UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: A Systems-Level Intervention for Rural Adults with Depression: Phase 3 (HUM00176192)

Company or agency sponsoring the study: Health and Human Services, Department of National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Addie Weaver, Ph.D., School of Social Work, University of Michigan
Study Coordinator: Caroline Landry, M.S.W., School of Social Work, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for depression/low mood. This research will test a new technology based program designed to help people with low mood to feel better. Please note that Christian images and message may be used during this program. Your health-related information will be collected for this research study.

This study involves a process called randomization. This means that the program you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include inconvenient lengths of

interviews or possible emotional discomfort. All medications prescribed by your outside physician should continue to be taken according to your physician's advice. The study team will not be following this aspect of your care. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by increasing access to care and improving the lives of rural residents with low mood and depression. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 6 months.

You can decide not to be in this study. Alternatives to joining this study include asking the researchers or doctor about other options you may have.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Depression is a common mental health problem that affects up to 20% of Americans throughout their lifetime. When depression is not treated, it has a negative impact on people's lives. People in rural areas and people in urban areas have similar rates of depression, but people in rural areas experience substantial challenges accessing care. These challenges relate to the lack of available mental health providers in rural America, travel burden, high costs, and stigma. This study is being done to test a new technology-based program, Raising Our Spirits Together (ROST), which is designed to help people with low mood and depression in rural Michigan feel better.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adults who are above the ages of 18, are currently living in Hillsdale, Lenawee, Jackson, Calhoun or Branch County, screen positive for at least mild depressive symptoms (PHQ-9>=5) and are currently not receiving regular cognitive behavioral therapy (more than one time per month).

3.2 How many people are expected to take part in this study?

Our goal is to recruit and enroll 128 people to participate in the study; 64 people in each arm (control vs intervention).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

BASELINE ASSESSMENT: If you agree to be in the study, you will be asked to complete a baseline assessment to determine your eligibility (based on the full exclusion/inclusion criteria) for participation. This means, after you complete the baseline assessment, there is the possibility of being deemed ineligible. This visit will take place either remotely (using university sponsored and issued software- for example; Zoom) or in-person at Trinity Lutheran Church in Hillsdale, Michigan or First Presbyterian Church in Jonesville, Michigan. This assessment will include both an interview and self-report surveys and it will be administered either in-person, on paper, or remotely, entered directly into REDCap (a secure web-based database through the University of Michigan). The baseline assessment will be completed in one session, unless there is an unexpected circumstance, then the baseline assessment will be completed on another date. The interview includes questions about your mood and other mental health conditions. The self-report survey includes questions about mental health, health, and thoughts about your healthcare. This visit should take approximately two hours and will be scheduled at a time that is good for you. If you qualify for the study, you will be randomly assigned (50/50 chance) to either the ROST group or the control group.

ROST PROGRAM: If you are randomly assigned to join the ROST group, you will attend eight small group sessions (approximately six people) focused on teaching tools and skills to improve overall mood. ROST group sessions will be held either remotely (using university sponsored and issued software – for

example Zoom) or in person in a private meeting room at either Trinity Lutheran or Jonesville First Presbyterian Church. The group sessions will be held once a week, and each session will last about 90 minutes. The group sessions will be led by pastors using a computer-based program. In addition, you will receive a workbook for completing in group activities. After each of the eight group sessions, you will be asked to compete a short survey. These surveys will ask about your low mood or depression, the bond you felt with their group leader and fellow group members, as well as your treatment satisfaction.

The ROST program is based on Cognitive-Behavioral Therapy (CBT), which is a research supported depression treatment. All group sessions will be audio-recorded. If you choose to participate in this study, you must also agree to be audio-recorded.

CONTROL GROUP: If you are randomized to the control group, you will receive workbooks providing psychoeducation, local resource guides, and referrals.

If you and your healthcare provider believe that you need to change your mental health treatment, you will need to inform the study team. You may need to withdraw from this study. After the eight-week treatment period, you are free to start or change any mental health treatments that seem appropriate.

POST TREATMENT AND FOLLOW UP ASSESSMENTS: You will be asked to complete two additional assessments that each will take up to two hours to complete. These assessments will be either remotely (using university sponsored and issued software- for example; Zoom) or in-person done at Trinity Lutheran Church in Hillsdale, Michigan or First Presbyterian Church in Jonesville, MI. They will be completed either in-person or remotely on paper or entered directly into REDCap (a secure web-based database through the University of Michigan). After completing the ROST program, you will be contacted to schedule the post treatment assessment, and another assessment three months later. Both of these assessments are very similar to the baseline assessment.

QUALTITATIVE INTERVIEW: If you are randomized to the ROST group, you are invited to participate in a qualitative interview at your post-treatment assessment. This interview is one-on-one with a research staff member, and it will last approximately 60 minutes.

