MAYO CLINIC

Name and Clinic Number

Approval Date: **November 1, 2019**
Not to be used after: **October 31, 2020**

Subject ID:
Protocol Version #: 1
Protocol Version Date: 7/7/2019
Consent Version #: 1 **Consent Date: 7/7/2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Clinical Pilot of Augmented Human Intelligence in Major Depressive Disorder (AHI/Depression Pilot)

IRB#: 19-005341

Principal Investigator: William V. Bobo, MD, MPH, and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test whether a computer program (called a clinical decision support tool) can help clinicians predict how a patient with depression will respond to antidepressant medication. The antidepressants in this study are FDA approved for the treatment of depression. You have been asked to take part in this research because you have been diagnosed with depression and your health care provider thinks that you might be helped by taking an antidepressant.

What's Involved	Participation in this study includes four face to face and two phone visits with a doctor and/or study personnel, vital signs measured, answer questions and complete questionnaires about mood symptoms, and blood will be collected from a vein in your arm. You will also be given medication as a part of this study. During the study you will be monitored and asked about medication side effects. The clinical decision support tool will be used by the study personnel to collect information about you and your depressive symptoms. The tool will try to predict how you will respond to your antidepressant.
Key Information	Your depressive symptoms may improve from taking part in this study. There are also risks from taking part in this study such as, pain and bruising related to the blood draw, emotional upset from answering questions about your mood, and possible side effects from the medication. You will be required to pay, via insurance or out of pocket, for the medication. All other costs are covered by the study. You will be paid $100 for completing participation in the study. You do not have to participate in this study to receive care for your depressive symptoms.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** William V. Bobo, MD, MPH Phone: (904) 953-7286 **Study Team Contact Mayo Jacksonville:** Carolyne Stevens or Adrienne Graham (904) 953-3937 or (904) 953-3726 **Principal Investigator Rochester:** Paul Croarkin, DO, MS Phone: (507) 293-2557 **Study Team Contact Mayo Rochester:** Monica Walton (507) 422-0689 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224 Mayo Clinic Rochester 200 First Street SW Generose 2A Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681

If you have questions about …	You can contact …
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

A description of this research study will be available on *https://www.mayo.edu/research/clinical-trials*. This website will not include information that can identify you. You can search this website at any time.

Why are you being asked to take part in this research study?

You're being asked to take part in this research study because you are currently depressed and have major depressive disorder. About 120 people will take part in this research study. All participants in this research study will take part at Mayo Clinic Florida or Mayo Clinic Rochester.

Why is this research study being done?

The purpose of this research is to test whether a computer program (called a clinical decision support tool) can help clinicians predict how a patient with depression will respond to antidepressant medication. The antidepressants in this study are FDA approved for the treatment of depression.

Information you should know

Who is Funding the Study?

The Mayo Clinic Center for Individualized Medicine is funding this study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in the active study portion for up to 10 weeks. You will be contacted again at 24 weeks for a follow-up phone call. If applicable, a 2-8 week drug taper may occur before beginning the active portion of the study.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

The Screening Visit:
This visit will take about 60 minutes. We will do some assessments to see if you are eligible to take part in this research study. The study physician will review the results of these assessments. If you are not eligible for this study, the study physician will tell you why.

At this visit we will ask you:

- Questions about your medical history and about your emotional health
- To complete questionnaires about your symptoms of depression called the QIDS-SR
- To complete a questionnaire about exposure to childhood experiences (ACE)
- Assess the quality of social support (MOSS)
- Provide a urine sample for a pregnancy test and drug test (if recently done clinically the study clinician will determine if the testing needs to be completed again).
- Provide height and weight to determine your body mass index (BMI)
- Provide 54ml of blood collected from a vein in your arm.

We hope that you will answer all of the questions, but you can skip any questions you don't want to answer.

If you are eligible and agree to participate in this research study you will then be given a prescription for either an SSRI (such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, or sertraline) or SNRI antidepressant (such as duloxetine or venlafaxine). If you are currently taking an antidepressant medication you will be asked to taper off that medication before you start the new medication. The study physician will provide instructions for the taper. These antidepressants are all FDA approved for treating major depression in adults.

The blood will be used for genetic information, which may be used to help predict your response to study antidepressants. This genetic information, called "DNA," is what you inherit from your parents. Your blood samples will be stored at a Mayo Clinic lab. This will be the only time that blood is drawn in this research study. However, if the blood sample required for the genetic studies is missing or found to be inadequate for analysis, you will be contacted to determine if you would be willing to return for an additional blood draw.

Week 2 telephone visit:
Study personnel will contact you by phone 14 days after starting the medication to check on how the medication is working for you. They will ask you questions about your depressive symptoms to complete the QIDS-CR and HAMD17 assessments and about any side-effects you may be experiencing to complete the FIBSER and ASEC assessments.

Week 4 visit:
Four weeks after your first visit, you will again meet with a study doctor and a research study coordinator. At this visit we will take your vitals and ask you to complete questionnaires about depressive symptoms, side effects, and your experience:

- QIDS-SR
- PETS
- FIBSER
- ASEC

We will also ask you questions about your depressive symptoms to complete the QIDS-CR, HAMD17, and C-SSRS assessments. Also at this visit, the medication dose may be increased as determined by the study doctor. The new information about your depressive symptoms will be entered into the clinical decision support tool. The clinical decision support tool will try to predict how you will respond to your antidepressant at your final study visit (which will happen eight weeks after your first visit). This prediction that the clinical decision support tool makes at your 4 week visit will be compared to how you actually do at your 8 week visit.

