

[INSTITUTION LETTERHEAD]

Patient Information Sheet (HD gene-carriers) and Consent Form

PART I: Information Sheet

We would like to invite you to participate in our research study on Huntington's disease (HD). Before you decide whether you would like to take part, it is important that you understand why the research is being done and what it would involve for you. Please take the time to read through this information sheet and we will answer any questions you may have.

What is the purpose of the study?

HD is a rare genetic condition caused by a faulty gene inherited from either parent. Currently, there is no cure for HD and any treatment given is to help with symptoms such as chorea (jerky movement) or low mood. These symptoms are usually noticeable between 30 and 50 years, but it is likely that some appear in a mild form earlier on in life. We want to understand what the early stages of depression and anxiety might look like in people with the HD gene but who are not yet experiencing obvious symptoms. By identifying early markers of depression and anxiety in HD, treatments may be brought forward which could help improve mental health as the disease progresses.

Why have I been invited?

We are inviting all adults over the age of 18 and up to 30 years who have had a positive genetic test for HD but are showing no obvious symptoms (this will be determined by our study doctor). We are also inviting family and friends who are non-gene carriers as a comparison.

Do I have to take part?

Participation is voluntary and you may withdraw from the study at any stage.

What will happen to me if I decide to take part?

You will be asked to complete eight sets of questionnaires that explore daily living including sleep patterns, appetite, work life and how you feel day to day.

The study will take place at [X] and should take no longer than three hours.

Are there any possible disadvantages or risks from taking part?

There is a very small chance that some of the questions may cause distress. If this does occur, we will stop the study immediately and you will be given the option of taking a break and continuing or withdrawing completely.

Will I be reimbursed for taking part?

You will be reimbursed for any reasonable expenses including travel, meals and childcare.

What will happen to my data?

[X] researchers are responsible for looking after your information and using it properly. We will keep identifiable information about you until the study has finished. After this, any research data and documents with personal information will be held securely for up to ten years.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can find out more about how we use your information by contacting the study team.

What will happen to the results of this study?

When the results of the study are published it will not be possible to identify yourself, but we will be in touch to give you an overview of our findings.

What if there is a problem?

If you wish to complain, or have any concerns, please contact [X]

Who has reviewed the study?

This study has been reviewed and passed by an independent Research Ethics Committee [X] ref [X]

Do you have any questions?

Study ID:

Participant Identification Number:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study.

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2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

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4. I agree to take part in the above study.

☐

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant

Date

Signature

Name of Person
seeking consent

Date

Signature