4.2 How much of my time will be needed to take part in this study?

ASSESSMENTS: There are three assessments; the baseline assessment will last about 2.5 hours, and the post treatment and follow up assessments will last about 1.5-2 hours each.

PROGRAM: The ROST program has eight weekly sessions. Each session will last approximately two hours. For those randomized to the ROST program and you choose to participate in the qualitative interview that will last approximately 1.5 hours.

4.3 When will my participation in the study be over?

Participants should complete participation of the study within 6 months of beginning. The entire study is projected to last two (2) years.

4.4 What will happen with my information used in this study?

- With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

- Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.
- Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- The length of the interviews and sessions may be inconvenient to some participants.
- During the study we ask personal questions including questions about possible emotional difficulties. There is a chance these questions could make you feel uncomfortable, you could become upset, or even reveal to us that you feel suicidal.
- Possible emotional discomfort participating in some of the interviews or sessions.
- Possible symptom worsening due to delaying mental health treatment during active intervention period.
- Privacy of information provided to research staff.

The researchers will try to minimize these risks by:

- Making all possible efforts to conveniently fit interviews and/or sessions into your schedule.
- During the interview process, if it is revealed to us that you are experiencing suicidal feelings or thoughts, the research associate will contact Dr. Joseph Himle, PhD, LMSW, Ms. Katherine Check Tucker, LMSW, or Dr. Weaver, PhD, to help facilitate the necessary next steps. A team member will help decide the appropriate steps to assist you in finding help.
- Being sensitive to your feelings at all times. You may also choose not to answer questions you don't feel comfortable answering.
- We have listed below the ways we will protect your information. However, if we learn that you or someone else is in serious danger of harm (such as in case of child abuse or neglect) we may make disclosures to protect you and/or the other persons.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy. As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study; however, you may reduce your depressive symptoms. Participants in the study have the opportunity to learn more about depression and its treatment. However, others may benefit from the knowledge gained from this study. By incorporating rural residents' perspectives and treatment preferences, reducing practical barriers such as transportation and cost, and collaborating with informal providers within the de facto mental health system, we have the potential to make a large impact by increasing access to care and ultimately improving the lives of rural residents with depression.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is entirely voluntary; you have the option to not participate. If you choose not to participate, there is no penalty, and it will not affect any medical care you might later seek from the University of Michigan. Ask the researchers or your doctor about other options you may have.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No. You are under no pressure to participate in this study, and you may withdraw at any time by stating your wish to do so. If you choose to withdraw, the researchers will ask for the reasons you are leaving to record in the study record.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.

- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There will be no charge to you or your insurance company for participating. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

The maximum you can be paid for participating in this study is $175:

- Assessments/Interviews – up to $75 total ($25 for the baseline assessment/interview, $25 for the post-treatment assessment/interview, and $25 for the three-month follow up assessment interview). Participants will receive payment within two weeks of each interview.
- Attendance for group sessions - If you are randomized to the ROST group, you can receive up to $80 ($10 for each session attended).
- Qualitative Interview – If you are randomized to the ROST group, you can receive $20 for participating in a qualitative interview at the post-treatment assessment/interview.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them. No one will profit or financially benefit from the study results. The researchers are expected to publish the results of this research in medical journals, so that the results are available to the public.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

To help protect your privacy, all assessments will be completed either remotely or in private offices within the churches. Your research records will be kept confidential, meaning the pastors, your healthcare providers, and anyone other than our research team will NOT have access to your research records. We shall not allow anyone to see your record, other than people who have a right to see it. Under law, we must report if you disclose any cases of suicide, homicide, or sexual/child abuse or neglect.

All research records will be linked to you through a study ID. All research records will be kept in a private room at the researchers' home in a locked box when available or in a locked office at the University of Michigan School of Social Work. Any and all identifying information will be kept separate from the research records in a locked, secure space, accessed only by research team. All data will be entered into a password protected and encrypted data software, and all electronic records will be stored on a

password protected computer on the University of Michigan's server.

All audio recordings will be uploaded to a secure server, and they will be deleted off of the recorders immediately. The audio recordings of the ROST group sessions will not be shared with people who are not on the study team. The audio recordings will be transcribed, and both the recordings and transcriptions will be uploaded to the secure server. The transcriptions of audio recordings that do not contain subject identifiers may be shared with the NIH and other researchers that are not a part of the study team. The audio recordings will not be shared with anyone that is not part of the study team.All information is kept on the server for five years after the study has ended. You will not be identified in any reports on this study.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.2 What protected information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, leave the study before it is finished.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted proper

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Addie Weaver, PhD
Mailing Address: 1080 S. University, Ann Arbor, MI 48109
Telephone: (734) 615-2122

Study Coordinator: Caroline Landry, MSW
Mailing Address: 1080 S. University, Ann Arbor, MI 48109
Telephone: (734) 763-7784
Email: ckeep@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording. If you do not agree to be recorded, you cannot take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name:
_____

Title: _____

Signature: _____