Participant Information Form

Title	Australian Research Into Susceptibility and aEtiology of Familial Glioma
Short Title	ARISE Familial Glioma
Protocol Number	554/26
Coordinating Principal Investigator	Assoc Prof Tu Nguyen-Dumont (Monash University)
Associate Investigator(s)	Prof Enes Makalic (Monash University) Dr Karen Alpen (Monash University)
Location	Monash University

1 Introduction

You are invited to take part in this research study. This is because you or a close family member has glioma, which includes glioblastoma (GBM), astrocytoma and oligodendroglioma. You may be asked to donate a biospecimen (e.g., saliva or blood) which will be used to obtain your DNA for genetic research and you will be asked to provide medical, family history and lifestyle information.

This Participant Information Form is 7 pages long. Please make sure you read all the pages of this document. It tells you about the research study. It explains the tests involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. You can also contact us by emailing arise-study@monash.edu.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You or your family member will receive the best possible care whether or not you take part.

If you decide you want to take part in the research study, you will be asked to sign the consent section located below this document. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research study
• Consent to the use of your personal and health information as described.

You will be provided with a copy of this Participant Information Form and Consent Form to keep.

2 What is the purpose of this research?

The purpose of the research study is to improve the understanding of the genetic factors that may contribute to the development of glioma. You have been invited to join this study because you or a close family member (parent, sibling, child, grandparent, grandchild, aunt, uncle, niece, nephew or half-sibling) have glioma or there is a family history of glioma and other cancers in your family. Our study will establish a national register of glioma patients with a family history of glioma and other cancers. For some families, we will analyse DNA from selected family members to identify genes that may contribute to the risk of developing glioma.

This research is led by the Coordinating Principal Investigator Tu Nguyen-Dumont, Department of Cancer Medicine, School of Translational Medicine, Faculty of Medicine, Nursing and Health Science in Melbourne, Victoria. The Coordinating Principal Investigator is supported by a team of researchers and health professionals from around Australia.

3 What does participation in this research involve?

If you agree to take part in this research study, you will complete an online consent form and will be asked to complete one or more online questionnaires about your health, family history and lifestyle. Completion of all study questionnaires is expected to take approximately 30-45 minutes in total. They are presented one after another, and you may stop between questionnaires and return later using the same link. All participants will be asked to complete the study questionnaires. However, not all participants will be invited to provide a DNA sample for genetic analysis. Selection for the genomic component of the study will be based on the research needs of the project. For example, in some families we may only need DNA samples from a limited number of unaffected relatives to answer the research question, whereas we may seek DNA samples from all family members who have been diagnosed with glioma or another relevant cancer. Participants who are selected for the genomic component of the study will receive a biospecimen collection kit by mail. Instructions will be provided on how to collect a saliva sample and/or a finger-prick blood sample at home. The collection of a saliva sample usually involves spitting about half a teaspoon of saliva into a collection tube. Blood is collected by gently pricking your fingertip and placing a few drops of blood onto a special collection card. You will mail the sealed saliva tube or blood collection card back to the lab using the reply-paid packaging provided.

Participants with glioma or another cancer will be asked whether they consent to the research team accessing tumour samples collected as part of routine clinical care and relevant medical records, including information about diagnoses, treatments, medical imaging and pathology results. We may also ask you to share information about the study with eligible blood relatives who may wish to participate.

This study is interested in understanding glioma and cancer risk within families. If you are the first member of your family to join the study, you will be asked to complete a family history questionnaire that includes information about close relatives and whether they have had glioma or other cancers. Information about relatives is collected only to the extent necessary to document family relationships and relevant medical history, and will be handled confidentially.

You are welcome to share information about the study with relatives who may be interested in participating. However, your participation does not depend on whether any of your relatives choose to take part. Family members who wish to participate must contact the study team themselves and complete their own consent process.

With your consent, the study team will periodically obtain information from cancer registries, the National Death Index, Registries of Births, Deaths and Marriages, and other approved sources to

update and verify study records. To do this, we would need to pass some identifying details about you to these organisations. These organisations will not keep a copy of any information that we give them about you. We will also contact you from time to time to update your health information and study records.

There are no additional costs associated with participating in this research study, nor will you be paid.

It is desirable that your local doctor be advised of your decision to participate in this research study. If you have a local doctor, we recommend that you inform them of your participation in this research study.

4 Do I have to take part in this research study?

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you do decide to take part, you will be provided with a copy of this Participant Information and Consent Form to keep.

If you are a glioma or cancer patient, your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Monash University.

You can withdraw from the study at any time by completing a Withdrawal of Consent form available by emailing arise-study@monash.edu.

5 What are the possible benefits of taking part?

You may be contacted in the future if research identifies genetic information about you and your family, and you can choose whether to receive it. The information may help guide future health decisions for you and/or your family.

There may be no direct benefit to you; however, your participation may contribute to research that improves understanding, prevention and treatment of glioma.

6 What are the possible risks and disadvantages of taking part?

Genetic research involving your genetic material (mostly DNA) may identify information about an increased risk of developing a disease rather than certainty of developing a disease.

Learning about genetic results can be upsetting or create uncertainty; however, some people may also feel relief at having an explanation. For most people any initial feelings of upset often lessen over time.

Genetic information may have implications beyond your health care. Information about inherited disease risk may be relevant to health decisions made by you or by your biological relatives. Learning about a genetic finding can also create uncertainty, or raise concerns about privacy and about how genetic information might affect personal or family decisions.

From 8 October 2026, Australian law will prohibit life insurers from using or requiring the disclosure of genetic test results when deciding whether to provide life insurance cover, what premium to charge, or what conditions to apply.

This study does not disclose your genetic results to any employer, insurer or other organisation. Results are provided only to you, and only if you have chosen to receive them. If a clinically important genetic finding is identified and you choose to receive it, that finding becomes part of your health information. A genetic counsellor will discuss with you what the finding means, including any implications for insurance, employment and your family, both before and after the result is provided to you.

7 What is the potential impact on my family if I take part?

You may be asked to provide information about the health and cancer history of your relatives to help us understand patterns of cancer occurrence within families. Any information you provide about relatives will be kept confidential and used only for the purposes of this research.

Because this study investigates inherited factors that may contribute to glioma risk, participation by other family members may be valuable. However, participation is entirely voluntary. Your participation does not depend on the participation of any relative, and relatives are free to decide whether or not they wish to take part. We will not contact your relatives without your permission. If relatives are interested in participating, they will be asked to contact the study team directly and provide their own informed consent.

8 What will happen to my biospecimens?

We would like to store your biospecimens for use in any future research studies that are approved by a relevant ethics committee.

9 Banking (long term storage of biospecimens)

“Banking” is storing health information and/or blood or tissue for future research studies. A “bank” is the place where the health information and/or blood or tissue is stored. Your biospecimen will be stored as re-identifiable specimen(s).

We seek your permission to store your biospecimens for future research that has been reviewed and approved by a Human Research Ethics Committee. In the future, researchers at Monash University and other Australian or international medical and research institutions may use your biospecimen and associated research data for studies relating to glioma, brain tumours, cancer genetics, genomics and other cancer-related research.

Examples of future research include:

- identifying inherited genetic factors that increase the risk of glioma and other cancers;
- understanding why glioma occurs in some families;
- studying the biology of glioma and other cancers, including analysis of tumour tissue;
- developing or improving genetic tests, genomic biomarkers and risk prediction tools;
- investigating associations between genetic, clinical, family history, lifestyle and environmental factors and cancer risk;
- studying treatment response, disease progression and long-term outcomes; and
- evaluating new genomic or molecular technologies that may become available in the future.

Not all future research uses can be predicted at this time. However, any future use of your biospecimens will be required to be consistent with the consent you provide, approved by an appropriate Human Research Ethics Committee, and conducted in accordance with applicable laws, regulations and institutional policies.

Your biospecimen will be stored as a re-identifiable sample. This means that your sample will be identifiable by a code; it can be identified as yours even though the bank does not know your identity. You can have it removed and destroyed by contacting arise-study@monash.edu.

Your samples will be stored in the biobank indefinitely for future ethically approved research.

10 What are the possible benefits of banking my biospecimens?

There is no direct benefit to you. Other people might benefit if researchers learn more by using your banked biospecimens.

11 What are the possible risks and disadvantages of banking?

There is no extra physical risk to you.

12 Will I be informed of results of future research using my biospecimen?

Samples that we have collected from you, or collect in the future, are for research purposes, and not for the purpose of a medical diagnosis. Results will not be recorded in your medical record.

However, research may identify a finding that could be important for your health or the health of your family (for example, a genetic finding). If this occurs, and with your permission, we may contact you to offer you the opportunity to receive this information.

