

# Putting the Person in the PiCTuRE - Personalised Consent in Tissue donation for neuroscience Research, lived Experiences

<b>Submission date</b> 31/10/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/03/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Tumours of the brain and spine are individually rare but collectively put a huge burden on individuals, their families, and society. Diagnoses are often delayed and there are few joined-up research programmes dedicated to these tumours. We propose to change this. To succeed in the new era of 'personalised' or 'precision' medicine, engagement with people affected by these tumours is essential. Specifically, we need to ensure that optimal pathways for tissue donation are established, since modern tissue analysis underpins the identification of specific ('targeted') treatments that avoid the side effects of untargeted radio- or chemotherapy.

Therefore, we would like to explore with you the potential barriers to tissue donation for research through your lived experience of the consent and tissue donation process.

Our aim is to make taking consent easier and allow patients to fully participate in the decision process. This study will ask you a few questions online and invite you to participate in a further, optional short interview. The outcome will result in the development of a digital (online) consent and tissue donation tool, that will make participation in vital brain and spinal tumour research easier for patients and the doctors and scientists trying to find better ways for tissue diagnostics and identification of new targets for treatment. Your contribution is essential for progress in this field.

### Who can participate?

Patients that have a tumour of the brain or spine, aged 18 years old or over, can speak and understand conversational English and live in the UK.

### What does the study involve?

This study has two components. The first part is an online survey that will take approximately 15 minutes to complete. The second part consists of an interview with an experienced registered nurse who has been looking after patients with these complex tumours for many years. The interview will take place online and will last around 30 minutes. Additionally, if this study topic is of interest to you, you may be invited to review an online digital tool designed to provide patient information on shared decision making and informed consent around donating tissue for

research You can choose to only take part in the first phase – if you choose this, you will have completed the study after the survey.

What are the possible benefits and risks of participating?

While there are no immediate benefits for you, it is hoped that this research will lead to a better understanding of the ways we provide information to people living with brain and spine tumours, especially where consent for tissue donation for research is concerned.

The outcome of this project will contribute to a nationwide project to improve research participation by people affected with rare tumours, sponsored by the UK's Medical Research Council, . Your contribution will help more people benefitting from what modern tissue analysis can contribute to better treatment decisions, better outcomes and ultimately a better quality of life for those affected by these tumours.

There are no disadvantages in taking part and the risk of being recognised from quotes provided during the interview are minimal. You might find aspects of this interview upsetting. I will be asking for your opinions about donating your tissue for research, as this is the topic of interest for the study. To reduce any potential risks, you can choose not to answer any questions you do not want to, pause for a break, or stop the interview altogether.

Where is the study run from?

Nuffield Department of Clinical Neurosciences, University of Oxford (UK)

When is the study starting and how long is it expected to run for?

October 2023 to August 2027

Who is funding the study?

This study is funded by the Medical Research Council - Grant number [MR/X004317/1]

Who is the main contact?

Mr Gerard Mawhinney, [gerard.mawhinney@ndcn.ox.ac.uk](mailto:gerard.mawhinney@ndcn.ox.ac.uk)

Associate Professor Olaf Ansorge, [olaf.ansorge@ndcn.ox.ac.uk](mailto:olaf.ansorge@ndcn.ox.ac.uk)

## Contact information

### Type(s)

Public, Scientific

### Contact name

Mr Gerard Mawhinney

### ORCID ID

<http://orcid.org/0000-0002-4595-6482>

### Contact details

Nuffield Department of Clinical Neurosciences,  
University of Oxford,  
Level 6 - West Wing,  
John Radcliffe Hospital,  
Oxford University Hospitals NHS Foundation Trust  
Oxford  
United Kingdom  
OX3 9DU

+44 1865 231461  
gerard.mawhinney@ndcn.ox.ac.uk

**Type(s)**

Principal Investigator

**Contact name**

Prof Olaf Ansorge

**ORCID ID**

<http://orcid.org/0000-0003-1825-5434>

**Contact details**

Nuffield Department of Clinical Neurosciences,  
University of Oxford,  
Level 6 - West Wing,  
John Radcliffe Hospital,  
Oxford University Hospitals NHS Foundation Trust  
Oxford  
United Kingdom  
OX3 9DU  
+44 1865 231461  
[olaf.ansorge@ndcn.ox.ac.uk](mailto:olaf.ansorge@ndcn.ox.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PICTuRE\_R79248/RE001

## Study information

**Scientific Title**

Putting the Person in the PiCTuRE (Personalised Consent in Tissue donation for neuroscience Research, lived Experiences): an exploratory sequential mixed methods study, exploring how precision medicine is implemented and experienced by people living with a primary tumour of the brain or spine

**Acronym**

PiCTuRE

**Study objectives**

Tumours of the brain and spine are individually rare but collectively put a huge burden on individuals, their families, and society. Diagnoses are often delayed and there are few joined-up research programmes dedicated to these tumours. We propose to change this. To succeed in the new era of 'personalised' or 'precision' medicine, engagement with people affected by these tumours is essential. Specifically, we need to ensure that optimal pathways for tissue donation are established, since modern tissue analysis underpins the identification of specific ('targeted') treatments that avoid the side effects of untargeted radio- or chemotherapy. Therefore, we would like to explore with you the potential barriers to tissue donation for research through your lived experience of the consent and tissue donation process.

