HR#19813

EAU CLAIRE COMMUNITY HEALTH CENTER &
THE MEDICAL UNIVERSITY OF SOUTH CAROLINA
INFORMED CONSENT AGREEMENT

Eau Claire Focus Group Study: Identifying Factors and Barriers to Vitamin D Outreach and Education through Focus Groups

A. **Purpose**: You are being asked to participate in this study because you previously participated in a vitamin D supplementation study at Eau Claire Cooperative Health Centers, Inc. (ECCHC), and you gave written consent for future contact beyond the study period. This new study involves your participation in a one-time focus group, which involves research to better understand why pregnant women take or do not take vitamin D that has been prescribed to them. Your opinion and experiences are important to the research team at ECCHC and the Medical University of South Carolina (MUSC) to better understand what factors influenced your behavior during the vitamin D pregnancy study. You are being asked to attend a one-time focus group of 2-hours' duration that will be held at a convenient location within the Columbia, SC area at a date and time that is convenient to you. A total of four such focus groups will be held in the Columbia, SC area.

   This study is supported by ECCHC, the Medical University of SC's College of Nursing Community Based Participatory Research Program, and Select Health of South Carolina. Investigators at ECCHC include Joyce Winkler, R.N., M.S., Gloria Warner, M.S., and Carolina Cook, M.D.; Kathy Stone at Select Health; and Dr. Carol Wagner, Professor of Pediatrics at the Medical University of South Carolina.

B. **Procedure**: If you agree to be in the study, the following things will happen:
   1. Your medical record will be reviewed to confirm your medical history during your most recent pregnancy.
   2. The investigator running the group will introduce the topic and provide some ground rules so that everyone is comfortable with the discussion.
   3. Following the overview of the focus group session, if you have not already done so, you will be asked to sign this written, informed consent form.
   4. You then will be asked to complete a questionnaire that will gather important information about what influenced your decision to participate in the prior vitamin D study, what factors influenced your decision to take the vitamin D tablets, and your overall feelings about how vitamin D affected your health during your pregnancy.
   5. After you complete the short questionnaire, you will be asked to join a total of 10 women including yourself in the focus group discussion where you will have the opportunity to discuss your views and attitudes with other women who also participated in the study. Four to five main questions will be posed to the group, and you will be asked to give your opinions. The information will be recorded with a digital

recorder (like a tape recorder) so that the person running the focus group can pay close attention to what is being said and help guide the discussion.

6. The recordings will be transcribed so that the information can be coded and summarized. Your answers will be linked with your information obtained about your during the earlier vitamin D supplementation study to better understand the factors that had affected your vitamin D intake. Once the information has been transcribed, the information will be transferred to a separate database without any personal identifiers. Once this process has been accomplished, the digital/audio recording of the focus group will be destroyed.
7. After the focus group has ended, you will be given a $50 gift card.

C. **Duration**: This study will take place on one scheduled date and time for a total time period of two hours. You will decide how much you are willing to talk, but we will ask what you think during the discussion.

D. **Possible Discomfort and/or Risks**:

1. Embarrassment: We will ask questions in an open manner so that you will not feel pressured to answer if you are uncomfortable. If you feel embarrassed or uncomfortable during the discussion, you may stop participating at any time.
2. The risk of your participation in this research study is breach or loss of confidentiality. There is a small possibility that your opinions about vitamin D could be linked with you; however, every measure to safeguard this information will be taken by the research team. Your answers on the questionnaire will be kept in a secure computer file listed only by the study number assigned to you during your participation in the earlier vitamin D study. The digital recording of the session or audio recording will be destroyed after transcription and any identifying information will be removed after the audio recordings are analyzed. The study team will follow the measures already in place during your participation in the earlier vitamin D research study.

E. **Privacy Statement:** Information that is obtained from these focus groups that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

F. **Benefits**: A potential benefit to participating in this focus group study is that you will meet other women like yourself and come to understand how you and others feel about taking a vitamin D supplement. You may also learn about some of the important health effects of vitamin D. There is a possibility that you may not benefit from participating in this study, but society may benefit in that we may better understand factors that influence a woman's decision to take vitamin D supplements.

G. **Alternatives**: There are no other alternatives for collecting this valuable information accurately, except asking people questions directly, recording, and transcribing the answers. If you choose not to participate in the focus group, it will not affect the care that you receive at Eau Claire Cooperative Health Center or your ability to participate in future research studies.

H. **Costs of Participation**: There are no costs to participation in this study.

I. **Compensation**: Childcare will be provided free of charge during the focus group session. Transportation will be provided for those who will need it. You will receive a $50 gift card at the end of the focus group session. In addition, you will be served snacks and beverages during the session.

J. **New Information**: Should new information become available during the course of this study, you will be informed of those findings by letter.

K. **Student Participation**: If you are a student, your participation or discontinuation in this study will not constitute an element of your academic performance nor will it be part of your academic record at this Institution.

L. **Employee Participation**: If you are an employee of ECCHC, MUSC or Select Health, your participation or discontinuance in the study will not constitute an element of your job performance or evaluation nor will it be part of your personnel record at any of these Institutions.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the nearest emergency room and tell the physician on call about your injury and that you are in a research study. Please ask your emergency room physician to consult with your study doctor regarding your treatment.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

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Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Carol Wagner at (843) 792-2112. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843)792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining Consent	Date	Signature of Participant	Date

Signature of Legal Guardian (if applicable)	Date