

# Genetic Links to Anxiety and Depression (GLAD)

## Participant Information Sheet



To continue to enrol in the GLAD Study you need to read through these pages of information and then complete the consent items at the end.

### Overview page

Depression and anxiety disorders are the most common psychiatric disorders worldwide. To improve our understanding of the genetic risk factors behind anxiety and depression, we need to recruit thousands of participants. We therefore invite you to take part in the Genetic Links to Anxiety and Depression (GLAD) Study and to join the largest study of individuals who have experienced or are currently struggling with depression and/or anxiety. The project is led by the National Institute for Health Research (NIHR) BioResource Centre Maudsley (part of the NIHR BioResource) and researchers at King's College London.

Signing up to the GLAD Study will involve providing access to your medical records (so we can find out some important clinical information), completing some questionnaires, and giving a saliva sample.

On the website you can see information on a number of research studies that are being carried out aiming to understand the role our genes play on the development and treatment of depression and anxiety. If you decide to sign up to this project you will be able to take part in these studies should you wish to that are not limited to anxiety and depression.

You can stop taking part at any time by contacting the GLAD Study team.

## 1. About the Study

The GLAD Study is a project set up to explore genetic risk factors in individuals who have suffered with or been diagnosed with depression and/or anxiety. The GLAD Study is a way for those who have experienced depression and/or anxiety to join the NIHR Mental Health BioResource, an NHS NIHR funded project which is part of the NIHR BioResource for Translational Research. The NIHR BioResource is a national initiative where the aim is to collect genetic and clinical data from volunteers to build up a central library of information about people's health. It offers you the chance to take part in ground-breaking research aimed at improving the lives of those not only with depression and anxiety, but other health conditions.

**The GLAD Study aims to conduct research on mental health and treatment. We will:**

- Collect psychological data (questionnaire data) and biological (saliva) samples so that we can learn more about the factors that may influence anxiety and depression.
- Link members' psychological and biological data with their medical records.

**The GLAD Study also aims to create an online research active group of individuals with anxiety or depression as part of the NIHR Mental Health BioResource. We will:**

- Create an online resource of members interested in taking part in research.
- Provide members with information about research projects that they can get involved in.
- Regularly update members on the progress of the research and the contribution that they have made.
- Provide links to pages that provide detailed information on mental health difficulties, the treatments available and where to seek help if it is needed.

**All data use is strictly within the terms of the Data Protection Act 2018.**

## **2. What's involved?**

It is essential that all participants in the GLAD Study agree to take part of their own free will and indicate that they fully understand what signing up will mean. There is no obligation to sign up. Once you have provided consent you can unsubscribe at any time.

There are **three steps** to signing up to the GLAD Study, part of the NIHR BioResource.

### **Step 1: Giving consent to take part**

- The consent form includes a description of each of the types of activity you might be invited to take part in. It is up to you which ones you consent to.
- We will request access to your medical records. Your data would only be provided to the GLAD and NIHR BioResource teams and, having been de-personalised, to researchers approved by the GLAD Study, and/ or NIHR BioResource Steering Committee. De-personalised means that your identifiable, personal information is removed, including your name, date of birth, and address. We will also ask for your consent to be contacted in the future about other ongoing research studies that may be unrelated to anxiety and depression.

### **Step 2: Questionnaire data**

- We will ask you to complete some questions which will ask about your demographics (e.g. age, gender, and employment situation), emotional wellbeing, health and lifestyle, personality and experiences of depression and anxiety. This will take around 30-60 minutes to complete.

### **Step 3: Saliva sample**

- We will ask you to provide a saliva sample by spitting into a specially designed collection tube. This will be sent to you at home and you can send it back to us using a freepost envelope which we will provide.
- We will extract DNA (i.e. genetic material) from this sample.

- Samples will be stored without any of your personal details (e.g. name, date of birth, NHS number).
- If you are from England and Northern Ireland, your sample will be stored at the National Biosample Centre (NBC) in Milton Keynes or other approved laboratory. If you are from Northern Ireland, some of your sample will also be stored in secure facilities at Ulster University in Coleraine.
- If you are from Scotland, your sample will be stored at NBC or other approved laboratory and some will also be stored at the Wellcome Trust Clinical Research Facility at the University of Edinburgh.
- If you are from Wales, your sample will be stored at NBC or other approved laboratory and some will also be stored at National Centre for Mental Health/ MRC Centre for Neuropsychiatric Genetics and Genomics at Cardiff University.

## Confidentiality

- The data that you provide will be kept strictly confidential. You will be assigned a unique ID number which is used to link your questionnaire answers and medical records to your saliva sample. This means your data is linked-anonymous; the key that links ID numbers to your personal information is stored securely in the GLAD Study and NIHR BioResource databases and can only be accessed by members of the GLAD and NIHR BioResource teams. Everyone working at King's College London and the NIHR BioResource has a legal duty to keep personal information confidential.

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## 3. Should I take part?

### Benefits of taking part

- By joining the GLAD Study you are also joining the NIHR BioResource. Once you are a member of the GLAD Study and the NIHR BioResource, you will be able to see information about further optional questionnaires, as well as a number of research studies that you are eligible to take part in. You may also be contacted about Patient and Public Involvement (PPI) groups or studies you may be eligible for that are not only related to anxiety and depression. We may assess your eligibility for these studies based on information you have provided (i.e. questionnaires), or information we have accessed from your medical records (i.e. diagnosis, treatment outcome) or samples (i.e. genetic information). If you choose to do so, you can sign up to be a participant in up to 8 studies per year (4 face-to-face and 4 online). You are free to accept or reject these invitations.
- There may be no immediate benefit to you in terms of treatment, but you will contribute to knowledge about some of the causes of depression and/or anxiety. This knowledge may lead to better treatment guidelines and improve future care for patients.

- The GLAD Study is an information resource for members as well as researchers. With this in mind, you will have access to pages dedicated to providing useful information to members.

### **Possible disadvantages**

- Some of the questionnaires ask about topics which some people might find sensitive, and about experiences of anxiety and/or depression. You do not have to complete any questions that you do not wish to.
- Providing a saliva sample is a very low risk procedure but some people find it unpleasant.
- Your participation is strictly confidential and the risk of identifiable information being accidentally disclosed is extremely low.

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## **4. Final details**

### **What will my information be used for?**

King's College London is the sponsor for this study based in England. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for the GLAD study. This means that we are responsible for looking after your information and using it properly. Cambridge University Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource and acts as the data controller for the NIHR BioResource. Your data will be stored by King's College London and the NIHR BioResource for use in current and future ethically approved research aimed at better understanding the development and treatment of a range of health conditions.

If you are from outside of England, then a derived data set will also be shared with the local Principal Investigator in your country to help contribute to mental health research in your nation. Your data will also be stored securely at Ulster University if you are from Northern Ireland, the University of Edinburgh if you are from Scotland, or the National Centre for Mental Health/MRC Centre for Neuropsychiatric Genetics and Genomics at Cardiff University if you are from Wales. Your personal information will not be shared without your permission.

King's College London and the NIHR BioResource will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the NIHR BioResource and the NIHR BioResource Centre Maudsley, and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS sites will pass these details to King's College London along with the information collected from you. The only people in King's College London and the NIHR BioResource who will have access to information that identifies you will be people who need to contact you for follow-up questionnaires, send newsletters, invitations to open events, or to audit the data collection process. The

people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

King's College London and the NIHR BioResource will keep identifiable information about you from this study until you choose to withdraw.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep your de-personalised data that we have already used for analysis (e.g. we will keep scientific findings that we have obtained from your DNA sample). To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your information will only be used for scientific research purposes. Access to your de-personalised data and saliva sample may be made available to other scientists under strict and confidential legal data-sharing agreements. All requests for access to use the data will be reviewed by the Glad Study, and/or NIHR BioResource Steering Committee. Any data released to other researchers will be de-personalised using your unique ID number, and will contain no personal information.

If your de-personalised sample is used to make an invention (i.e. to develop a product to aid the diagnosis or treatment of a disease), you will not receive compensation or recognition for your contribution. We partner with companies to develop inventions that can benefit patients, service users and donors with the aim of improving healthcare in the future.

You can find out more about how we use your information by contacting us at [www.gladstudy.org.uk/contact](http://www.gladstudy.org.uk/contact).

### **Will I get information about my genetic results?**

The NIHR BioResource Centre Maudsley does not plan to routinely feedback any genetic results obtained from your sample. The results are for research purposes only, and thus are not for clinical diagnosis or treatment. **In the extremely rare instance that we do find something that is of known clinical importance, we will write to your GP recommending further investigation, if you wish.**

### **What if I no longer want to be a member of the GLAD Study, part of the NIHR BioResource?**

Volunteers are free to withdraw from the GLAD Study, part of the NIHR BioResource at any time without giving a reason. If you choose to withdraw:

- You will be asked to specify whether you would like us to destroy the sample(s) you have donated and which are stored at the central archive.
- It will not be possible to destroy samples already prepared or already distributed for testing.
- Details of your initial consent and the withdrawal process will be maintained along with your name and date of birth.
- Should you wish, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.

- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once confirmation of your decision to withdraw is received, you will not be contacted again by the GLAD Study or NIHR BioResource Teams.
- If the GLAD Study, part of the NIHR BioResource is unable to confirm your decision, your sample(s) and data will be retained for future use, but you will not be contacted again.

To withdraw, please contact the GLAD Study, or NIHR BioResource team by email or phone. Please note that by withdrawing from the GLAD Study you will also be withdrawn from the NIHR BioResource and vice versa.

### **What if something goes wrong?**

We do not anticipate that anything will go wrong but if you have a concern about any aspect of this project, please call on [0207 848 1638] (Freephone [0800 634 4504]) and leave a message for the GLAD Study team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting The South London and Maudsley NHS Foundation Trust Complaints office (020 3228 2444/2499).

In the unlikely event that something does go wrong and you are harmed during the research due to someone's negligence, then you may have grounds for a legal action for compensation against King's College London. You may have to pay your legal costs.

### **Need more information before consenting?**

Contact our research team here [([www.gladstudy.org.uk/contact](http://www.gladstudy.org.uk/contact))] and they will be happy to provide you with any information you need about the project and the consenting process.

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If you would like to contact us, please give us a call on [020 7848 1638], or our Freephone on [0800 634 4504], or if you would like to email us at [[gladstudy@kcl.ac.uk](mailto:gladstudy@kcl.ac.uk)].

