# Consent Cover Sheet

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**Study Title:** Implementing to Sustain: Determining the Minimum Necessary Intervention to Maintain a Postpartum Depression Prevention Program (ROSE) in Clinics Providing Prenatal Services to Low-Income Women

**Co-Investigators:** Caron Zlotnick, PhD; Rebecca Weinberg, PhD; Ellen Poleshuck, PhD; Tiffany Moore-Simas, MD, MPH, Med; Laura Carravallah, MD; Shannon Wiltsey-Stirman, PhD

**NCT Number:** NCT03267563

**Study Sponsor/Funding Source:** National Institute of Health

**IRB Submission Number (if applicable):** 17-1052

**Date:** 01/30/2023

**CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT**

Michigan State University (MSU), Brown University/Butler Hospital, and University of Rochester

# Implementing ROSE in prenatal clinics: Clinical and organizational representatives

**The project.** You are invited to participate in a research project. The goal of the research project is to find out what implementation supports are needed to help organizations providing prenatal services to low-income women implement and sustain ROSE. ROSE is a postpartum depression prevention intervention delivered in 4 sessions during pregnancy and one phone call after release. The intervention is easy to learn and can be delivered by nurses, social workers, case managers or other health care providers. It has been shown to reduce incidence of post-partum depression among low income women by 50%. Your organization was invited to participate in the study because it provides prenatal services to pregnant women on public assistance. Your organization has agreed to participate in the study. You were nominated as someone who might be able to provide clinical or organizational data to over the course of the study. However, whether or not you want to do this is 100% up to you and won't have any effects on your employment (see below).

To help you decide if you would like to be a part of this research study, we will tell you about the risks and benefits. This consent form gives you information about the research study. Once you understand, you will be asked if you wish to participate. If you do, you will be asked to sign this form.

**What will be done.** If you decide to participate, you will be one of your organization's representatives to complete study assessments and provide data to the study. Study procedures will occur over about 30 months (2.5 years).

ASSESSMENT PROCEDURES

Study assessments will occur at 0, 3, 6, 9, 12, 15, 18, 24, and 30 months**.** Each clinic or agency will identify two people: the person most involved in ROSE (1) clinical, and (2) operational (e.g., billing, scheduling) functions. At each time point:

1. You will complete an online survey (it can also be mailed on paper, if that is easier). Survey data will include (a) descriptive information on the clinic or agency (size, # of pregnant and low-income patients/clients seen per year); and (b) other questionnaires about ROSE and about the clinic or agency (e.g., communication, attitudes toward postpartum depression, organizational context). Either you or the other person at your clinic or agency will also be asked to provide: (c) dates ROSE sessions were provided and number of patients/clients enrolled in and completing ROSE; (d) quarterly rates of postpartum depression at the clinic or agency (if this data is available); and (e) clinic or agency costs for study training and delivery of ROSE (including staff salaries, fringe, overheads) for one pay period. We can also administer surveys by phone, if helpful. Study staff will provide assistance with other aspects of study data collection (e.g., cost, postpartum depression rates each quarter) if needed. These surveys may take up to 2 hours to complete.
2. At some time points, you will also complete ~45 minute qualitative interviews by phone. These interviews will be audio-recorded. Audio-recordings will be kept confidential; only study staff will have access to them.
3. If your clinic or agency allows we will reimburse you $100 for completing the surveys and qualitative interview (if chosen for a qualitative interview at that assessment), plus an extra $40 for the person reporting the aggregated ROSE participation and postpartum depression rate data each quarter.

**Benefits.** Your organization will receive free training in ROSE, free ROSE manuals and supportive materials, and free support with practical issues such as how to maintain ROSE at your organization, be reimbursed for services associated with ROSE, integrate ROSE into your existing clinical services, etc. Clinic or agency patients/clients may have the opportunity to receive an evidence-based postpartum depression prevention intervention (ROSE) that will be available at the clinic or agency as a result of the study.

There is also the more general benefit to the public in learning whether and how the implementation of an effective intervention to reduce postpartum depression can be sustained in community settings. Untreated postpartum depression has severe and lasting consequences for mother and child, including maternal increased risk for suicide, compromised functional status, and adverse infant developmental outcomes.

**Risks or Discomforts.** The risks of this study are minimal. The risk of participation in the study involves the possibility of breach of confidentiality due to the audio recording of the interviews.

**Confidentiality.** Your organization director has agreed that information you tell us in interviews and surveys will be kept confidential. Materials will be identified by an assigned provider ID number (which will not involve personal identifying features such as date of birth, etc.). No individual-level data will be shared with employers, with two exceptions:

(1) Feedback about administrative or operational challenges to ROSE implementation will be given to the operational/administrative study respondent at some clinics or agencies.
(2) Feedback about clinic/agency-as-a-whole performance (e.g., postpartum depression rates each quarter, etc.) will be provided only to staff from that clinic or agency.

