



Consent Form

Validation of dried blood spot biomarkers for identification of depressed patients with bipolar disorder misdiagnosed as having major depressive disorder

Conducted by the Cambridge Centre for Neuropsychiatric Research at the University of Cambridge (ccnr@ceb.cam.ac.uk).

Please make sure you have read the [Participant Information Sheet](#) on the previous pages before completing this section.

We need to first check your eligibility to participate in this study. Please tick the box that applies to you for each of the questions on the following pages. If you are eligible, you will then be asked to consent to participate in this study.

Eligibility criteria

First, please answer the following questions to confirm you are eligible to participate:

1. I confirm I am between 18 and 45 years old.
Yes / No
2. I confirm I am a UK resident (England, Wales, Scotland, or Northern Ireland).
Yes / No
3. I confirm I have been diagnosed with major depressive disorder by a healthcare professional within the last 5 years.
Yes / No
4. I confirm I am not experiencing any suicidal thoughts.
Yes / No
5. I confirm I have never been diagnosed with bipolar disorder (formerly known as manic depression).
Yes / No
6. I confirm I have never been diagnosed with schizophrenia.
Yes / No

7. I confirm I do not have any known blood-borne illness such as hepatitis or HIV infection.
Yes / No

 8. I confirm I am not pregnant or breastfeeding.
Yes / No
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[IF ELIGIBLE]

Your current mood

Now, we would like to ask you a few questions regarding your current mood.

[PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9) AS FOLLOWS:]

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. Little interest or pleasure in doing things?
Not at all / Several days / More than half the days / Nearly every day
 2. Feeling down, depressed, or hopeless?
Not at all / Several days / More than half the days / Nearly every day
 3. Trouble falling or staying asleep, or sleeping too much?
Not at all / Several days / More than half the days / Nearly every day
 4. Feeling tired or having little energy?
Not at all / Several days / More than half the days / Nearly every day
 5. Poor appetite or overeating?
Not at all / Several days / More than half the days / Nearly every day
 6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down?
Not at all / Several days / More than half the days / Nearly every day
 7. Trouble concentrating on things, such as reading the newspaper or watching television?
Not at all / Several days / More than half the days / Nearly every day
 8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?
Not at all / Several days / More than half the days / Nearly every day
 9. Thoughts that you would be better off dead or of hurting yourself in some way?
Not at all / Several days / More than half the days / Nearly every day
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10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
Not difficult at all / Somewhat difficult / Very difficult / Extremely difficult/Not applicable

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[IF PHQ-9 SCORE \geq 5 (AT LEAST MILD DEPRESSIVE SYMPTOMS)]

Thank you for answering these questions. Your answers indicate that you are eligible to participate in this study.

On the next page, we would like to ask you to fill in the consent form for your participation.

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Consent form

Please make sure you have read the [Participant Information Sheet](#) on the previous pages before completing this consent form. Tick each of the boxes below to confirm your agreement with each statement and record your electronic signature to sign up to the study.

1. I confirm that I have read and understood the Participant Information Sheet. I have had the opportunity to consider the information and ask questions.
Yes / No
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
Yes / No
3. I understand that the personal information collected about me will be kept confidential and that all efforts will be made to ensure I cannot be identified (except as might be required by law).
Yes / No
4. I agree that data gathered in this study may be stored securely and may be used for future research and product development by the research group and collaborators.
Yes / No
5. If selected, I agree to donate a blood sample, and for my sample to be stored and used for research.
Yes / No
6. I agree that my contact details can be used as part of the study as specified in the Participant Information Sheet.
Yes / No
7. I agree to take part in this study.
Yes / No

You can download a copy of this Consent Form for your future reference by clicking [here](#).

Please note that to participate in this research, it is necessary to answer 'Yes' to all of the above questions. If you find that you are unable to do so, we fully understand and would like to thank you for considering participating in our study.

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[IF CONSENTING]

Signature [please type in your full name]

Date

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Thank you for consenting to participate in this study.

Your participant ID is: [ID]

Please make a note of it. We will also email you this ID after you complete this survey. You will need this ID if you are selected for part two of the study and asked to provide a blood sample. You will also need it if you decide you wish to withdraw your data at any point.

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[IF NOT ELIGIBLE/PHQ-9 SCORE < 5 (LOW DEPRESSIVE SYMPTOMS)]

Thank you for answering these questions.

Unfortunately, your answers indicate that you are not eligible to participate at this time.

We would like to thank you for considering participating in our research.

If you feel you may require professional help, please contact a healthcare professional such as your General Practitioner (GP), or seek support via the following links:

- The NHS recommended list of mental health helplines: <https://www.nhs.uk/nhs-services/mental-health-services/>
- The Samaritans: <https://www.samaritans.org/> (or call 116 123 for a free 24-hour helpline)

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[IF NOT CONSENTING]

To participate in the study, you need to agree to all of the statements below.