University of North Carolina at Chapel Hill
Study Information Sheet: Pharmacy staff

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IRB Study # 22-2602
Title of Study: Addressing COVID-19 Vaccine Hesitancy in Rural Community Pharmacies Reducing Disparities Through an Implementation Science Approach
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CONCISE SUMMARY

The purpose of this research study is to see how we can best support pharmacists in having discussions with COVID-19 vaccine hesitant patients. Continuing education (CE) credit will be provided for completing the vaccine hesitancy training. Pharmacies can receive up to $2600 for completing all components of the study. Your participation is completely voluntary and you can choose to discontinue participation at any time. Participation will last between 6-12 months, depending on the study block to which your pharmacy is randomly assigned. Participation includes completing two trainings (~1.5 hours total), a technical assistance call (1 hour), and two surveys (~20 minutes each). Additionally, there will be one virtual visit of your pharmacy (30 minutes) and at least six virtual coaching sessions (30 minutes each). Some pharmacies will be selected to complete one ~60-minute interview. We do not anticipate major risks during the study; however, the greatest risks of this study include breach of confidentiality.

What are some general things about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

What is the purpose of this study?

The purpose of this research study is to see how we can best support pharmacists in having discussions with COVID-19 vaccine hesitant patients. You are being asked to participate because

you are a pharmacist or other staff member at a rural community pharmacy that provides COVID-19 vaccines and is part of RURAL-CP.

Are there any reasons you should not be in this study?
You should not be in this study if you are not at least 18 years of age, cannot read and speak English, have been employed by the pharmacy for less than 1 month, or your pharmacy does not stock the COVID-19 vaccine.

How many people will take part in this study?
Approximately 150 RURAL-CP pharmacy staff are being asked to participate.

How long will your part in this study last?
If you choose to be in this study, your participation will last between 6-12 months, depending on the study block to which your pharmacy is randomly assigned. Participation includes completing two trainings (~1.5 hours total), a one-hour technical assistance call, and two surveys (~20 minutes each). Additionally, there will be one virtual visit of your pharmacy (30 minutes) and at least six virtual coaching sessions (30 minutes each). Some pharmacies will be selected to complete a ~60-minute interview.

What will happen if you take part in the study?
There are two parts to your participation, each lasting 2-4 months.

- During the first few months, you will be asked to:
    - Complete a 30-minute online training about COVID-19 vaccine hesitancy counseling
    - Watch a webinar with up-to-date information about COVID-19 vaccinations
    - Complete a 1-hour technical assistance call
    - Deliver the vaccine hesitancy counseling intervention to 5 vaccine hesitant patients per month
    - Document some basic information about the results of the vaccine hesitancy counseling with at least 5 patients per month
    - Complete an online 20-minute interaction to enact 3 standardized patient scenarios each month
    - Complete an online survey about the feasibility, acceptability, and appropriateness of delivering the counseling intervention

- During the second few months, the following will take place:
    - A virtual site visit from a trained virtual "facilitator" or coach (30 minutes)
    - Weekly or bi-weekly calls where the coach will assist with any implementation challenges and provide feedback on the delivery of the counseling intervention
    - Deliver the vaccine hesitancy counseling intervention to 5 vaccine hesitant patients per month
    - Document some basic information about the results of the vaccine hesitancy counseling with at least 5 patients per month
    - Complete an online 20-minute interaction to enact 3 standardized patient scenarios each month

- Completing an online survey about the feasibility, acceptability, and appropriateness of delivering the counseling intervention

- After the two 2-4 month periods described above, your pharmacy may be selected for an interview. If selected, study staff will ask to interview you to assess the feasibility of the counseling intervention and ways it could be improved. The interview will last about 60 minutes. Study staff will provide more details about the interview and ask for your consent if your pharmacy is selected.

- ***Follow-up (select pharmacies, 2 months).*** During a follow-up period (which your pharmacy may or may not be involved in depending on when your pharmacy starts the study), you will be asked to:
  - Continue to document your delivery of the vaccine counseling intervention. Specifically, this includes the number of customers you offered the counseling to, the number who refused the vaccine and the number who agreed to be vaccinated.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. It is not expected that you will receive direct benefit from participating. However, you might learn lessons about talking with patients and implementing practices that could carry over to other activities in your pharmacy.

What are the possible risks or discomforts involved from being in this study?

We do not anticipate major risks during the study; however, the greatest risks of this study include breach of confidentiality. A breach of confidentiality may mean that the information you share on the surveys or in an interview could lead to discrimination or could possibly have a negative effect on your pharmacy if it were to become public. There is also a small chance you could be identified if your voice were to be recognized on the recordings. To prevent this, the surveys are completed on a secure, online survey application and stored on a secure server at UNC. The data are not viewable by anyone outside the study team once they are completed. All survey data and interviews will be kept completely confidential. The information on the recordings is secured in a password-protected database, will not be copied or written down elsewhere, and will be permanently deleted with the recording. You will not be identified in any written interview transcripts. Also, you or your pharmacy will not be identified in any report or publication of the research study or its results. You may also experience discomfort at times when discussing the intervention with the virtual coach. The feedback provided to you by the coach will be constructive in nature. You can withdraw or stop your participation at any time without penalty.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

You will be assigned an identification number when you agree to participate in the study. All data collected in this study will be recorded under the identification number, not your name. A list which links your name to the identification number will be kept in a password-protected file on a secure UNC server. Only study staff members will have access to the list that links names to identification numbers. We will not use de-identified data from this study in future research without additional consent.

Fidelity observation guide information will not be shared outside the study team. You will meet with simulated patients via Zoom but only the audio will be recorded (no video). Recordings are only sent to study personnel. The recording is temporary and will remain on a secure UNC server only until study staff are able to complete the pharmacist's evaluation on an observation guide. Then the recording will be permanently deleted. Recordings will not be transcribed. You can refuse to have a conversation recorded or stop a recording at any time. However, in order to participate in the study, you must agree to meet with a simulated patient once per month and have your interactions with the 3 patient scenarios they portray recorded.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researchers or the University of North Carolina-Chapel Hill. The investigators also have the right to stop your participation at any time. This could be because

you have failed to follow instructions or because the entire study has been stopped.

Will you receive anything for being in this study?
Individual pharmacy staff will receive continuing education (CE) credit for completing the vaccine hesitancy trainings. Pharmacies can receive up to $2600 for completing all components of the study. They will submit invoices for payment following the schedule for incentives described below:

- Completion of standard vaccine hesitancy trainings: $100
- Completion of a 1-hour technical assistance call: $100
- Documentation of 10-20 conversations with vaccine hesitant patients (5 per month) during the first 2-4 months: $800
- Completion of acceptability survey: $50
- Completion of virtual facilitation site visit: $100
- Documentation of 10-20 conversations with vaccine hesitant patients (5 per month) during the second 2-4 months: $800
- Completion of second acceptability survey: $50
- Completion of interview at end of study (select pharmacies): $100
- Completion of any requested follow-up (select pharmacies will continue to document 5 conversations with vaccine hesitant patients per month): $500

Will it cost you anything to be in this study?
There will be no monetary costs for being in this study.

Who is sponsoring this study?
This research is sponsored by the National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. In addition, Dr. Noel Brewer, a co-investigator on this study, has received money from Moderna Therapeutics and Novavax AB for work that is not part of this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports. Moderna Therapeutics and Novavax AB are vaccine manufacturers who may have an interest in the outcome of this study. If you would like more information, please ask the researchers listed on the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, or concerns, you should contact the study PIs listed on the first page of this document.

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

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement (verbal):

Do you have any questions?

Do you voluntarily agree to participate in this research study?