Any published reports or presentations will only include data that is aggregated in a manner that does not allow the identities of providers, administrators, or agencies.

Electronic study data will be stored on MSU and Brown University's secure research servers; paper data will be stored in locked filing cabinets in locked offices. It may be stored indefinitely. Only the researchers will have access to the data. The MSU Human Research Protection Program and the funding agency (NIMH) may have access to the data in an audit, but they will also keep the data confidential. De-identified data will also be placed into the appropriate National Institutes of Health data repository and provided to other qualified researchers.

**Protection of organization employee participants**. To protect your confidentiality, your organization director has agreed that s/he will not request or require access to the data that are collected. Your employer will know that you are participating in the study as a respondent, but your study responses will remain confidential. Your employer has agreed that you can choose or decline study participation at any time without any effect on their employment status, employment record, eligibility for training opportunities, etc.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;

- individuals at the Michigan State University, Butler Hospital, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA

**Decision to Participate and Right to Quit at Any Time.** You are free to decide whether or not to participate in this study. You are also free to quit the study at any time by telling the researchers. Research information collected up to the time that you quit will remain as part of the study data.

**Questions.** Please ask any questions you may have now. If you have any questions please contact the ROSES Study Team at ROSES.Study@msu.edu.

**Who to Call.** If you ever have concerns or questions about this study, such as scientific issues, how to do any part of it, or to withdraw from the study, please contact Dr. Jennifer Johnson of MSU at 810-600-5669 or Dr. Caron Zlotnick of Brown University and Butler Hospital at 401-474-4332. Dr. Johnson may be reached by email at Jennifer.Johnson@hc.msu.edu or use regular mail to reach her at: 200 East 1st St, Room 366, Flint, MI 48503. Dr. Zlotnick may be reached by email at CZlotnick@butler.org or use regular mail to reach her at 345 Blackstone Blvd. Providence, RI 02906. If you have any questions or concerns about your role and rights as a research participant, if you would like to get more information or offer input, or if you would like to make a complaint, you may contact the MSU Human Research Protections Program at 517-355-2180, FAX 517-432-4503, or e-mail irb@msu.edu, or regular mail at: 4000 Collins Rd, Suite 136, Lansing, MI 48910. If you like, your comments can be anonymous.

**Authorization**: **BY SIGNING BELOW, YOU AGREE TO PARTICIPATE IN THE STUDY.** I will participate in this study.

_____ ___ Name (please print) _____

Date

_____ _____ __

E-Signature

*(consent form will be e-signed, with an option for the signee to print out/save a pdf version for themselves)*

**CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT**

Michigan State University (MSU), Brown University/Butler Hospital, and University of Rochester

# Implementing ROSE in prenatal clinics and agencies: ROSE providers

**The project.** Your organization is invited to participate in a research project. The goal of the research project is to find out what implementation supports are needed to help organizations providing prenatal services to low-income women implement and sustain ROSE. ROSE is a postpartum depression prevention intervention delivered in 4 sessions during pregnancy and one phone call after release. The intervention is easy to learn and can be delivered by nurses, social workers, case managers or other health care providers. It has been shown to reduce incidence of post-partum depression among low-income women by 50%. Your organization is being invited to participate because you provide prenatal services to pregnant women on public assistance. Participation is voluntary.

To help you decide if your organization would like to be a part of this research study, we will tell you about the risks and benefits. This consent form gives you information about the research study. Once you understand, you will be asked if you wish to participate. If you do, you will be asked to sign this form.

**What will be done.** If you decide to participate, study procedures will occur over about 30 months (2.5 years) and will include both training and assessment procedures.

TRAINING PROCEDURES

1. Initial ROSE training and support. This will includes: (a) A 1 ½ -hour brief clinical and operational overview of ROSE, with problem-solving and discussion to help determine who should be at the next set of meetings. At this meeting, study staff will meet with key clinical and operational staff (i.e., individuals who have a solid working knowledge of how best to implement ROSE at your organization from a clinical and/or administrative perspective). These individuals will be selected by your organization's director/leaders. (b) As a ROSE provider you will receive a 3 ½ -hour training on how to conduct ROSE. (c) A 30-60 min operational training to discuss administrative needs (such as payor reimbursement, identification and referral procedures, identification of suitable providers). All of these meetings will take place by videoconference (we will provide a webcam if needed), and all will be recorded so that the study can characterize training procedures. Your organization will have access to your training recordings to train any new staff.
2. First level additional support. Some clinics or agencies will also receive additional support at various times during the study. This first-level additional support will include two telephone meetings (one clinical and one operational) each quarter for coaching and feedback, as well as the option to participate in quarterly phone meetings with study staff and other implementing organizations for problem-solving and support. These additional support calls would also be recorded.
3. Second level additional support. Some clinics or agencies will also receive second-level support at various times during the study. This support will include monthly coaching and feedback calls, and a monthly invitation to participate in phone meetings with study staff and other implementing organizations. It will also include one in-person clinical and administrative training meeting. The additional training would also be recorded. There is no reimbursement for study training procedures.

