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**Phase II RCT evaluation of a treatment decision-aid for
patients with bipolar II disorder and their family**

PARTICIPANT INFORMATION STATEMENT FOR INDIVIDUALS WITH BIPOLAR II DISORDER

(1) What is this study about?

You are invited to take part in a research study to evaluate the usefulness of a decision-support resource, known as a decision-aid. This decision-aid is designed to help patients diagnosed with bipolar II disorder (and their family) to decide on medication and psychological treatment options to prevent relapse.

You have been invited to participate in this study because you have a confirmed diagnosis of bipolar II disorder from the Black Dog Institute and are currently making/ or have made a decision with your clinician about your treatment to maintain wellness and prevent relapse. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

Alana Fisher is conducting this study as the basis for the degree of PhD in Psychology at The University of Sydney. This will take place under the supervision of A/Prof Ilona Juraskova and Prof Louise Sharpe at the University of Sydney and Dr Josephine Anderson and A/Prof Vijaya

Manicavasagar Director of Psychological Services and Director of the Psychology Clinic, at the Black Dog Institute.

(3) What will the study involve for me?

If you agree to participate, you will need to sign the enclosed Participant Consent Form. The researchers will have randomly assigned you to receive access to:

EITHER

i) online factsheets, information brochures or website details that you usually receive through the Black Dog Institute

OR

ii) this usual information **plus** the online decision-aid.

This means you may or may not receive access to the online decision-aid. You will have been sent an email containing a link to register on this website portal. When you click on this email link, you access the website portal and complete three online questionnaires.

The first questionnaire, you complete when you log in for the first time, *before* gaining access to the full decision-aid (if you received access). The second questionnaire, you complete three weeks later *after* using the decision-aid (if you received access).

These questionnaires asks for some background information about yourself, how you are feeling, your understanding of the treatment options, and your views on the treatment decision-making process.

Three months later you will be contacted and asked to complete a similar but shorter online questionnaire.

(4) How much of my time will the study take?

Reviewing the online decision-aid and completing first lot of questionnaires will take approximately 40-50 minutes. The follow-up questionnaire will take approximately 15-20 minutes.

(5) Who can take part in the study?

You may take part in this study if you have been diagnosed with bipolar II disorder and are currently having to make and/or have made a decision with your clinician about your treatment to maintain wellness and prevent relapse. This study is not suitable for you to take part in if you are under 18 years old, or have insufficient English to participate, are not able to give informed consent to research, are experiencing acute symptoms of depression and/or hypomania, have a substance abuse disorder, or a neurological or major psychiatric condition. This is because these issues may affect your ability to participate fully in the research, and provide meaningful responses to the questionnaires.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or the Black Dog Institute.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the study coordinator Alana Fisher on 02 9036 9258 or at a.fisher@sydney.edu.au

Even after submitting your completed questionnaires, you can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, there is a chance you may find some of the material in the decision-aid or the questionnaires confronting or upsetting, or that it raises new issues. If you decide that you need help in dealing with these issues, please contact the Study Coordinator, Alana Fisher, on 02 9036 9258 or at a.fisher@sydney.edu.au.

Alternatively, you can call Lifeline on 13 11 14 or BeyondBlue helpline on 1300 22 4636 which are free confidential telephone information and support services available to anybody affected by mental health issues.

We do not expect that there will be any other risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

This study aims to determine whether or not this decision-aid will help future patients and their family members make better decisions within consultations about treatment and management of bipolar II disorder. This study may not directly benefit you, however, you may gain some benefit from the information in the decision-aid (if you receive it). If you receive a copy of the decision-aid, it is for you to keep. All participants may request access to the online decision-aid once the study is completed.

(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Electronic copies of questionnaire data will be kept on a password-protected computer accessible only to members of the research team. Hardcopies of the data will be kept in locked filing cabinets; all identifying information will be removed from your data and stored separately in locked filing cabinets accessible only by members of the research team. Study findings will be published in a student thesis and articles in academic journals, and presented at conferences, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects. We don't know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects. After five (5) years, your data will be disposed of by secure destruction methods such as shredding of paper documents or erasure of computer generated data.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study. However, we ask that you *do not* show the decision-aid to others involved in the study because this may change their responses on questionnaires.

(11) What if I would like further information about the study?

When you have read this information, Alana Fisher will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Study Coordinator Alana Fisher on 02 9036 9258 or at a.fisher@sydney.edu.au.

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a brief summary using plain English. You will receive this feedback after the study is finished.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [*INSERT protocol number once approval is obtained*]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep