



## **National Centre for Mental Health (NCMH)**

### **Participant Information Sheet: Brief Assessment**

You are being invited to take part in a research study. Before you decide whether or not to take part, you should understand why the research is being done and what it will involve. Please take time to read the following information. Contact us if anything is not clear or if you would like more information. Take as much time as you need to decide whether or not you wish to take part.

#### **What is the purpose of the research?**

We are trying to understand why some people experience problems with their mental health. The purpose of this study is to collect information and samples for genetic, biological, psychological and clinical research. This will allow us to look for genes and other factors which make some people more likely than others to become ill. We hope that our study will improve understanding of these conditions and help find better treatments in the future.

#### **Who is being asked to take part?**

You have been invited for one of two reasons

1. Because you or one of your relatives have experienced a mental illness.
2. Because neither you nor your relatives have experienced a mental illness.

By comparing information from people who have experienced a mental illness with information from people who have not experienced such problems, we hope to learn more about the factors that may make some people more susceptible to these illnesses.

We aim to invite several thousand people to take part and we would be very grateful if you would be kind enough to help with this study.

#### **What does taking part involve?**

- A meeting with a member of our research team in your own/family member's home or if you prefer, at a local health clinic, at a University site or a voluntary organisation site.
- We will discuss the details of the study and you will be able to ask any questions you may have. You will be asked to sign a consent form stating that you agree to take part in the study. You will be given a copy to keep along with this information sheet.
- The researcher will complete a brief assessment with you (this will take approximately 30-60 minutes). They will ask to take a blood sample from your arm (a maximum of 50ml of blood, about 9 teaspoons of blood). If taking blood is not possible, you may be asked to provide a saliva (spit) sample.

- With your permission, we will look at your medical records in strict confidence. This is to gain further details about the kinds of symptoms and treatments you have had. With your permission, we would also like to look at your records in the future to see if there has been any change in your health.
- With your permission, the information you provide for this study, including clinical and genetic data, may be linked in an anonymous format (this will not include any of your personal details, such as your name and address) to routinely collected, anonymised datasets. These existing datasets, and data that may be collected in the future, contain anonymous health and social record information (for example, general practice records, hospital records). An example of such a databank that we will link to in Wales is the Secure Anonymised Information Linkage (SAIL) dataset at Swansea University. All data linkage is undertaken in line with the Data Protection Act (1998) and University governance.
- Reasonable travel expenses will be paid by Cardiff University
- We may ask you if any other members of your family would like to take part as this enables us to acquire a wide base of family genetic information. However, we would only contact your relatives with your full agreement.

### **What will my samples and data be used for?**

Our research uses the samples and information you have provided to help understand these disorders better. We study the huge number of tiny genetic differences found between one person and another. We hope to find out if these genetic variations are related in any way to mental health problems. Technical terms for the methods we use are linkage, association and gene sequencing studies. In recent years, these kinds of studies have led to major advances in understanding many common disorders. For example, asthma, several types of cancer, diabetes and heart disease. Your sample may be used in studies in which the entire length of the genetic code is examined. This is called genome-wide sequencing. These data and samples are available for use by other researchers under a system that strictly protects your confidentiality. To make best use of resources we will share data and tissue samples (anonymised to exclude any personal details) with different groups of researchers from the NHS, universities and commercial companies, both within the UK and abroad. However, we would stress that those organizations will never obtain access to personal/ identifying information (for example, your name, address, date of birth).

### **What are the possible benefits of taking part?**

There have been recent important discoveries of genetic factors in several common disorders, including mental disorders and developmental problems. We hope that these findings will lead to new ways of diagnosing, treating or even preventing these disorders. However, these remain long-term aims and you will not benefit directly from taking part in this study.

### **What are the possible disadvantages and risks of taking part?**

This study does not include any treatment changes or invasive techniques. Some people feel mild discomfort when giving a blood sample. Sometimes there is mild bruising afterwards. Very rarely we may find a genetic risk factor which may have important implications for your future health – or for the health of your family. In these rare circumstances, we will take advice from a clinical geneticist who may advise us to re-contact you and/ or your GP. You may be offered the option to seek further advice through a genetic counselling service. Please initial the appropriate box on the consent form if you would prefer for us not to contact you about such findings.

### **Declining and withdrawing from the study**

You do not have to take part in this study. If you do decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not alter the care you receive. If you decide to withdraw from this study, all details and samples you have provided will be destroyed.

These will not be used further in the research. In the unlikely event that you lose capacity, the research team will retain your identifiable sample and data and continue to use it in the research.

### **Data confidentiality**

All information and samples collected during the course of the research will be kept strictly confidential. There are strict laws that safeguard your privacy at every stage. In accordance with the Data Protection Act, your personal information will be kept confidential by assigning a unique study code to your sample and data. Your name or any identifying information will not be passed onto anyone. We will not routinely inform your GP that you are taking part. We will not pass on any of the information we collect unless we have serious concerns about your mental or physical health.

To make best use of resources we will share data with different groups of researchers from the NHS, universities and commercial companies, both within the UK and abroad. However, we would stress that those organizations will never obtain access to personal/ identifying information (for example, your name, address, date of birth).

### **What happens when the study is finished?**

This is a long-term study that will allow us to learn a lot about the causes and triggers of mental health problems.

You will not receive specific results or feedback about your clinical information or sample. You will not have any claim to any future commercial use of results from the study in which your data/ sample has been used.

With your permission, your sample will be passed to a Cardiff University biobank when it is no longer required for this study. You can withdraw your sample from the biobank at any point without giving a reason, to do this please contact the original study team. If you do withdraw your consent any sample that has not already been used for research will be destroyed according to local practices.

In order to maximise the potential of your sample, information collected through this study might also be passed to the biobank, such as your NHS number and information from your medical records (both now and in the future). The biobank might also access your data through the Secure Anonymised Information Linkage databank funded by the Welsh Government and hosted by Swansea University. Neither your name nor any other identifying information from any of these sources will be shared with researchers and your identity will always be protected.

Researchers in the UK and abroad, including certain commercial companies, may request permission to use your sample. This research may involve genetic testing, e.g. looking at DNA, or other research studies. Samples will only ever be used in research that has the ultimate goal of helping patients or the general public.

The biobank may seek to recover costs for the work it does but your samples will never be sold for profit. By signing the biobanking statement on the consent form you are agreeing for your sample to be used for these purposes.

### **What will happen to the results of the study?**

It is our intention to publish the results of this study in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation.

We will keep in touch with you via our website and by sending an annual newsletter to let you know how the research is going and to ask you to let us know if your contact details change.

### **Who is organising the research and why?**

This study is led by Cardiff, Swansea and Bangor Universities. It is being funded by Health and Care Research Wales, Welsh Government. The Director of the National Centre for Mental Health is Professor Ian Jones.

### **Future research opportunities**

We may contact you again about other related research. We very much hope that many of the individuals who join NCMH will also take part in these future research opportunities. You will be free to decline if you do not want to take part in these other research opportunities – just as you are free to withdraw from this study at any time.

### **Who has reviewed this study?**

The study has been given a favourable ethical opinion by Wales Research Ethics Committee (REC) 2 and NHS (Research and Development) permission has also been obtained

**If you have further questions about the study please contact the study team:**

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**If you would like to discuss this study with someone independent of the study please contact:**

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