Cover Page

Informed Consent

Study Title: Goal Elicitation, Treatment Prioritization, & Electronically-Practiced Discussion – Pilot Study (Aims 2 and 3)

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH
Goal Elicitation, Treatment Prioritization, & Electronically-Practiced Discussion –
Pilot Study (Aims 2 and 3)

ABOUT THIS RESEARCH
You are invited to participate in a research study looking at how mental health coaching sessions and practice with a Virtual Provider program (a program that uses a computer avatar to interact with patients on different topics) may help improve patient communication with psychiatric providers (mental health medication prescribers). You were selected as a possible participant because you are currently receiving outpatient care at the Sandra Eskenazi Mental Health Center (SEMHC).

This study is being conducted by Michelle Salyers, PhD, and Adam Hirsh, PhD, at the IUPUI Department of Psychology. It is funded by a grant from the National Institute of Mental Health (NIMH).

This consent and Authorization form will give you information about the study to help you decide if you want to participate. 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 see if mental health coaching sessions and using the Virtual Provider program help improve communication between clients and their mental health medication prescribers. We also hope to learn more about what people like or don't like about the coaching sessions and using the Virtual Provider program.

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 clients at the SEMHC taking part in this study. If you agree to be in the study, you will be asked to do the following things over about the next 3-4 months:

Research Visit 1:
- During this in-person visit, eligibility to participate will be reviewed and you will be asked to complete short questionnaires to collect demographic and contact information. You will be asked about your computer and internet use.
- If you qualify for the study, you will be asked to complete some forms with questions about talking to doctors, how you manage your mental health, and how you are feeling about yourself.
- We will attempt to audio record your appointment with your mental health medication prescriber if he or she has also agreed to participate.
- We think this visit will last about 1 hour and 15 minutes, not including the time for your regular appointment with your prescriber.
- After this visit, research staff will collect your mental health diagnoses from your medical record.

Weekly Coaching Sessions:
- You will be assigned to a coach who is a member of the study team. There will be 4 sessions in which you will meet one-on-one with your coach (about one time per week for 4 weeks). The first one will last about 1 hour and will take place in-person at the SEMHC after Research Visit 1. Ideally, this will occur right after your appointment with your prescriber, but it can be scheduled for a different time if needed. In certain circumstances, this coaching session could be done by phone or video call (e.g., Zoom, FaceTime).
- The rest of the coaching sessions (3) will last up to about 1 hour each and can be done in-person, by phone, or video call.
- Each coaching session will be audio recorded with your permission.
- You will be given an optional worksheet to complete at each session. You will not be asked to return the worksheets.
- During the first session, your coach will provide an introduction about what you will work on together and will ask questions to get to know you better. During all the sessions, you and your coach will talk about your goals,

treatment preferences, and how to use the Virtual Provider program to practice talking with your prescriber. More information about the Virtual Provider program is given below. Your coach will ask you to try out using different parts of the Virtual Provider program at the end of each coaching session. You will talk about your experience using the program with your coach.

Virtual Provider Program:

- During the coaching sessions, you will be given instructions about how to access the online Virtual Provider program. This is not a real-life provider. This is a computer program designed to help you practice some of the skills that you and your coach will talk about. The program has a computer-generated person on the screen and the person will ask questions. There will be responses on the screen for you to choose from. No information that could identify you is entered into the program. This program is not part of your clinical treatment, and your real-life provider will not see any information from the Virtual Provider program unless you decide to share that information yourself.
- Your coach will show you how to use the program during your coaching sessions. You can use this program as little or as much as you would like outside of the coaching sessions and research visits. The coaches or other research team members will help you if you have trouble using the program.

Research Visit 2:

- If your prescriber is also participating in the study, with your permission, we will audio record your next appointment with your prescriber after the coaching sessions have been completed. We think this will be within about 3 months after Research Visit 1.
- During an in-person visit after the coaching sessions are completed, you will be asked to complete the same forms you completed during Research Visit 1. These forms ask questions about talking to doctors, how you manage your mental health, and how you are feeling about yourself.
- A member of the research team will complete an interview with you about your experience with the coaching sessions and the Virtual Provider program. We are interested in what you found most and least helpful. This interview will be audio recorded.
- The completion of forms and the interview about your experience may take place on a different day than your next appointment with your prescriber, but still within about 3 months of Research Visit 1.
- This visit will last about 1 hour and 15 minutes, not including the time for your regular appointment with your prescriber.

During Research Visits 1 or 2 or during the weekly coaching sessions, if you disclose thoughts of suicide, the study staff may immediately contact your mental health provider or another mental health provider at SEMHC to assist you. If this happens while you are not at the study site, the study staff will connect you to the Eskenazi Health crisis line.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

The potential risks for participating in this study are minimal. Potential risks may include feeling uncomfortable, nervous, or anxious while talking with study staff (including your coach), practicing with the Virtual Provider program, completing surveys and interviews, or practicing new skills you may learn with your real-life provider. There is also a risk of loss of confidentiality. You can let study staff know at any time if you do not want to answer a question asked for any reason. You can also choose not to answer questions on the Virtual Provider program. You can choose not to practice newly learned skills with your real-life provider.

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

Potential benefits are that you may experience improved communication skills and improved outcomes by having individual coaching and practice sessions to help develop those skills. While there is no guarantee you will receive direct benefits from participating, we hope that results from this study may help others in the future.

HOW WILL MY MEDICAL RECORD 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. This may include gathering information about your mental health diagnoses to include in the research data.

The information released and used for this research will include: your mental health diagnoses, date(s) of diagnoses, and type of provider who made the diagnoses.

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

- Eskenazi Health

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 or foreign governments 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)

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. If you tell a member of the research team about an intent to harm yourself or others, we are required to tell appropriate staff at the SEMHC and/or community authorities.

No information which could identify you will be shared in publications, study reports, or databases in which results may be stored. Data logs from your use of the Virtual Provider program will not contain any identifiable information. Only members of the research team will have access to the audio recordings and any identifiable characteristics will be removed from transcripts. Audio recordings will be destroyed at the soonest opportunity allowed by federal and institutional regulations surrounding human subjects research. All audio recordings collected during the study will be stored on a secure server that only approved research personnel can access and only used for approved research purposes.

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.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigators and their research associates, the Indiana University Institutional Review Board or its designees, NIMH, and any state or federal agencies who may need to access your research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP) and National Institutes of Health (NIH).

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the NIH. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research: (1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); (2) if you consent to the disclosure, including for your medical treatment; (3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects; (4) for the purpose of auditing or program evaluation by the government or funding agency. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
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.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the NIH. NDA is a large database where deidentified study data from many NIMH studies is stored and managed. Information which could identify you will be removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health more quickly than before.

During and after the study, the study team will send this deidentified data to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The data provided to NDA may help researchers around the world learn more about mental health and how to help others. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA. You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher. If you decide after today that you do not want your data to be added to the NDA, contact a member of the research team, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study team cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available online at http://nda.nih.gov.

WILL I BE PAID FOR PARTICIPATION? / WILL IT COST ANYTHING TO PARITICIPATE?
You will be paid $25 for Research Visit 1 and $25 for Research Visit 2 ($50 if you complete both). Payment is for completion of forms and the interview; there is not a separate payment for recording your appointment with your prescriber. You will be paid $10 for your travel time for each coaching session you attend in person ($40 total if all coaching sessions are in person). If you agree to be in the study, but then found to not be eligible to participate, you will be paid $5. There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?
This is a low-risk study and the odds of a physical injury occurring are small. However, in the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher, Michelle Salyers, at 317-274-2904 / mpsalyer@iupui.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.

TAKING PART IN THIS STUDY IS VOLUNTARY / CAN WITHDRAW AT ANY TIME

Participating in this study is completely voluntary. You may choose not to take part or to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with SEMHC or IUPUI. If you decide to participate in this study, you can change your mind and decide to leave the study at any time. If you decide to withdraw, please simply let a member of the research team know. If you withdraw from the study, you may request to have the information that has already been collected from your participation in the study removed from the overall study data set. If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Michelle Salyers, 402 N. Blackford St., Rm. 126, Indianapolis, IN 46202. If you withdraw your authorization, your participation in this study may end. 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.

PARTICIPANT'S CONSENT AND AUTHORIZATION

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

Participant's Printed Name: _____

Participant's Signature: _____**Date**: _____

Participant's Address: _____

_____

(Required for Authorization)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____**Date**: _____