

## **Eating Disorders Genetics Initiative (EDGI) part of the NIHR BioResource**

### **Participant Information Sheet V4 03/10/2023**

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

#### Overview page

Eating disorders are severe psychiatric illnesses and are associated with one of the highest mortality rates within mental health. To improve our understanding of the genetic and environmental risk factors behind eating disorders, we need to recruit thousands of participants. We therefore invite you to take part in the Eating Disorders Genetics Initiative (EDGI) and to join a large study of individuals who have experienced or are currently experiencing anorexia nervosa, bulimia nervosa, binge-eating disorder or any other eating disorder. The project is led by the National Institute for Health and Care Research (NIHR) BioResource Centre Maudsley (which is part of the NIHR BioResource), researchers at King's College London and Beat, the UK's eating disorder charity.

Signing up to EDGI will involve providing access to your medical records, health-related and social care records (so we can find out some important clinical information), completing some questionnaires, and giving a biological sample. Providing access to your medical, health related and social care records will help to gather more information in order to examine risk factors associated with eating disorders and other health disorders, and establish more in-depth information relating to eligibility for future research.

On the website [www.edgiuk.org](http://www.edgiuk.org) 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 eating disorders. If you decide to sign up to this project you will be able to take part in these other studies should you wish to, that are not limited to eating disorders.

You can stop taking part at any time, without giving a reason, by contacting the EDGI or NIHR BioResource teams.

### **1. About the Study**

EDGI is a project set up to explore genetic and environmental risk factors in individuals who have experienced or been diagnosed with an eating disorder. EDGI is a way for those who have experienced anorexia nervosa, bulimia nervosa, binge-eating disorder

or any other eating disorder to join the NIHR BioResource Centre Maudsley. NIHR stands for the National Institute for Health and Care Research, which is the research arm of the NHS. The NIHR is the nation's largest funder of health and care 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 eating disorders, but with other health conditions.

**EDGI aims to conduct research on mental health and treatment. We will:**

- Collect psychological data (questionnaire data) and biological (saliva and/or blood) samples so that we can learn more about the factors that may influence anorexia nervosa, bulimia nervosa, binge-eating disorder or any other eating disorder.
- Link members' psychological and biological data with their medical, health and social care records.

**EDGI also aims to create an online research active group of individuals with anorexia nervosa, bulimia nervosa, binge-eating disorder, or any other eating disorder 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 EDGI agree to take part at 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 withdraw at any time.

There are **three steps** to taking part in EDGI, part of the NIHR BioResource.

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

- You will be asked to consent to take part in the sign-up questionnaire, follow up questionnaires and other optional questionnaires.
- We will request access to your existing and future medical, health and social care records, which will be stored securely. More information on how we store your data securely can be found below under "Confidentiality".
- We will also ask for your consent to be contacted in the future about other ongoing research studies that may be unrelated to eating disorders.

## 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 an eating disorder. This will take around 30-45 minutes to complete.
- You will also have the option to consent to receive invitations to take part in brief follow-up questionnaires. These questionnaires would be sent via email 3 months and 6 months after completion of the sign-up questionnaire and take 5-10 minutes to complete. After the 6 month follow up, a follow up questionnaire will be sent every 6 months. You can opt-out of receiving the follow-up questionnaires at any time.

## Step 3: Biological 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.
- If you are recruited directly from a clinic, you will also be asked to provide a blood sample (maximum of 50ml or 3.5 tablespoons) that will be collected in person by a qualified, experienced member of staff.
- Blood samples will be processed when they arrive at our laboratory into DNA and different components of blood, such as serum and plasma. These components will be stored for as long as deemed scientifically useful. No whole blood will be stored.
- We are requesting a very limited amount of blood samples therefore there will be no surplus blood samples. All of the processed samples can be destroyed if requested by the donor.
- In the future, you may be invited to provide further biological samples;
- We will extract DNA (i.e. genetic material) from saliva and blood samples.
- The processed samples collected for this project will only be used for the analyses mentioned in the protocol, namely to study molecular processes related to eating disorders and general health research.
- Samples will be stored without any of your personal details (e.g. name, date of birth, NHS number).
- Your sample will be stored at a secure central storage facility, the NIHR National Biosample Centre (NBC) in Milton Keynes or other approved facility.

