Official Study Title: Implementation of Harmonized Depression Outcome Measures in a Health System to Support Patient-Centered Outcomes Research

Document Title: Baystate Health Consent Form_Version_1 _20Sep2020

NCT Number: NCT04235712

Document Date: 9/20/2020

Baystate Health

RESEARCH CONSENT FORM

Title of Project *(define any abbreviations)*: Implementation of Harmonized Depression Outcome Measures in a Health System to Support Patient-Centered Outcomes Research

Study Sponsor: Agency for Healthcare Research and Quality

Principal Investigator: Dr. Barry Sarvet and Dr. Jessica Wozniak

Study Participant: _____

KEY INFORMATION

You are being invited to participate in a research study because you because *you have been diagnosed with major depression or dysthymia (persistent mild depression).*

If you have questions or do not understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The purpose of this research is to determine whether it is useful to provide information on a core set of depression outcome measures to health care providers. Your health care provider can use this information when discussing your depression treatment and progress over time. At the end of the study, health care providers will complete a brief survey about how often they used the information and whether it was helpful.

- **If you join this research,** you will be required to allow the research team to access your medical record. You will not be required to complete any additional scales, assessments, or procedures outside of your standard clinical treatment. Participation in this research will not affect your clinical treatment in any way.

You may not want to be in this study if you are uncomfortable with:

- Sharing your private information with researchers

Risks:

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

The most important risks or discomforts that you may expect from taking part in this research include psychological stress. If you feel uncomfortable at any time you will not be required to complete the Patient Health Questinonaire-9 (PHQ-9).

There may also be risks that we do not know yet.

Benefits:

We cannot promise any benefits if you take part in this research.

Possible benefits to others include improved understanding of depression treatment and outcomes, which can lead to more effective treatment options in the future.

Alternatives:

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research. Your treatment will not be affected by your decision to participate.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH?

We are talking to you about this research study because *you have been diagnosed with major depression or dysthymia (persistent mild depression).*

This form gives you important information. Please read it carefully and ask questions before you make a decision. Ask your study doctor or the study team to explain any words or information in this form that you do not understand. You may want to talk about this study with your family, your friends, and your other health care providers. Please take your time. You should not sign this form until all of your questions are answered.

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care, any legal rights, or any benefits that you are otherwise entitled to.

The study doctor will tell you about new information or changes in the study that may affect your willingness to continue in the study.

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research is to determine whether it is useful to provide information on a core set of depression outcome measures to health care providers. Health care providers will see the outcome measures within the electronic medical record system. Information from your medical record and from a questionnaire that you complete on a regular basis (the Patient Health Questionnaire-9 [PHQ-9]) will be combined to calculate the outcome measures and show your health care provider whether your depression symptoms are improving or worsening over time. Your health care provider can use this information when discussing your depression treatment and progress over time. At the end of the study, health care providers will complete a brief survey about how often they used the information and whether it was helpful.

HOW IS THIS RESEARCH STUDY BEING FUNDED?

Some research studies are paid for by the center the study is being conducted in and some by an outside grant or sponsor. This research study is being funded by the Agency for Healthcare Research and Quality.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study will enroll up to *50* people from a total of *five* practices here at Baystate Medical Center.

HOW LONG WILL YOU BE IN THIS STUDY?

Your participation in this research study is expected to last for *12 months*.

CAN I STOP TAKING PART IN THIS STUDY?

Tell the study doctor if you have decided to or are thinking about leaving the study. You may be asked to have some follow up care or evaluations. The study team may ask your permission to continue to contact you or follow your medical information to see how you are doing. Information that has already been collected about you will remain part of the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available

- If you do not follow the study rules
- If the study is stopped by the sponsor
    - You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

WHAT WILL HAPPEN IN THIS STUDY?

If you decide to take part in this research study, a software application will combine results from the questionnaire given to you by your health care provider (the PHQ-9) with data from your medical record. The application will show your depression treatment outcomes and changes over time to your health care provider. You will not be required to complete any additional scales, assessments, or procedures as part of this study. Participation in this research will not affect your clinical treatment in any way.

