

A Lack of Consent to Donate Tissue

Hampers Progress

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Introduction

Brain tumour tissue can be difficult for researchers to access. Currently, NHS central nervous system biopsy archives hold around 400,000 stored samples, accruing a further 18,500 annually. BRAIN UK is a collaborative virtual brain bank, facilitating access to these under-utilised neuropathology archives for research. Without obtaining consent, it may not be possible to carry out testing on brain tissue samples using emerging diagnostic, prognostic or predictive tests which could improve disease management and access to new treatments.

Methods

24 UK neuropathology centres were surveyed on their consent processes, recording and rates of consent.

Results

23/24 (96%) centres responded to the survey about obtaining prospective informed consent (see Figure 1):

- 16/23 (70%) obtain consent
- 1/23 (4%) were unsure
- 6/23 (26%) do not have a procedure for obtaining consent

Of the 16 centres obtaining prospective consent, 9 provided quantitative data on consent rates, 7 (44%) were unable to provide quantitative data (see Figure 2):

- 6/9 (37%) have consent rates of 95-100%
- 3/9 (19%) estimate consent rates of 10%

19 centres provided quantitative or qualitative data regarding rates of consent (see figure 3):

- 7/19 (37%) have consent rates of 0%
- 6/19 (32%) have consent rates of 95-100
- 6/19 (32%) have varying rates of consent which we have estimated to be around 10%

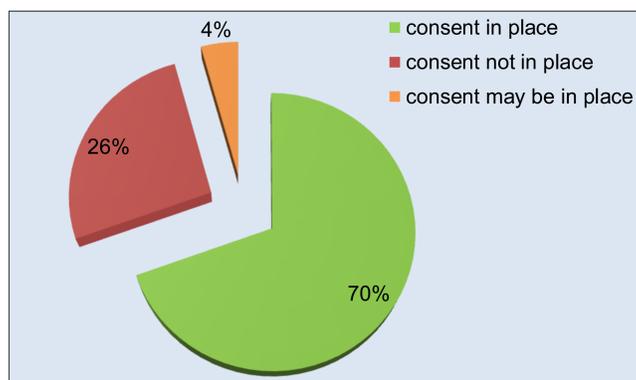


Figure 1. Percentages of centres prospective consent procedures in place, n=23.

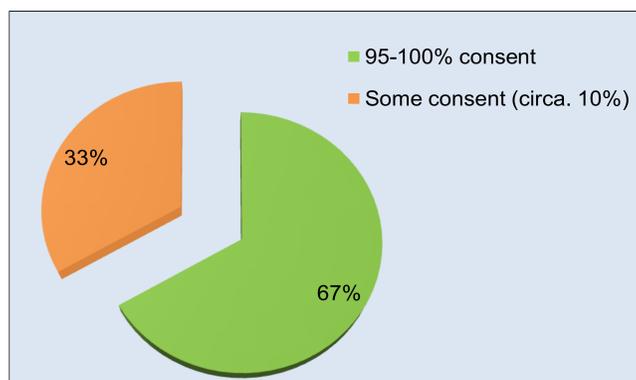


Figure 2. Percentages of centres gaining generic, informed, prospective consent to use residual tissue for research use, using quantitative data, n=9.

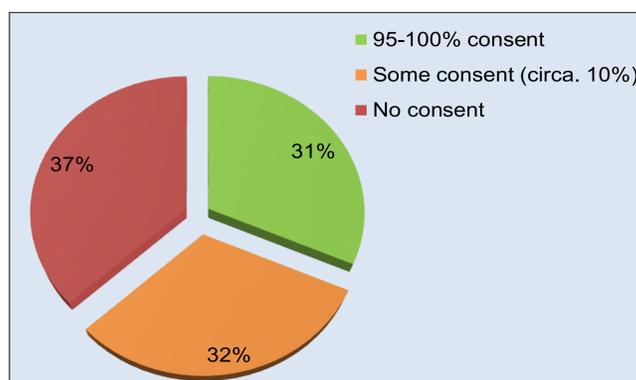


Figure 3. Overall picture of percentages of centres gaining consent to use residual tissue for research use, using both quantitative and qualitative data, n=19.

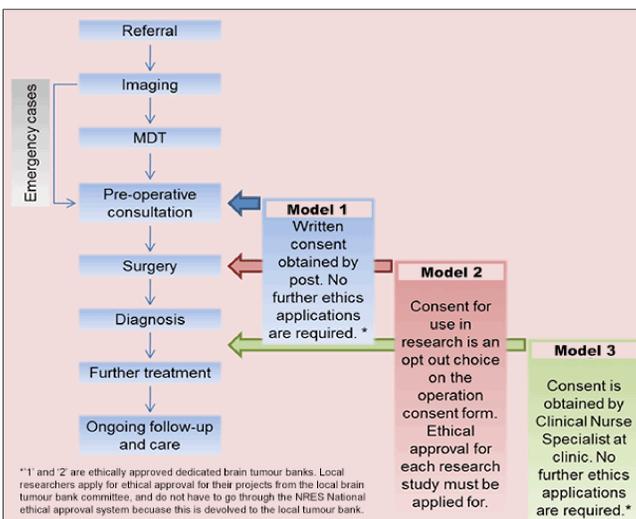


Figure 4. Variation in patient pathways (A lack of brain tumour tissue donation for research and genetic analysis hampers progress with the management and treatment of this disease (K Kurian)).

Conclusion

Consenting procedures and rates are very variable across the UK. In some centres consent rates are high but much less in others. We estimate that the overall current consent rate to be about 30%, which may reduce the number of samples available to research.

Robust systems for recording consent accurately in electronic records are not consistent across the NHS and not all centres have 'consent to research' procedures in place. Three different approaches to collecting consent in centres that are successful are illustrated in Figure 4.

Archived residual tissue could be a valuable research resource but could go unused due to lack of consent. This is despite research to suggest that patients are largely supportive of the use of their tissues in research and a fundamental legal and ethical right to determine what happens to their own bodies.

We are supporting the *brainstrust* in leading a campaign to support both:

- Centres, with example consent forms and participant information leaflets
- Patients, with information on research and documentation to encourage a conversation with professionals.



Figure 5, *brainstrust* campaign

Without consent, research on tissue is limited and it may not be possible to investigate tissues thoroughly, such as correlating pathological and genetic findings with clinical outcomes and treatments.

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