Consent to Participate in Research

Title of Research Study: ***Self Management and Care Collaboration for Perinatal Depression***

Principal Investigator: [redacted]

Supported By: This research is supported by the National Institute of Mental Health (#T32MH115882) and in part by the National Institutes of Health's National Center for Advancing Translational Sciences (#UL1TR001422).

Conflict of Interest Disclosure:

If your doctor is also the person responsible for this research study, please note that they are interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to understand your experience using COMPASS services and how we can design technologies to improve those services.
- You will be asked to complete one virtual interview/focus group session.
- We expect that you will be in this research study for about one hour (the length of the interview/focus group session).
- The primary potential risk of participation is that questions about your use of mental health services might lead to feelings of discomfort, stress, anxiety, or other similar symptoms.
- There are no direct benefits to you, but a main benefit of being in this study is that the information you provide will inform the design of future technologies to improve COMPASS services for people like yourself.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are at least 18 years old, are fluent in English, and have been referred to the COMPASS program.

How many people will be in this study?

We expect about 50 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You do not have to answer any question you do not want to answer.

What happens if I say, "Yes, I want to be in this research"?

A research team member will ask you some questions about your previous experiences with the COMPASS program at Northwestern. You will then be shown examples of technologies that COMPASS might offer to its patients, and will be asked to provide your feedback on these examples. You will also be asked to share other ideas you might have to improve COMPASS services. This should take about one hour.

Our session will be audio and video recorded for data analysis. To participate in this study, you must agree to audio and video recording.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include sharing information that will help the research team create useful technologies to improve COMPASS services for future people like yourself.

Is there any way being in this study could be bad for me?

Because we are asking about your experience with mental health services, some possible risks include feelings of discomfort, stress, anxiety, and elevation or recurrence of depressive symptoms.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship or healthcare services with Northwestern University/Northwestern Memorial Healthcare or result in any loss of benefits to which you are otherwise entitled.

You can leave the research at any time and it will not be held against you.

If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used.

How will the researchers protect my information?

All study data will be stored electronically in HIPAA compliant and password protected locations. Each participant is given a unique number that the research team will use when analyzing and reporting study data. Any personally identifying information (for example, names of people or hospitals) will be removed, blurred, or masked before it is shared outside of the research team. Demographic information will be reported in aggregate in publications or presentations of this study data.

If you are participating in a focus group

Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.
- We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.
- We may be required by law to report to appropriate NU authorities any information you provide to me that indicates sexual misconduct, including sexual assault, sexual exploitation, dating violence, domestic violence, stalking, and sexual harassment. Therefore, we cannot promise you complete confidentiality of any information you share with me about experiences of sexual misconduct.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

The researchers may contact you again as part of this research study.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for future research without your additional informed consent. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data.

We would like to share your identifiable information with other researchers for future research studies. We will ask for your consent to do so at the end of this form. You can be in this current research study without agreeing to future research use of your identifiable information.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

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

As part of this study, you may be asked to participate in up to 3 interviews/focus groups, with the possibility of earning up to $75 total ($25 for each completed interview/focus group).

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator, [redacted]

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may use blurred and masked screenshots of my video recordings in scholarly presentations or publications when it might serve to

help others understand the research. I may be identifiable as part of this activity.

_____ _____ The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies.

_____ _____ The researcher may keep my contact information in order to inform me that the findings from this study have been published.

Do you wish to participate? Record participant's response: Yes No

Participant name or study ID number (if not recording participant's name on the consent form to minimize risks to the participant, record study ID number instead):_____

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date