TITLE: Testing an Arts-based Program to Reduce Nurse Stigma Towards Perinatal Substance Use

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

Study title: ArtSpective™ Study
Principal Investigator: Clayton Shuman, PhD, MSN, RN; University of Michigan, School of Nursing, Ann Arbor, MI.
Co-Investigator(s): Carol Boyd, PhD, MSN, RN, FIAAN, FAAN; University of Michigan, School of Nursing, Ann Arbor, MI; Michael Rubyan, PhD, MPH; University of Michigan, School of Public Health, Ann Arbor, MI; Deanna Isaman, PhD; University of Michigan, School of Nursing, Ann Arbor, MI
Study Coordinators: Mikayla Morgan, BSN, RN, CCRN; University of Michigan, School of Nursing, Ann Arbor, MI
Study Sponsor: National Institute of Health, National Institute on Drug Abuse, RDA055067A

You are invited to take part in a research study that is interested in the feasibility of a clinical-education intervention. This form contains information that will help you decide whether to join the study.

1. KEY INFORMATION

Things you should know:

- The purpose of the study is to evaluate the feasibility of a digital educational intervention about perinatal substance use.
- If you choose to participate, you will complete the online educational module. You will have one month to complete the module. You may complete the module early in the month, or you may complete it later in the month. You will also complete 1-2 follow up surveys over the course of 2 months. This will take approximately 15 minutes in total.
- You may be randomly selected to participate in a voluntary interview instead of completing a follow up survey. Interviews will be scheduled based on your availability and last no longer than 30 minutes.
- Risks or discomforts from this research include possible breach of confidentiality, but we have identified ways to reduce this risk (described below).
- A potential benefit of being in this study is you will receive education on perinatal substance use and a certificate of completion.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of the study is to evaluate the feasibility of a digital educational intervention about perinatal substance use.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? Registered Nurses who meet the following criteria:

- $\geq$ 18 years of age.
- Can read and understand English.
- Employed by a hospital participating in this study.
- Work in a maternal and/or newborn unit (e.g., labor, postpartum, LDRP, NICU, pediatrics, newborn nursery).
- Licensed as a registered nurse.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- Two hospitals are participating in this study. Your hospital is helping us recruit participants. If your hospital is selected to complete the educational program first:
    - You will be asked to access the web-based educational program, create a profile, and complete a brief survey which also collects some demographic information. This will take about 5 minutes and is embedded in the module.
    - You do not have to answer all questions, you may choose to skip questions that you do not wish to answer.
    - You will then complete a web-based educational module about perinatal substance use. This will take approximately 30-minutes, and you can complete it at your own pace. After the module, you will be asked to complete second brief survey.
    - At one and two months after completing the module, you will be sent follow up surveys that will take about 5 minutes to complete.
    - You may be randomly selected to participate in a 30-minute interview instead of completing a second follow up survey.
- If your hospital is selected to receive the educational program second:
    - You will be asked to complete a web-based survey that should take about 5 minutes to complete.
    - Approximately one month later, you will be invited to complete the educational program. You will be asked to access the web-based educational program, create a profile, and complete a brief survey which also collects some demographic information. This will take about 5 minutes and is embedded in the module.
    - You do not have to answer all questions, you may choose to skip questions that you do not wish to answer.
    - You will then complete a web-based educational module about perinatal substance use. This will take approximately 30-minutes, and you can complete it at your own pace. After the module, you will be asked to complete second brief survey.
    - About one month after you complete the program, you will asked to complete a follow up survey that should take about 5 minutes to complete.
- Participants from both sites can choose to end participation and withdraw from the study at any time.
- All survey responses and data collected in the educational module will be stored and analyzed confidentially.
- Only the researchers involved in this study will have access to the information that you provide.

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

The total amount of time you will spend in this study will range from 5 to 70 minutes depending on how much of the study you participate in (e.g., surveys, completion of the educational program, interview).

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?

Breach of confidentiality is a potential risk in all research that collects or maintains personally identifiable information.

The researchers will try to minimize these risks by maintaining confidentiality of the survey results (See Section 8 below). Only researchers will have access to the information that you provide in the survey. In the survey, you do not have to answer any questions you do not want to answer.

5.2 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, others may benefit from the knowledge gained from this study.

6. ENDING THE STUDY

6.1 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. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record but will be confidential. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive up to $60 as a cash gift card for your participation in the study. There are three phases in this study, and each phase offers a $20 incentive. If you complete one phase, you will receive $20. If you complete two phases, you will receive $40. Incentives will be sent to you after all three study phases end (approximately 3-4 months after you begin). The incentive is voluntary. To receive it, we must collect your name, email address, and mailing address. This information is used only to mail your incentive to you. We will not use this information for anything else and will delete it after sending your incentive.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Only the researchers involved in this study will have access to the information that you provide by completing the surveys.

8.1.1 Special Protections
This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- 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 and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. At the end of the study, we will delete files containing your name or other identifiable information.

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

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). 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.

9. CONTACT INFORMATION

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
- 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: Clayton Shuman
Email: clayshu@med.umich.edu
Phone: (734) 763-1302

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

The University of Michigan is an owner, and researchs working on this project (Drs. Clayton Shuman, Michael Rubyan, and Carol Boyd) are inventors of the ArtSpective intervention used in this study that is licensed to a company called ArtSpective LLC. The University of Michigan has a financial interest in ArtSpective LLC and Dr. Shuman is partial owner of ArtSpective LLC. This means that the University of Michigan, these researchers, and ArtSpective LLC might one day benefit financially from this study. 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.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By completing the research phases described in this document, you are agreeing to be in this study. Make sure you understand what the study is about before you begin. You may keep a copy of this document for your records. If you have any questions about the study before or after you begin participating, you can contact the study team using the information in Section 9 provided above.