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

Submission date
31/10/2023

Recruitment status
Recruiting

Registration date
11/11/2023

Overall study status
Ongoing

Last Edited
10/03/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
Associate Professor Olaf Ansorge, olaf.ansorge@ndcn.ox.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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.
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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), ref: R79248/RE001

Study design
Exploratory sequential mixed methods study

Primary study design
Observational

Study type(s)
Other, Quality of life, Safety, Efficacy

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(s)

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.

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

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
United Kingdom

England

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
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Sponsor information

Organisation
University of Oxford

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
United Kingdom

Results and Publications

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?
Protocol article		07/03/2025	10/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes