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Informed Consent

Study Title: Equity Using Interventions for Pain and Depression (EQUIPD) - Phase 1

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH
Equity Using Interventions for Pain and Depression (EQUIPD) – Phase 1
National Institutes of Health
Protocol # 16571

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about the study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in the study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to help primary care patients who identify as Black learn about different ways to manage chronic pain and symptoms of depression that do not involve medications. This study aims to help address inequalities in pain and depression treatment for Black patients.

We are asking you if you want to be in this study because you identify as Black, are currently receiving primary care services at Eskenazi Health that include management of chronic pain and have symptoms of depression.

The study is being conducted by Dr. Marianne Matthias at the Indiana University School of Medicine. It is funded by the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART AND WHAT WILL HAPPEN DURING THE STUDY?
If you agree to participate, you will be one of up to 40 Eskenazi primary care patients taking part in this study. You will be asked to do the following things over about 6 months:

Baseline Assessment:
- If you are eligible, (you qualify to be in the study), you will be asked some demographic information questions and your contact information will be collected.
- You will then complete additional surveys asking about anxiety and depression, your pain (duration, intensity, interference, self-care), your confidence while doing activities, substance use, your physical functioning and sleep, how you communicate and interact with healthcare providers, and how you feel you are treated by healthcare providers.
- We think this assessment conducted on the phone, will last about 1 hour.
- You will then be randomly assigned (like flipping a coin) into one of two groups: intervention group or control group.

<u>If you are randomized to the intervention group,</u>
- You will be paired with a trained coach who will meet with you one-on-one by phone for a series of four sessions over a period of about three months. You will also continue to receive your normal health care.
    - Sessions with your coach will focus on talking about ways to manage your pain that do not involve medication as well as strategies for discussing these options with your doctor.
    - During these sessions, you will complete and review with your coach a “decision aid” which is a tool to help patients make choices among management options. The “decision aid” will be sent to you before your coaching sessions start.
    - Each session with your coach may last up to about 45 minutes. Sessions may be audio-recorded with your permission for quality assurance purposes.

- After the third session with your coach, you will meet with your primary care provider for your next scheduled visit. We will ask you to bring the decision aid that you have worked on with your coach to this primary care appointment, so that you can talk about the non-medication options you and your coach discussed.
- Your fourth coaching session will occur after your primary care appointment.

- **Three- and Six-Month assessments:**
  - After the 4th coaching session (about 3 months after you started the study) and again about 3 months later (about 6 months after you started the study), you will be asked to complete a one-on-one interview with a study team member in which you will complete most of the same surveys you completed for the baseline assessment about your pain, confidence, about your mental health, substance use, physical functioning, sleep, and how you communicate and interact with healthcare providers. If you were assigned to the intervention group, you will be asked about your satisfaction with coaching during the 3-month assessment. These assessments may be completed online or on paper (sent by mail and postage paid envelope provided).

Each of these assessments will last about 45 minutes and will be completed over the phone with a study team member.

<u>If you are randomized to the control group,</u>

- After the baseline assessment, you will continue to receive your normal health care. About 3 months and 6 months after the baseline assessment, you will be asked to complete a one-one one interview with a study team member in which you will complete most of the same surveys you completed for the baseline assessment about your pain, about your mental health, and how you communicate with healthcare providers. These assessments may be completed online or on paper (sent by mail and postage paid envelope provided).

- After you complete your last study survey, at the 6-month assessment, you will be given a copy of the "decision aid" which is a tool to help patients make choices among pain management options. You will also be offered the opportunity to have a brief session (approximately 20 minutes) with a member of the research team to walk you through the decision aid and answer any questions you may have.

You will not receive the results of any of these surveys because they are being done only for research purposes.

During any of the research visits described above, if you disclose thoughts of suicide, the study staff will ask you additional questions. A research team member, who is a clinical psychologist, may reach out to you and we may contact your provider at Eskenazi Health to assist you. You may be provided with 24-hour phone numbers for people who are having thoughts of suicide and encouraged to call to seek assistance.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

The potential risks for participating in this study are minimal and may include:

- Risk of being uncomfortable, nervous, or anxious while participating in the study (i.e., while talking with study staff, completing surveys, interviews, or coaching sessions). At any point, you may refuse to answer any question that research staff (including your coach) may ask that makes you uncomfortable. You can also choose to take a break or stop the interview or coaching session at any time if you are feeling any of these things, just let the research staff know.
- There is also a risk that someone outside the study team could get access to your research or medical information from this study. More information about how we protect your information to reduce this risk is below.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

If you are randomized to the intervention group, possible benefits of participation include:

- Receiving support from a coach who may help you understand non-medication options that are available to you to help manage your pain.
- By learning about new pain management options, you may find additional ways that will help you to manage your pain.
- Developing skills to help you get the most out of your pain management treatment, in part by being able to better communicate with your provider and being more involved in your treatment decisions.

Even if you do not personally benefit from taking part in this study, we hope to learn things that will help other people in the future.

HOW WILL INFORMATION BE USED?
The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. These purposes include: (1) making sure you meet the criteria to be in this study, and (2) verifying your medical history to ensure it matches information reported on your surveys or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Medical history of chronic pain, depression
- Scheduled doctor's appointments
- Medical history of severe medical conditions
- Prior participation in a pain study
- Medications used to treat pain

If you agree to participate, you authorize the following to disclose your medical record information:

- Eskenazi Health, including Eskenazi Health Physicians

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US government or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be disclosed if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. If you tell a member of the research team about an intent to harm yourself or others, we are required to tell appropriate Eskenazi staff and/or community authorities.

Only members of the research team will have access to the audio recordings stored on a secure server. Audio recordings will be destroyed at the soonest opportunity allowed by federal and institutional regulations surrounding human subjects research.

A description of this clinical trial will be available on **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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, or documents that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WILL I BE PAID FOR PARTICIPATION?
You will be paid $30 for the baseline assessment and $30 each for the 3- and 6-month visits (possible total of $90) in the form of gift cards. Payment is for completion of surveys over the phone; there is not a separate payment for coaching sessions.

WILL IT COST ME ANYTHING TO PARITICIPATE?
There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher, Marianne Matthias, at 317-278-3154 / mmatthia@iu.edu or the project manager, Jennifer Garabrant, at 317-278-2510 / jwilkers@iu.edu. For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT WANT TO PARTICIPATE OR CHANGE MY MIND?
After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Eskenazi Health or Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please simply let a member of the research team know. If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Marianne Matthias, 1101 W 10th St, ATTN: RF-237, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

We would like to communicate with you about this study by text message and/or email. We might use text or email to remind you about or schedule upcoming assessments or coaching sessions, send information about online surveys, or relay study information.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, we need your permission to do so.

Do you authorize the researchers to send emails to you related to this research study?

☐ Yes, please provide your email address for this communication

☐ No

Do you authorize the researchers to send text messages to you related to this research study?

☐ Yes, please provide your phone number for this communication

☐ No

You can still participate in this study even if you do not want us to contact you by text or email.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of the above, I verbally agree to participate in this research study. I will be given a copy of this document to keep for my records.