## 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, health and social care records to your biological sample. This means your data is de-personalised; the key that links ID numbers to your personal information is stored securely in the EDGI and NIHR BioResource databases and can only be accessed by members of the EDGI 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 EDGI, you are also joining the NIHR BioResource. Once you are a member of EDGI 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 may be eligible to take part in. You may also be contacted about studies you may be eligible for that are not only related to eating disorders. 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, health and social care records (i.e. diagnosis, treatment outcome) or samples (i.e. genetic information). We closely monitor how many times you are approached for future studies and restrict invitations. You may be invited 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. We will also contact you from time to time with information about the progress of the research through newsletters etc.
- There may be no immediate benefit to you in terms of treatment, but you will contribute to knowledge about some of the causes of anorexia nervosa, bulimia nervosa, binge-eating disorder, or any other eating disorder. This knowledge may lead to better treatment guidelines and improve future care for patients.
- EDGI 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 an eating disorder. 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 may find it unpleasant.
- The blood sample, including repeat samples, you may donate will be taken, where possible, at the same time as your clinical samples are taken for your healthcare, however this may not always be possible. Qualified, experienced staff will collect these samples according to best clinical practice, but as with any blood sample, it can cause some discomfort or bruising.
- 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 project based in England. We will be using information from you and your medical, health and social care records in order to undertake this project and will act as a data controller for EDGI. Cambridge University Hospitals NHS Foundation Trust is the sponsor responsible for managing the NIHR BioResource and acts as the data controller for the NIHR BioResource. This means that we are responsible for looking after your information and using it properly. 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.

King's College London and the NIHR BioResource will use your name, NHS number and contact details to contact you about the research project, and make sure that relevant information about the project 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, health and social care 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, to invite you to further studies, send you newsletters/updates if you have opted to receive these, 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 (i.e. information that identifies you such as your name, date of birth, and address) 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 biological 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 EDGI and/or the Data Accessing Committee and/or the 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.edgiuk.org/contact](http://www.edgiuk.org/contact).

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

The NIHR BioResource Centre Maudsley and the NIHR BioResource do 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, the NIHR BioResource Centre Maudsley will write to your GP recommending further investigation, if you wish.**

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

Volunteers are free to withdraw from EDGI, 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.
- Your personal information and details of your initial consent and withdrawal process will be retained in an archive so that a record remains of your initial study consent and the withdrawal process.
- Should you wish, by choosing “no further use” withdrawal 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 EDGI or NIHR BioResource teams.
- If the EDGI team, part of the NIHR BioResource, is unable to confirm your decision of whether you want to withdraw from further contact only, or from further use of your samples and data, your sample and data will be retained for future use, but you will not be contacted again.

To withdraw, please contact the EDGI or NIHR BioResource team by email or phone. Please note that by withdrawing from EDGI 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 [020 7848 1639 (Freephone 0800 917 6016) and leave a message for the EDGI 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.

### **Can I access my data?**

You have the right to access information held about you, which can be exercised in accordance with the UK General Data Protection Regulation (GDPR). You also have other rights including rights of correction, erasure, objection, and data portability.

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

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

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

If you would like to contact us, please give us a call on 020 7848 1639, or our Freephone on 0800 917 6016, or if you would like to email us at [edgi@kcl.ac.uk](mailto:edgi@kcl.ac.uk). You can also contact the NIHR BioResource team on 0800 090 2233 or e-mail us on [nbr@bioresource.nihr.ac.uk](mailto:nbr@bioresource.nihr.ac.uk) or visit our website <https://bioresource.nihr.ac.uk/>

### **If you would like independent advice please contact:**

South London and Maudsley (SLaM) Patient Advice and Liaison Service (PALS), open Monday to Friday, 9am to 5pm. **Website:** [slam.nhs.uk/pals](http://slam.nhs.uk/pals) **Telephone:** 0800 731 2864 **Email:** [pals@slam.nhs.uk](mailto:pals@slam.nhs.uk).