Week 8 visit:
Eight weeks after your first visit, you will again meet with a study doctor and a research study coordinator. At this visit we will take your vitals and ask you to complete questionnaires about depressive symptoms, side effects, and your experience:

- QIDS-SR
- PETS
- FIBSER
- ASEC

We will ask you questions about your depressive symptoms to complete the QIDS-CR, HAMD17, and C-SSRS assessments. During this final visit, the study physician will discuss further treatment options based on your response of the medication through the evaluations completed.

24 week phone call:
Twenty-four weeks after your first visit, study personnel will contact you by phone to check on how you are doing after the study is completed. They will ask you questions about your depressive symptoms to complete the QIDS-CR and HAMD17 assessments and about any side-effects you may be experiencing to complete the FIBSER and ASEC assessments. They will also answer any questions you have about the study that you may have thought of after it ended.

If you withdraw from the study you will be asked to complete an early termination visit which will take about 15-20 minutes.

We are asking for your permission to re-contact you in the future, in the event that we need additional samples, or to obtain information about your satisfaction and experience related to this study. Researchers will contact a small subset of participants to complete an evaluation questionnaire. You have a say in whether you are contacted in the future. If you agree to be re-contacted, your future involvement would be entirely optional. Not everyone who gives permission will be re-contacted and you can decline to be re-contacted if you wish. You can still participate in this research study if you decline to be re-contacted.

I permit Mayo to contact me in the future:

Please mark one box:

☐ Yes ☐ No Please initial here:_____ Date:_____

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Possible side effects of SSRIs and SNRIs are:

- lightheadedness
- fainting
- dizziness
- confusion
- hallucinations
- rhinitis
- dry mouth
- tremor
- nausea
- decreased libido
- fatigue
- nausea
- diarrhea (or constipation)
- sleep disorders (somnolence)
- agitation
- restlessness
- anxiety
- sweating
- ejaculation disorder (primarily ejaculatory delay)
- erectile dysfunction
- impotence

NOTE: Some SNRIs like venlafaxine can cause an increase in blood pressure.

In people under the age of 24 years, there may be a risk of suicidal thinking. This has been reported as an uncommon side effect. As part of this research, suicide risk is assessed very carefully both before and after starting study antidepressants. If you start having thoughts of suicide, or these thoughts increase, you should contact your study doctor right away.

There are certain other medications that can interact with the study drug that should not be taken, such as St. John's Wort. You should notify your study doctor before taking other prescription drugs.

While you are taking part in this study, you are at risk for these side effects. You should talk to the researcher and/or your medical doctor about these side effects. There also may be other side effects that are not known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Many side effects go away shortly after the antidepressant medication is stopped, but in some cases side effects can be serious, long lasting, or may never go away.

If you are sexually active and able to become pregnant or able to father a child, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

You must use birth control for the entire study.

The effect of antidepressant medication on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

If you or your partner miss a period, or think you or your partner might be pregnant during the study, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your permission to collect information about the outcome of your pregnancy and your newborn.

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing will include whole genome sequencing (mapping your entire genetic code). Whole genome sequencing generates a large amount of information that may provide, now or in the future, important insights into your health as well as the health of your biologic family members.

If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if your mood or symptoms significantly worsen as determined of study physician
- if you are female and become pregnant
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

All of the antidepressants used in this study are FDA approved for treating major depression in adults. Therefore, participating in this study may improve your depression. However, it is also possible that this study may not make your health better.

What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your condition. Your other choices may include visiting with your regular physician to receive treatment for your depressive illness. SSRI and SNRI antidepressants are available by prescription without participating in this study. You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- *All study visits*
- *Urine drug test*
- *Urine pregnancy test*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- *Antidepressant medication*

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

If you are able to complete the entire study, you will receive to $100. You will receive part of this money if you leave the study early, an amount based on how many visits are completed. If the blood sample required for the genetic studies is missing or found to be inadequate, and you return for an additional blood draw, you will receive an additional $20.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Your sample of blood will be kept at Mayo for use in future studies. This future will involve collecting and testing your DNA. This future research could also involve turning white blood cells into what is called a cell line. The white blood cells in this sample are a type of primary cell. When primary cells are collected, they can no longer divide and make copies of themselves. There is a process that can change primary cells into a cell line. A cell line is a group of cells that are exactly the same and have the ability to divide and make more exact copies forever if kept in the right conditions. Turning your blood cells into a cell line would allow the researchers in this study to use your cells for future research without having to ask you to come back to give another blood sample. You have the right to say whether the researchers in this study can change your cells into a cell line. You can still take part in this study if you decide that you do not want your cells changed to a cell line.

I permit Mayo to transform my blood sample into a cell line:

Please mark one box:

☐ Yes ☐ No Please initial here: _____ Date: _____

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future

research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of_____ mental health at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

If you want your sample destroyed at any time, write to:

William V. Bobo, M.D., M.P.H.
Department of Psychiatry and Psychology
Davis 4N
4500 San Pablo Road
Jacksonville, FL 32224

Mayo has the right to end storage of the sample without telling you. If you move please send your new address to Mayo Clinic Rochester, Section of Registration, 200 First Street Southwest, Rochester, Minnesota 55905.

If you agree to give your sample, it will be the property of Mayo and may be used for research by Dr. Bobo and other staff at Mayo Clinic.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

The Clinical Decision Tool will only be accessed by authorized study team members who have been provided an access code and password. All collected research data is coded with the unique study ID and kept electronically on secured servers. Inputs into the Clinical Decision Tool will use the same unique study ID given to each enrolled participant. No protected health information will be entered into the Clinical Decision tool.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature