DELPHI SURVEY BACKGROUND INFORMATION (V2.0 12.01.2022)

You are being invited to take part in a two-round online survey developed by the COBra study team. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully and discuss it with others if you wish. Please feel free to get in touch if you have any questions. The study is funded by The Brain Tumour Charity, and is registered with COMET, the Core Outcome Measures in Effectiveness Trials group, at https://www.comet-initiative.org/Studies/Details/1793 (please see study summary overleaf).

1. What is the purpose of this research project?

Research trials use 'outcomes' to measure the impact of a particular intervention. For example, in a trial exploring the impact of radiotherapy upon glioma, 'tumour response' which can be measured by change in tumour size, may be used as an outcome. However, trials often report the effectiveness of a treatment in different ways. This can make it difficult to compare different trials and treatments. The outcomes reported by the trials also may not take into account the issues that are most important to patients and families. This makes it more difficult to relate the results of trials to a person's own lived experience, and therefore to make informed choices about care. In brain tumour trials, a way to overcome these problems is to have a common way of reporting results across all trials. Cardiff University is working with the University of Birmingham to develop a standard way of reporting results, made up of outcomes, which together are called a Core Outcome Set (COS). In particular the study wants to understand what outcomes of a treatment are most important to patients and those close to them.

Key Definitions:

Interventional trial *– a type of clinical study that explores how different interventions impact upon a health condition/disease. In COBra, we are interested in glioma. Glioma interventional trials may include those exploring the impact of chemotherapy, radiotherapy, surgery, or supportive care.*

Outcome *– a measurable impact of an intervention. For example, in a trial exploring the impact of radiotherapy upon glioma, 'Tumour Response' may be used an outcome measured by change in tumour size.*

2. Why have I been invited to take part?

You have been invited to take part as:

1. You have been diagnosed with a glioma brain tumour;
2. You are a caregiver or close family member with experience of living with a close person with glioma;
3. You are a clinical professional with experience of managing glioma;
4. You may be a researcher, policymaker, work at a third sector organisation, regulator, or part of the pharmaceutical industry with clinical trial experience.

3. Do I have to take part?

No, you do not have to take part. Your participation in this study is entirely voluntary, and it is up to you to decide whether to take part. If you decide to take part, please follow the link of the email provided or get in touch with one of our researchers to proceed with the survey. If you decide not to take part, then you do not need to do anything more. We will only be able to use fully completed survey responses (from both rounds of the survey); if you withdraw from the survey at any stage, you do not have to give any reason. If you withdraw from the survey before completion, we will delete the data that you have already provided. If you withdraw after taking part in the first round, your data will not be used. If you would like to withdraw at any point, please contact the researchers Elin Baddeley (baddeleye1@cardiff.ac.uk) or Dr Ameeta Retzer (a.retzer@bham.ac.uk). Please be aware that it will not be possible to withdraw once both surveys are complete and responses have been anonymised and analysed.

4. What will I be asked?

If you decide to take part, you will be invited to rank outcomes identified as important to those with glioma, from 1 (not important) to 9 (critically important) and decide how important each outcome is to you. This will be in the form of an online survey and will take part in two-rounds. We anticipate the survey will take 30-60 minutes to complete. We will provide more information on 'how to complete' the survey if you decide to take part. At that point, you will be asked to register to the online platform, provide some demographic details (which will remain anonymous: see 'Data Protection' sections below), followed by ranking outcomes, as described above. You will have the opportunity to add comments in the free text boxes provided, and to come back to the survey as many times as you like during the time the survey is open. You are welcome to ask a friend or relative to help you complete the survey. Please see the supporting documents [V1.0 'How to' navigate DelphiManager – Round 1] on how to navigate the survey if you decide to take part.

5. Will I be paid for taking part?

No. Any feedback you give will be voluntary, and you will not benefit financially, either now or in the future.

6. What are the possible risks and/or benefits of taking part?

There will be no direct advantages or benefits to you personally from taking part in this study. However, we hope that the study will help to improve the experiences of future patients and caregivers living with glioma and help to improve the approach health care practitioners and clinical researchers take towards managing gliomas.