WHAT RISKS OR PROBLEMS COULD YOU HAVE BY BEING IN THIS STUDY?

Risks of Survey Questions: The questionnaire includes some questions that may be sensitive or personal.

The greatest risk that you could experience is psychological stress from completing the questionnaire. If you do begin to experience psychological stress related to your participation in this study, we can end your enrollment at any time. There is the risk of a loss of confidentiality of your research-related information.

WE WILL DO THE FOLLOWING TO DECREASE THE RISKS OF THIS STUDY:

Loss of confidentiality: We will take steps to protect the confidentiality of your research information. These steps are described in more detail later in this form.

WILL YOU BENEFIT FROM BEING IN THIS STUDY?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include improved understanding of depression treatment and outcomes, which can lead to more effective treatment options in the future.

WHAT OPTIONS OTHER THAN THIS STUDY ARE AVAILABLE TO YOU?

You do not have to join this study to get treatment or supportive care. Other options include:

- Receiving the same treatment, but not as part of a research study.

Before you decide about being in this study, you should discuss these other options with your doctor.

WILL BEING IN THE STUDY COST YOU ANYTHING?

You will not be charged for participating in this study. Clinical services provided during a research study are either research-related or related to usual medical care. Research-related services are not the responsibility of you or your insurance.

Usual medical care costs include those services that are considered medically necessary to manage your condition. The costs of usual medical care will be the responsibility of you or your insurance and may include deductibles and co-payments. Although unusual, some insurance companies will not pay for usual medical care if you are participating in a research study. This study will be looking at data that is already being collected as a part of your routine care.

WILL YOU RECEIVE ANY PAYMENTS OR GIFTS FOR PARTICIPATING?

No. You will not receive any payments or gifts for participating in this study.

HOW WILL YOUR PRIVACY AND INFORMATION ABOUT YOU BE PROTECTED?

We will protect your privacy as a participant in this research study and the confidentiality of your research information. *Y*our study visits will take place in a private exam room in your provider's offices. Your study file will be stored in a secure area in the provider's office.

INFORMATION ABOUT THE PRIVACY OF PROTECTED HEALTH INFORMATION

Baystate Health has rules in place to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form and may include information from your medical record if needed for the study. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Baystate may see or give out your information. These include people who review the research studies, their staff, administrative personnel, or other Baystate staff.

The fact that you are taking part in this study and information from procedures (such as lab tests) that are done for the research may become part of your medical record.

If we publish information from this research study or use it for teaching, your name will not be used.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

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

People outside of Baystate may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), organizations that accredit hospitals and research programs, study monitors, other hospitals in the study, and companies that sponsor the study.

We may be required by law to report some information (for example; certain infectious diseases, suspected abuse) to a state agency for public health or safety reasons.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside of Baystate who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by contacting the Principal Investigator of this study. The Principal Investigator can be reached at:

Dr. Barry Sarvet
759 Chestnut Street, Springfield, MA 01199
(413) 794-4235

If you send a letter, please be sure to include the study name and your contact information.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

You can ask to see your research records but sometimes that can only happen after the research is completed. If you would like to see your research records please discuss this with your study doctor or a member of the research team.

WHO DO YOU CONTACT IF YOU HAVE STUDY QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact: *Dr. Barry Sarvet*. If you experience a complication or injury that you believe may be related to this study, please contact: Dr. Barry Sarvet at *(413) 794-4235 or Dr. Jessica Wozniak at (413)794-6630*. After hours, please call (413) 794-3222 and the assistant will page Dr. Sarvet.

If you would like to discuss your rights as a research participant, or wish to speak with someone not directly involved in the study, please contact the Baystate Institutional Review Board (IRB) at (413) 794-4356.

STATEMENT OF VOLUNTARY CONSENT

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study and authorizing the use of my information for the research.

Participant's Name (Print): _____

Signature: _____ Date: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves (for example, due to a medical condition or language barrier). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

Witness's Name (Print): _____

Signature: _____ Date: _____

Reason for Use of Witness: _____

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated