INFORMED CONSENT FORM FOR PATIENTS

Title: Asian Bipolar Genetics Network (A-BIG-NET)

Introduction

You are being invited to take part in the research study named "**Asian Bipolar Genetics Network (A-BIG-NET)" because you have been diagnosed with bipolar disorder**. Before you decide, it is important for you to understand why this research is being done and what will be involved. Please take time to read the following information sheet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you would like to take part in the study.

What is the purpose of the study?

Bipolar disorder (BD) is a severe disorder with a life-time prevalence of 1-2%, that causes emotional distress to patients and their families, and can harm family, social, and work roles. Available treatments can help, but do not "cure" the disorders. Partial or complete failure to respond to available medication and psychological treatments is common, and those who do respond to medication treatment may experience serious adverse side effects. Better treatments for bipolar disorder are urgently needed. The purpose of this research is to try to understand better why some people develop bipolar disorders and to develop better treatments.

Our body is made up of many tiny parts called cells. These cells contain genes made of DNA, which tell the cells how to grow and work. We get our DNA from our parents. Every cell in your body has the same DNA. But nobody else in the world has the same DNA as you, unless you are a twin. Differences in DNA can be why some people are tall and others are short, and it's what makes men and women different. Some illnesses are caused by problems with DNA. In these illnesses some cells do not work the way they should. The study of DNA is called genetics. All of the genes in one of your cells are called your "genome." Your genomic data is the information about all of your genes. This study will try to find out about genes that may be related to why some people develop bipolar disorders and others do not. We would like to be able to compare the genes from people who do have bipolar disorders to the genes of people who do not. We hope that this will help us in the future to plan better treatments for people who develop psychiatric disorders.

Why I am being invited?

We have invited you to take part in a research study because you have been diagnosed with bipolar disorder.

Do I have to take part?

It is your choice whether or not to participate. It is entirely voluntary. Please read the consent form and these questions and answers carefully and take your time in making decisions about participating in this research. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will not in any way interfere with your treatment. You will continue to get treatment from your treating doctor as usual.

What will happen to me if I take part in this study?

As a participant, if you choose to take part in the study, you will be expected to complete the following:

- Sign the informed consent: our research team will explain the details of the study, and review risks and benefits before you sign the consent form.

- Complete some questionnaires: one of the researchers will ask you some questions about your socio-demographic background, medical, psychiatric and family history. This may take 60-90 minutes overall. We will also access your hospital records or any other previous medical records that you may provide to us to obtain full history of your health problem.
- Provide a blood sample: a nurse, or a doctor will draw a tube of blood (3 table spoons, 15ml) from you.

This entire process will take about 2-3 hours to complete and may be conducted with breaks in between to ensure your comfort.

We will share any new information gained during the course of the study that might affect your willingness to continue your participation with your treating team with your consent.

You will also be asked if you are willing to be contacted for future studies. If you consent to be contacted for future studies, study staff will ask you for your contact details. If you consent, we may also ask the contact information of your family members we can contact if we have difficulty reaching you.

Will I benefit from this study?

There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, if this study contributes to our understanding of psychiatric illnesses, then it may be possible in the future to develop better diagnostic tests, improved treatments, or preventive measures based on this knowledge. This might benefit persons in the future (possibly including some of study participants or your descendants) who have or are at risk for bipolar disorder, schizoaffective bipolar type and related disorders.

Risks – What are the risks that I am likely to face if I participate in this study? What if something goes wrong?

There are some minor risks in participating in this study.

<u>Interview</u>

You may experience distress or discomfort when answering questions about yourself. You do not have to answer questions if they make you uncomfortable. You may also ask to take a break at any time. Provisions are in place to minimize potential stress and discomfort over questions. Assessments will take place in a private space to maximize confidentiality, and you do not have to answer any questions that make you feel uncomfortable, and can ask to take a break at any time. If you exhibit acute psychological distress, you will be referred to the attending clinician in the hospital.

<u>Blood Sample</u>

As with any time that a blood sample is taken, there is a small risk of pain, swelling, bruising, or infection at the site of the blood draw. Some people occasionally faint when having their blood drawn. Blood will be collected by experienced phlebotomists, or other persons trained to draw blood (e.g., physicians, nurses) to minimize the risks of any adverse events.

<u>Privacy</u>

There is a small risk that your genetic information or information linking your name to stored samples

and/or your blood results could be mistakenly shared. It is possible that you could be identified from the sample if someone has another sample from you. The two samples could be matched to identify you from the sample given for this study. Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. If this information was shared with your family members, it could affect them as well because genes are inherited within families.

All information collected in this study will remain confidential unless you, the participant, is in danger of harming yourself or someone else. In that case, the study staff has an Emergency Care Procedure in place should it need to be invoked. There is no risk of criminal or civil liability associated with participation.

How will my confidentiality be protected?

We will limit who can see the data that we collect about you in this study. We cannot promise complete secrecy, but we have multiple safeguards in place to ensure confidentiality.

We will be collecting two types of information:

- Health information: for example, your background, medical history, interviews and questionnaires
- Genomic information

Your information will be coded with a unique study identification number that is linked to your personal information in our database. This will be stored securely at NIMNHANS. This identification number will be used to identify your blood and DNA samples. Your personal information will not be shared with anyone outside NIMHANS.

Your individual health information and genomic data will be put in a controlled-access database, using the unique code described above. Only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. In essence, your data will be de-identified and stored.

All efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. The sponsor, monitors, auditors, and the Institute Ethics Committee / Review Board will be granted direct access to your research data to conduct and oversee the research. Researchers approved to access information in the database will agree not to attempt to identify you.

What if I don't want to participate in this study, or I want to withdraw later?

You can leave the research at any time; it will not be held against you. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to stop taking part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

What happens with the data collected / results / my samples?

Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. The coded data will be encrypted and stored on a secure server to prevent improper access. Some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by this institution, some are maintained by the government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the United States of America government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with information from many other people. Your name and other information that could directly identify you will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential. The data transfer with foreign collaboration will happen only after obtaining necessary permission form health Ministry of Government of India.

The de-identified data or sample (i.e., without any personal identifiers) could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We will also store your DNA sample indefinitely. This is because new and better ways of analyzing DNA will become available and we may then use other technologies to study your DNA that become available in the future. Your DNA sample will be stored in the molecular genetics laboratory, Neurobiology Research Centre, NIMHANS. Information that identifies you personally will be removed from the sample, which will then only have a de-identified study identification number.

Will I receive results from research involving your specimens?

Most people who participate in this study will not receive results of their genetic tests because they may not have any immediate clinical relevance.

Rarely, we might find an important genetic change. If we do, our team will contact you to explain the situation and answer your questions. You can then decide if you do or do not want to know your DNA results. You can decide that you do not want to know your DNA results. If you want to know, you can decide which types of DNA results you want to know. Based on your choices, we can arrange for you to talk with a medical genetics expert. You will need to sign a release of medical information form so we can have this talk. We will then discuss what we have found with you.

Who is organizing the study?

The study is funded by the National Institute of Mental Health in the USA and will involve a collaboration between the Broad Institute, Massachusetts, USA and NIMHANS, Bangalore, India and other Indian Hospitals.

Who has reviewed this study?

The Institutional Review Board and Ethics Committee at NIMHANS, Bangalore, India has reviewed the study.

If you need any more information about this study please contact:

Principal Investigator:
Dr. Biju Viswanath, Associate Professor of Psychiatry. Ph: 08026995250/61

Co-principal investigator:
Dr YC Janardhan Reddy, Professor, Dept of Psychiatry, NIMHANS, Bangalore, Ph No: 080 26995250/78
Dr Muralidharan K, Professor, Dept of Psychiatry, NIMHANS, Bangalore, Ph No: 080 26995250/52

Undertaking by the investigator:

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. In such an event, you will still receive the best possible treatment, without any prejudice. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire. All the information/data collected from you will be kept in strict confidence

Consent:

I have read the participant information sheet / participant information sheet has been read out to me. I have been informed about the procedures of the study. The possible risks too have been explained to me as stated in the Participant Information Sheet. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction I am aware that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my treatment. I am aware that by subjecting to this research, I will have to give more time for assessments by the investigating team and that these assessments do not interfere with the benefits.

I_____, the undersigned, voluntarily give my consent to be a participant of this research study.

Name and Signature of participant

Date

Name and signature of investigator

Date

Name and signature of witness (if required, as in case illiterate participants and consent by LAR)

Date