Our aim is to make taking consent easier and allow patients to fully participate in the decision process. This study will ask you a few questions online and invite you to participate in a further, optional short interview. The outcome will result in the development of a digital (online) consent and tissue donation tool, that will make participation in vital brain and spinal tumour research easier for patients and the doctors and scientists trying to find better ways for tissue diagnostics and identification of new targets for treatment.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 05/10/2023, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), University of Oxford (Research Services, Research Governance, Ethics & Assurance Team, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 616575; [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk)), ref: R79248/RE001

### **Study design**

Exploratory sequential mixed methods study

### **Primary study design**

Observational

### **Secondary study design**

Exploratory sequential mixed methods study

### **Study setting(s)**

Charity/Voluntary sector, Hospice, Hospital, Other

### **Study type(s)**

Other, Quality of life, Safety, Efficacy

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Lived experiences of primary tumours of the Brain and Spine (Sarcoma)

### **Interventions**

PICTuRE is a multistage mixed method exploratory sequential study set to explore lived experience of donating tissue for research. The study consists of three phases:

Phase1 (a): An online survey will capture lived experienced data that will take approximately 15 minutes to complete; (b) semi structured in-depth interviews will explore individual experiences. The interview will take place online and will last around 30 minutes. Thematic analysis of the data will identify key themes.

Phase 2: Through co-design, patient reported experience data will be collected and statistically analysed to validate content for subsequent use in developing the digital intervention.

Phase 3: Integration of phase 1 + 2 results will assist in refining the digital intervention. Post intervention feedback will inform future research.

## **Intervention Type**

Mixed

## **Primary outcome measure**

Current primary outcome measures as of 15/01/2025:

Phase 1: Will identify key lived experience themes of donating tissue for research, data will be collected via an online survey and using semi-structured interviews. Thematic analysis will be used to analyse the collected qualitative data.

Phase 2: Through co-design methods we will gather user feedback using two Patient Reported Experience Measures (PREMS) (quantitative data): (i) Client satisfaction Survey (CSQ-8), an 8-item satisfaction score (ii) Involvement in the process of decision making from a user perspective will be collected using a 3 - item survey (Collaborate (TM)).

Phase 3: Will evaluate the newly co-designed interactive personalised consenting platform. Outcomes will be measured both qualitatively and quantitatively, PREMS outlined in phase 2 will gathered post-intervention and reviewed for statistical significance. Post-user feedback also will be explored using semi-structured interviews.

Previous primary outcome measures:

Phase 1: Will identify key lived experience themes of donating tissue for research, data will be collected via an online survey and using semi-structured interviews. Thematic analysis will be used to analyse the collected qualitative data.

Phase 2: Through co-design methods we will gather user feedback using two Patient Reported Experience Measures (PREMS) (quantitative data): (i) Client satisfaction Survey (CSQ-8), an 8-item satisfaction score (ii) Involvement in the process of decision making from a user perspective will be collected using a 9-item survey (SDM-Q-9).

Phase 3: Will evaluate the newly co-designed interactive personalised consenting platform. Outcomes will be measured both qualitatively and quantitatively, PREMS outlined in phase 2 will gathered post-intervention and reviewed for statistical significance. Post-user feedback also will be explored using semi-structured interviews.

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

05/10/2023

## **Completion date**

01/08/2027

## **Eligibility**

### **Key inclusion criteria**

1. Over the age of 18 years old
2. Have lived experience of having a primary tumour of the brain or spine.
3. Deemed to have capacity to provide informed consent.
4. Able to communicate via digital media.
5. Have access to an internet enabled device e.g., smartphone / tablet/ computer.

**Participant type(s)**

Patient, Service user, Other

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Phase 1: (Online survey – up to 45) + Semi-structured online interviews (up to 10); Phase 2: up to 6 participants; Phase 3: up to 6 participants

**Key exclusion criteria**

1. Under the age of 18 years old
2. Unable to provide informed consent.
3. No access to internet enabled devices.
4. Unable to communicate using digital media

**Date of first enrolment**

01/11/2023

**Date of final enrolment**

01/09/2026

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Nuffield Department of Clinical Neurosciences, University of Oxford**

Level 6, West Wing, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust,  
Headley Way, Headington

Oxford

United Kingdom

OX3 9DU

# Sponsor information

## Organisation

University of Oxford

## Sponsor details

Nuffield Department of Clinical Neurosciences

Level 6 - West Wing

John Radcliffe Hospital - OUH NHS FT

Headley Way

Oxford

England

United Kingdom

OX3 9DU

+44 1865 234829

Enquires@ndcn.ox.ac.uk

## Sponsor type

University/education

## Website

<http://ndcn.ox.ac.uk>

## ROR

<https://ror.org/052gg0110>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

## Results and Publications

### Publication and dissemination plan

Planned publication in high-impact peer-reviewed journals

### Intention to publish date

01/09/2027

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Gerard Mawhinney (Gerard.mawhinney@ndcn.ox.ac.uk)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		07/03/2025	10/03/2025	Yes	No