1. Title of research

Clinical implementation of preemptive pharmacogenomics-guided prescription in psychiatry

2. Principal Investigator

Dr Majid Alabdulla, Sr Consultant, Medical Director of the Mental Health Services at Hamad Medical Corporation

3. Why are we inviting you to join this research?

The investigator and colleagues at Hamad Medical Corporation (HMC) and Qatar Precision Health Institute (QPHI) are conducting this research.

We are inviting you to join because you are eligible to participate in this study as you are using psychotropic medications

4. What should you know about this research?

We invite you to take part in a clinical research study called Clinical implementation of preemptive pharmacogenomics-guided prescription in psychiatry that is taking place at HMC.

- This form is called a consent form. The purpose of this consent form is to explain the study and what happens if you decide to join. You have a choice whether or not you would like to participate. Please read this form carefully before making a decision about joining the study.
- The information in this consent form will also be discussed with you by the research team. If there is anything you do not understand about this study, please ask the study doctor and/or the research team any questions you have before you make your decision. If you decide to take part in this study, you will be asked to sign this form, and you will be given a signed copy of this form.
- Being in this research study is voluntary. You do not have to take part in this study if you do not want to and, there will be no penalty if you choose not to participate. If you do take part in this study, you can leave the study at any time and for any reason. You do not have to participate in this research study in order to receive treatment.

5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:

Noriya Mohd Al-Khuzaei, Director of Pharmacy Mental Health Service – HMC Mob :55516733/4438
If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC-IRB Office at +974 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

6. Why are we doing the research?

- The purpose of this research study is to find out the best medication type and dose each individual should receive for psychotropic therapy
- People respond differently to medicines, so some may need higher or lower doses to work well and avoid side effects.
- By looking at your genetic information, doctors can choose the medicine and dose that suit you best.
- Your saliva contains DNA, which is like an instruction book for your body. We will collect a small saliva sample from you to study how genes can help improve treatment for psychiatric patients in Qatar

7. How long will the research take?

Your participation in this research study will require 4 months from your enrollment on the study through your clinical routine visit in order to take a saliva sample for genetic testing. The demographic, clinical and biological data as acquired for your clinical care will be accessed directly from your medical record. Future studies that use information from this research study will continue after your participation in the research study ends. We expect the research study to last for 3 years.

8. How many people will take part?

We plan to study 150 patients. The study will be conducted in HMC.

9. What happens if you take part?

If you agree to join, we will ask you to do the following:

- Take a 2 ml saliva sample for genetic testing
- Continue your regular clinic visits at HMC Mental Health Hospital for at least 4 months
- Information about your current medication as well as information about your medical condition and other medications will be collected.

This information will help us understand how your body responds to medicines. Your psychiatric medicines may be chosen based on your genetic test results from the list of medicines available at HMC

10. Could the research be bad for you?

- No anticipated risk is associated with this study.
- The research team will employ several methods to protect the participants' identity and confidentiality. All identifiers will be saved in protected and encrypted files.
- The research team will ensure the security and privacy of participants' data using encrypted and protected files. However, there is a very minimum risk of unauthorized access to and misuse of information, if there is a leak of any information or hacking to the system.
- Genetic information is highly sensitive, and the research team will implement maximum-security measures to protect the participants' genetic data. There are a few approaches that link the genetic information back to the persons' identifiers. There are some potential risks with the advances of genomic research, including development of new methods to link the genetic material to the person's identifiers, risks to

