope that it will benefit future patients and health care professionals. It may allow us to provide GPs with guidance on how they should talk to their patients about testing for prostate cancer so that those who are most likely to benefit are tested, and those who are unlikely to benefit are not.

Will my General Practitioner (GP) be informed of my participation?

- Your GP will **not** be told about your participation.
- Whether or not you decide to take part will not affect your medical care.

Will my taking part in the study be kept confidential?

- Yes, everything you say will be kept in the strictest confidence. The interview recording will be labelled with a code number and transcribed. The transcriber has signed a confidentiality agreement and will keep everything you say in the interview confidential.
- The digital recording of your interview and the typed-up record (transcript), and your personal information, for example your age, will be identified only by a code number and stored securely. Please see the *What will happen to my data* section for more information.

- You may ask for a copy of your own de-identified interview transcript to be emailed or posted to you to keep if you would like to.
- The interview transcript will not include any information about your identity and the audio recording will be deleted once the transcript has been written and checked. Names, places, or any other information mentioned in the interview that could help to identify you will be removed from the transcript.
- We plan on writing up the findings of the study so that other researchers and health care professionals can learn from what we find. In the paper we will use quotes to help make our points. These quotes will be carefully chosen so that the interview participant is not identifiable from them. No names, either of the participants, their doctors or loved ones, or place names will be given in the paper.
- We would like to keep your transcript indefinitely so that it might be used to answer related research questions in the future. We will also keep a table of the demographic characteristics of the interview participants but specific details will not be linked to the transcripts. We will ask for your permission to do this in the study consent form. If you do not want to give this permission you may still participate in this study and we will delete your data at the end of the period that we are required to keep your data for.
- The study researchers will keep all that you tell us confidential as far as possible. However, if you tell us something that a health care professional has done which we think is medical malpractice or which places you or others at an immediate risk of harm, we are required by law to tell the local authorities who will make sure that no one is being put in danger.
- Responsible members of the University of Oxford, and regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

- After the interview you will be offered a £30 shopping voucher as a thank you for your time. Unfortunately, we are not able to offer cash instead of the voucher. You do not have to accept the voucher if you would prefer not to.
- If you need to travel to your interview your travel expenses will be reimbursed by bank transfer.
- We will not reimburse any other expenses e.g., meals.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your interview for this research project. We will share your information related to this research project with the following types of organisations: University of Oxford

This information will include your:

- study identification number assigned to you when you agree to take part,
- your demographic information,
- and the audio recording of your interview.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by:

- Storing it in secure folders in the University of Oxford's servers that can only be accessed by specific members of the research team
- If we have any information about you in hardcopy, for example a hardcopy consent form, we will make a digital copy of it as soon as possible to be stored in the secure folders described above and the hardcopies will be securely destroyed
- We will delete the audio recordings of your interview as soon as the transcript has been produced and checked by the research team.

International Transfers

Your personal data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by the University of Oxford Policy on Management of Data.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can find out more about how we use your information by:

- asking one of the research team cancer@phc.ox.ac.uk
- sending an email to Claire Friedemann Smith claire.friedemann@phc.ox.ac.uk
- calling us on (0)1865 617869
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: <https://compliance.admin.ox.ac.uk/research-data>.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. transcription services). We may therefore share your personal data with Optimising Primary Care Risk Stratification for Clinically Significant Prostate Cancer: ProsDetect II. Participant information sheet. V1.0 20.10.2025. Chief Investigator: Dr Claire Friedemann Smith. REC ref: 25/NW/0341 IRAS ID: 360965

these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

Your bank details will be stored for 7 years in accordance with University of Oxford Financial policy.

After your interview, the audio file we record will be encrypted and sent securely to one of the research team's contracted transcribers. Once your interview has been transcribed, the transcription will be sent securely to the research team and checked for accuracy against the audio. When the research team confirms that they have received the transcript, the transcriber will be instructed to destroy the copy of the transcript and audio recording that they have. The research team will also destroy the copy of the audio recording that they have on the University of Oxford's folders once the transcript has been checked.

Your interview will be analysed by the research team at the University of Oxford along with interviews from about 50 other participants.

You can find out more about how we use your information by contacting Dr Claire Friedemann Smith on claire.friedemann@phc.ox.ac.uk

What happens at the end of the study?

- At the end of this study, we plan to publish the results in scientific journals, on our departmental website and present them at medical conferences. We will also submit a report to our funder – the National Institute for Health and Care Research (NIHR) School for Primary Care Research.
- You will not be identified in any papers or reports and if we use quotations from your interview, we will remove any details like the names of places, people, or organisations that might be used to identify you.
- We will not contact you again after your interview unless you tell us that you would like to receive a short summary of the results of this study. If you would like to receive a summary of the study findings, please indicate this in the space provided at the end of the consent form and provide us with an email or postal address to send them to.
- We will keep the data that you provide to us for 5 years. After 5 years, if you have given us permission, we will archive your transcript so that it might be used by other researchers to answer other research questions related to this one. These transcripts will only be identified by a code and will have all details that might be used to identify you, like names of people, places, or organisations, removed. We will also keep a table of the demographic details of all of the participants who have agreed that we may archive their transcript. These researchers will only be able to use these pseudonymised transcripts if they apply to and are approved by the lead researcher in this study, and sign a data sharing agreement.
- If you decide to not give us permission to archive your transcript, after 5 years we will delete your transcript and your demographic information.

What if I decide to withdraw after the interview has taken place?

Your participation in this study is entirely voluntary and you may withdraw at any time without giving a reason. If you decide to withdraw after your interview has taken place, all recordings, transcripts, and notes from your interview will be destroyed. However, it will not be possible to withdraw interview data from the study analysis once the analysis is complete or the findings from the study are published.

What if there is a problem?

Given the nature of this study, it is very unlikely that you will suffer harm by taking part.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Dr Claire Friedemann Smith on claire.friedemann@phc.ox.ac.uk or (0)1865 617869, or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) at RGEA.complaints@admin.ox.ac.uk.

How have patients and the public been involved in this study?

The ProsDetect II study has a Patient and Public Involvement (PPI) group that has reviewed the draft study documents and will be involved in the recruitment to the interviews, interpretation of the data, and dissemination of the results by assisting in the creation of public-facing summaries and dissemination at conferences.

Who is organising and funding the study?

- The research study is sponsored by the University of Oxford.
- The research is organised by researchers in the Nuffield Department of Primary Care Health Sciences, University of Oxford.
- The project is being funded by the National Institute of Health Research's School for Primary Care Research (NIHR SPCR) (reference NIHR SPCR-2021-2026).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by North-West Greater Manchester Research Ethics Committee (ref: 25/NW/0341).

Contact for further information

We hope that this information sheet has told you what you need to know before deciding whether or not to take part. If you have any questions at all about the project, please email the research team on cancer@phc.ox.ac.uk at the Nuffield Department of Primary Care Health Sciences.

Many thanks for reading this information sheet.

Claire Friedemann Smith

Senior Researcher