ASSESSMENT PROCEDURES

Providers delivering ROSE will:

1. Complete 3-minute (4-5 yes/no questions) checklists after each ROSE session. We will collect these at each time point.
2. Keep good ROSE attendance records for clinic or agency use (e.g., # patients/clients who agree to come to ROSE, # who attend at least 1 session, # of attend 3 of 5 sessions).
3. Once your clinic/agency has reached about 12months participation in the study, you may be selected for a 1-hour phone interview to ask about ROSE delivery. There is no compensation for these interviews.

**Benefits.** Participating organizations will receive free training in ROSE, free ROSE manuals and supportive materials, and free support with practical issues such as how to maintain ROSE at your organization, be reimbursed for services associated with ROSE, integrate ROSE into your existing clinical services, etc. Clinic or agency patients/clients may have the opportunity to receive an evidence-based postpartum depression prevention intervention (ROSE) that will be available at the clinic or agency as a result of the study.

There is also the more general benefit to the public in learning whether and how the implementation of an effective intervention to reduce postpartum depression can be sustained in community settings. Untreated postpartum depression has severe and lasting consequences for mother and child, including maternal increased risk for suicide, compromised functional status, and adverse infant developmental outcomes.

**Risks or Discomforts.** The risks of this study are minimal. The risk of participation in the study involves the possibility of breach of confidentiality due to the audio recording of the interviews.

**Confidentiality.** Your organization director has agreed that information you tell us in interviews and surveys will be kept confidential. Materials will be identified by an assigned provider ID number (which will not involve personal identifying features such as date of birth, etc.). No individual-level data will be shared with employers, and any published reports or presentations will only include data that is aggregated in a manner that does not allow the identities of providers, administrators, or agencies. Feedback about individual provider performance will be shared with that provider only, or with the provider's written permission, in a group.

Electronic study data will be stored on MSU and Brown University's secure research servers; paper data will be stored in locked filing cabinets in locked offices. It may be stored indefinitely. Only the researchers will have access to the data. The MSU Human Research Protection Program and the funding agency (NIMH) may have access to the data in an audit, but they will also keep the data confidential. De-identified data will also be placed into the appropriate National Institutes of Health data repository and provided to other qualified researchers.

**Protection of organization employee participants**. To protect organization employees' confidentiality, your organizations director has agreed that s/he will not request or require access to the data that are collected. Study data (such as ROSE performance) will remain confidential and will not be made available to employers.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the Michigan State University, Butler Hospital, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA

**Decision to Participate and Right to Quit at Any Time.** You are free to decide whether or not to participate in this study. You are also free to quit the study at any time by telling the researchers. This will not affect your employment status, employment record, or your eligibility for other training opportunities, promotions, etc. Research information collected up to the time that you quit will remain as part of the study data.

**Questions.** Please ask any questions you may have now. If you have any questions please contact the ROSES Study Team at ROSES.Study@msu.edu.

**Who to Call.** If you ever have concerns or questions about this study, such as scientific issues, how to do any part of it, or to withdraw from the study, please contact Dr. Jennifer Johnson of MSU at 810-600-5669 or Dr. Caron Zlotnick of Brown University and Butler Hospital at 401-474-4332. Dr. Johnson may be reached by email at Jennifer.Johnson@hc.msu.edu or use regular mail to reach her at: 200 East 1st St, Room 366, Flint, MI 48503. Dr. Zlotnick may be reached by email at CZlotnick@butler.org or use regular mail to reach her at 345 Blackstone Blvd. Providence, RI 02906. If you have any questions or concerns about your role and rights as a research participant, if you would like to get more information or offer input, or if you would like to make a complaint, you may contact the MSU Human Research Protections Program at 517-355-2180, FAX 517-432-4503, or e-mail irb@msu.edu, or regular mail at: 4000 Collins Rd, Suite 136, Lansing, MI 48910. If you like, your comments can be anonymous.

**Authorization**: **BY SIGNING BELOW, YOU AGREE TO ALLOW YOUR ORGANIZATION TO PARTICIPATE IN THE STUDY.** I will participate in this study.

_____ _____ Name (please print)

Date

_____

E-Signature

*(consent form will be e-signed, with an option for the signee to print out/save a pdf version for themselves)*