- certain medical conditions that cannot be predicted at the time of conducting the research, and the results of the current research might be different in the future with more research outcomes related to the subject.
- The genetic information is unique to each person. However, individuals share some of the genetic information with their blood relatives. This genetic information could help to identify the individual who shares the same genetic material. Also, the person's genetic information can be used to identify his/her relatives.
- Strict access to data will be implemented to protect participants information (see Section 12). However, people may develop ways in the future to link genetic or medical information in the research databases back to participant's identifier. For example, someone could compare information in the research databases with information from the participant (or a blood relative) in another database which may lead to the participants' identifier you (or the participant's blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking participant's genetic and medical information to participant's identifier.
- Some genetic variations may provide insights into an individual's potential risk for certain health conditions. While this information is primarily used for research and clinical purposes, there may be theoretical concerns that such data could be of interest to third parties, such as health providers, insurance companies, or law enforcement agencies. However, in this study, all genetic information will be handled with strict confidentiality and will not be shared with any external parties unless required by law or with the participant's explicit consent. Measures are in place to protect the privacy of participants and their families, and all data will be securely stored and de-identified to minimize any risk of misuse or unintended disclosure.
- It is possible that study findings could one day help people of the same ethnicity or gender as the study participants. However, it is also possible that genetic traits might become associated with the study group and might reinforce harmful stereotypes.

11. Could the research be good for you?

- The possible benefits include knowing your genetic test results and personalizing your therapy that may contribute in maximizing your response with the least amount of adverse effects based on your DNA. We hope the information we get from this study may help develop a greater understanding of genetic testing in the future.
- This kind of research usually takes a long time to produce medically useful results, so we will report genetic test to your doctor only and it may be linked to your electronic health record
- Your participation may, however, help patients in the future by improving the knowledge of response to drugs and improving medical care.

12. What happens to information about you?

- Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.
- This is the information we will use and include in our research records:
- Demographic and other information like date of birth, gender, medication list. Data will be collected de- identified, codes will be used to cover patient identifiers such as Name, HC no., DOB. The link between the code and the identifier will be destroyed once the study finishes and the de-identified data will be stored for at least five years
- Related medical information about you like your current and past medical conditions, family medical history, medication allergies
- All laboratory tests that will be done in the study
- Genetic testing results
- We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research.
- We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:
- Members of the research team and other representatives whose work is related to the research or to protecting your rights and safety

- Representatives of the Ministry of Public Health in Qatar, HMC or QPHI who make sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses
- If you do not want us to use information about your health, you should not be part of this research.
- Few members of the research team will have access to the participants' identifiers to ensure the quality of the study. Those members will not share any personal identifiers with other research members and will keep all personal information confidential.
- The results of this study will be discussed at scientific meetings and/or published in scientific journals. Personal identifiers of study subjects will not be used in any scientific meeting or written publication.
- All saliva samples collected for the research study will be considered as donations from the study participants. All personal identifiers that link the blood samples to the participants will not be used to label or identify the samples.
- The research team or the treating physician may inform the participants about the genetic variations identified in the study that may have an impact on the participants health if they are interested in receiving this information.
- The research team may request to integrate the clinical genetic test results in the electronic medical record. The research team may use information from the participants' electronic medical records to study the relationship between genetic makeup and health and disease.

- 13. What if you don't want to join?

- Participation in this research study is voluntary. You do not have to take part in the research project to continue to receive care at HMC. If you decide not to take part in this research study, your current and future medical care at HMC will not be affected in any way and you will receive the same standard of heath care.

- 14. What if you join but change your mind?

- You can stop participating at any time and we will not hold it against you.
- We will tell you about any new information that might affect your health or welfare, or might affect your willingness to continue in the research.
- If you stop early, please contact us. There is no safety or legal concerns about your decision
- If you stop participating, we will ask you for permission to keep the processed data in out records. Your donated sample will be destroyed, and no further analysis will be done

15. What else should you know?

- This research is funded by HMC and QPHI
- If you are injured as a direct result of research procedures, contact the investigator and appropriate care will be made available at HMC. If you seek care outside of HMC, such care will be at your expense. Compensation is not available in case of injury.
- The investigator or sponsor may stop the study or take you out of the study at any time, even if you would like to continue.
- You will not receive any financial compensation for your participation in the study or for your donating sample.
- The original and one copy of this consent form will be kept in a research folder and a copy of this Consent Form will be given to you to keep.

16. Additional Choices

We would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_____YES, you may contact me

_____NO, you may NOT contact me

Signature Page for Capable Adult

Volunteer

I voluntarily agree to join the research described in this form.

Printed Name of Volunteer

Signature of Volunteer Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the volunteer.*
- *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.

Printed Name of Witness

Signature of Witness Date