If you choose to receive this information, you will be supported to discuss the finding with a genetic counsellor or other qualified health professional. They will explain the potential significance of the finding, possible next steps, and future options.

The research team will not directly contact your family members about genetic findings identified through this study without appropriate permission. If a finding has potential relevance to your relatives, this will be discussed with you by a genetic counsellor, and you can decide whether and how to share this information with your family.

13 Banking of health information

The health information that will be collected and stored in a secure database includes information collected directly from you through questionnaires and, where applicable and with your consent, information obtained from medical records, pathology reports and other approved clinical sources. This may include information about your cancer diagnosis, treatments, medical imaging, pathology results, medical history and family history.
We may also collect information about your lifestyle and environmental exposures and information relating to the impact of your treatments on your life. We will collect your contact details so that we can contact you in the future. Your identifiable health information will be stored in a secure, controlled-access storage system and database that meet national and international data standards. They will be accessed by research staff at Monash University. Stringent security

measures will help prevent unauthorised access to or misuse of the data. Your health information will be stored separately from your biospecimens. The information you have provided will be a valuable resource for current and future research hence we will keep this information indefinitely.

14 What will happen to information about me?

By signing the consent form, you consent to the Coordinating Principal Investigator and relevant research staff collecting personal information about you for the research study. Any information obtained in connection with this research study that can identify you will remain confidential. Personal information (including your name, date of birth and address) will be removed and replaced with a unique study code. Only the minimum, necessary data will be shared with study researchers. This maintains your privacy, while allowing our study teams to link any research findings back to you if necessary. This will be important if there are findings that have implications for your future health care, so that we can contact you to return these results.

Your data obtained through this research study:

- will be accessed by authorised members of the research team and, where relevant, health professionals involved in your care;
- may be provided to an appropriate genetic counselling service if a clinically actionable genetic finding is identified and you have consented to receive such information. The genetic counselling service will provide information and support regarding the implications of the finding for you and your biological relatives;
- may be stored and made available for future Human Research Ethics Committee-approved research if you consent to the future use of your data; and
- will otherwise remain confidential, except where disclosure is required or permitted by law.

Information collected as part of this study will be stored securely within Monash University's protected research data systems. Only authorised members of the research team will be able to access your information, and strict security measures are in place to protect your privacy. Your data will not be stored on personal devices, USB drives, or unsecured cloud storage services.

We will not use your data for a different research study without the permission of a Human Research Ethics Committee (HREC). Once direct personal identifiers (such as your name, date of birth, address, contact details) have been removed or replaced with a study code, de-identified information may be used or shared for future ethically approved research without seeking additional consent. The code linking your identity to your research data will be stored separately and securely. It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

Researchers may use advanced computer-based analytical methods, including machine learning and artificial intelligence (AI), to analyse genetic, clinical, family history and questionnaire information collected as part of this study. These methods help researchers identify patterns and relationships within large and complex datasets that may improve understanding of why glioma occurs in some families and assist in the development of future risk prediction tools. Any AI methods used in this study will operate within secure institutional computing environments. Participant data will not be uploaded to publicly accessible or commercial AI platforms, and study data will not be used to train external AI models. All AI-generated outputs will be reviewed by researchers and will not replace scientific or clinical oversight.

In accordance with relevant Australian and State Government privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected.

Please contact the study team at arise-study@monash.edu if you would like to access your information.

15 What happens if I die during the research?

If you die during the course of this research, it may still be possible for research findings to be identified that are relevant to your family's health.

We suggest you nominate a person (such as a next of kin or a legal representative) who can be contacted about any findings that may be important to your family.

If a relevant finding is identified, we may contact your nominated person to offer them the opportunity to receive this information. They will also be offered appropriate support, including referral to a genetic counsellor or other qualified health professional.

16 Complaints

If you have any concerns or complaints about the conduction of this study, you can contact:

Complaints Officer
Office of Ethics and Research Governance, Bayside Health (Alfred)
Telephone: (03) 9076 3619
Email: research@alfred.org.au
Please quote the following study ID number: 554/26

17 Who has reviewed the research study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research study have been approved by the Alfred Hospital Ethics Committee.

This study will be carried out according to the *National Statement on Ethical Conduct in Human Research (2025)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

The person to contact depends on the nature of your query.
If you want any further information concerning this study, please visit our study website or email arise-study@monash.edu.