

## Eating Disorders Genetics Initiative (EDGI)

### Participant Information Sheet

To continue to enrol in the 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 these disorders and to help improve treatments, 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 struggling with anorexia, bulimia, binge-eating, or any other eating disorder. The project is led by the National Institute of Health Research (NIHR) Mental Health BioResource and is in collaboration between the eating disorder charity Beat and researchers at King's College London.

Signing up to the EDGI will involve completing some questionnaires, giving a saliva sample and providing access to your medical records. Providing access to medical records will help to gather more information in order to examine risk factors associated with eating disorders and establish more in-depth information relating to eligibility for future research.

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 eating and other related disorders. If you decide to sign up to this project you will be able to take part in these other studies that are not limited to eating disorders.

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

## 1. About the Study

The EDGI is a project set up to explore genetic and environmental risk factors in individuals who have suffered with or been diagnosed with an eating disorder. The EDGI is a way for those who have experienced anorexia, bulimia, binge-eating or any other eating disorder to join the NIHR Mental Health (MH) BioResource. The NIHR MH BioResource is a national initiative where the aim 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 not only of those experiencing eating disorders, but with other related health conditions.

**The EDGI 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 anorexia, bulimia, binge-eating or any other eating disorder.
- Link members' psychological and biological data with their medical records.

**The EDGI also aims to create an online research active group of individuals with anorexia, bulimia, binge-eating, 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 the 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 take part. Once you have provided consent you can withdraw at any time.

There are **three steps** to taking part in the EDGI, part of the NIHR MH 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 EDGI and NIHR MH BioResource teams and, having been pseudo-anonymised, to researchers approved by the EDGI, and/or NIHR MH BioResource Steering Committee.
- 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 about 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.

### **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 at the NIHR National Biosample Centre (NBC) in Milton Keynes, or on occasion at the NIHR BioResource Centre Maudsley, without any of your personal details (e.g. name, date of birth, NHS number).

### **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 EDGI and NIHR MH BioResource database 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**

- Once you are a member of the resource, 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 that are not related to eating disorders but to general health. 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 4 studies per year.
- 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, bulimia, binge-eating, or any other eating disorder. This knowledge may lead to better treatment guidelines and improve future care for patients.
- The 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.
- 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?

The NIHR Mental Health BioResource is made up of the NIHR BioResource Centre Maudsley, based at King's College London and the NIHR BioResource based in Cambridge. King's College London is the sponsor for the EDGI based in England and will act as the data controller. In the future, we hope to expand to the entire UK. For this study, we will be using information you provide as well as your medical records. We will be responsible for looking after your information and using it securely. Cambridge University Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource and acts as the data controller for the NIHR MH 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.

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, 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. Some participants may join the study through NHS sites and these sites will pass the 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 identifiable information will be people who need to contact you for follow-up questionnaires or to audit the data collection process. This includes being contacted up to four times a year for studies you may be eligible for that are not only related to eating disorders but to general health. The people who analyse the genetic and questionnaire data 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 anonymised data that we have already used for analysis (i.e. we will keep scientific findings that we have obtained from your DNA sample and/or from health related medical records) as well as your name and date of birth information. 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 anonymised 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 EDGI and/or NIHR BioResource Steering Committee. Any

data released to other researchers will be anonymised using your unique ID number, and will contain no personal information.

If your anonymous 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.EDGI.org/contact](http://www.EDGI.org/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 general 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 EDGI, part of the NIHR BioResource?**

Volunteers are free to withdraw from the 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.
- Details of your initial consent and 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 EDGI or NIHR BioResource teams.
- If the EDGI team, part of the NIHR BioResource is unable to confirm your decision, 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.

### **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.

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

Contact our research team here ([www.edgi.org/contact](http://www.edgi.org/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 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).