You may find going through these questions on outcomes associated with glioma to be upsetting. You are free to pause the survey and come back to it, or decide to go no further, at any time. If you need any further information about cancer care and support, then please contact one of the following charities:

Brain Tumour Charity	**Brainstrust**	**Macmillan Cancer Support**
online at: https://www.thebraintumourcharity.org/ by phone: 0808 800 0004 (Mon-Fri: 9am-5pm)	online at: https://brainstrust.org.uk/ by phone: 01983 292 405	online at: http://macmillan.org.uk by phone: 08088080000 (Mon-Sun: 8am-8pm)

To minimise the risk of compromising privacy, confidentiality and/or anonymity we are using a secure online survey platform, 'DelphiManager', hosted by Cardiff University.

DATA PROTECTION AND CONFIDENTIALITY

7. What information collected in this research will be kept confidential?

All information collected from you during the research study will be kept confidential. Any personal information you provide (including name and contact details) will be managed in accordance with data protection legislation and will not be shared with other survey participants. Anonymised data from people taking part in the survey will be summarised by group (e.g. patients, caregivers, healthcare professionals) and fed back to all survey respondents between each round. Ethical approval to conduct the study has been granted by the School of Medicine Research Ethics Committee at Cardiff University. Any information that you provide, including any quotations that we use from explanations of responses, will be anonymised to make sure you cannot be identified.

8. What will happen to my personal data?

Cardiff University is the Data Controller and committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection can be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection and includes:

- Your rights
- The legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- How to contact the Cardiff University Data Protection Officer
- How to contact the Information Commissioner's Office

Any personal data obtained will remain confidential in line with the Data Protection Act (2018) and GDPR (2016). No identifiable information will be included in the data that is to be reported. For example, your name and contact email will be stored separately to your responses, and you will have an ID number linked to your responses, so you are not identifiable. Individual details such as diagnosis, treatment, and/or occupation details will not be included in the report and data will be stored in a secure folder on the Cardiff University Network, only accessible to the research team. In line with Cardiff University policies and General Data Protection Regulations (GDPR; EU 2016/679) and Data Protection Act 2018 (DPA 2018), your research data will be kept securely for 10 years after the study is completed and securely destroyed at the end of the 15 years. If you provide us with contact details for follow up, these will be kept securely for up to a year after the study ends and securely destroyed when no longer needed. Anonymised data will be archived so that it can be used by other researchers.

9. What will happen to the data collected within the survey?

By participating in this survey, you are agreeing that we may include your survey responses (anonymously) in future reports, professional journals and research. Anonymised data may also be shared with colleagues in the UK and Europe. Anonymised study findings may be presented at conferences, in promotional material (e.g. press releases) and in educational settings. All data collected in the on-line survey will be held securely by the survey software provider, 'DelphiManager', and retained by Cardiff University in accordance with the GDPR; EU 2016/679 and DPA 2018. For more information on data protection, please follow the link: General Data Protection Regulation (GDPR; EU 2016/679).

10. What if there is a problem?

If you wish to complain or have grounds for concerns about any aspect of how you have been treated or approached during this research study, please contact Professor Anthony Byrne at Anthony.Byrne2@wales.nhs.uk). If your complaint is not managed to your satisfaction, please contact mariecuriecentre@cardiff.ac.uk

11. Who is organising and funding this research project?

The COBra study is led and managed by Professor Anthony Byrne at the Marie Curie Palliative Care Research Centre at Cardiff University and is funded by The Brain Tumour Charity.

12. Who has reviewed this research project?

The School of Medicine Ethics Committee has reviewed and approved this research project (REF SMREC 21/59).

13. Further information and contact details.

Should you have any questions relating to this research study, or would like to know more information on the study, please contact one of the researchers at the following and they will be happy to answer any questions you should have:

- Elin Baddeley (Research Associate): COBra@cardiff.ac.uk, OR Baddeleye1@cardiff.ac.uk

Marie Curie Palliative Care Research Centre, Division of Population Medicine, School of Medicine, Cardiff University

- Dr Ameeta Retzer (Research Fellow): a.retzer@bham.ac.uk
- Professor Anthony Byrne (Principal Investigator): Anthony.Byrne2@wales.nhs.uk

Additionally, for more information on the COBra study, please see our website: https://www.cardiff.ac.uk/marie-curie-palliative-care-research-centre/research/research-portfolio/cobra

For additional information on the full study, please do not hesitate to get in contact with one or all of the researchers (details above).