Informed Consent Cover Page

Official Title: Pregnancy and Contraception Education in Chronic Kidney Disease (PACE-CKD): A Pilot Study

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Decision support for reproductive health in women with CKD: A pilot study
HUM00233787 (*Also referred to as Pregnancy and Contraception Education in Chronic Kidney Disease, PACE-CKD)*

Principal Investigator: Andrea Oliverio, MD, MSc, Department of Internal Medicine—Nephrology, University of Michigan

GENERAL INFORMATION

We're conducting a study to learn more about how patients with chronic kidney disease like to use and receive educational materials about pregnancy and contraception (birth control). If you agree to be in this study, we will ask you to review an educational document about pregnancy, birth control, and kidney disease, discuss these materials with your nephrologist at an upcoming appointment, and answer a survey. We expect it to take about 15 minutes to review the materials yourself and 15 minutes to complete the survey. This does not include the time it takes for your nephrology appointment which can vary. We would like 60 people with chronic kidney disease to participate in the study. 30 participants will receive commonly available educational materials from a reputable kidney foundation, and 30 participants will receive more advanced materials that incorporate questions about your priorities and information developed to guide you and your nephrologist to discuss pregnancy and contraception. Assignment to the groups is randomized and you will not be able to choose which materials you receive.

If you choose to enroll in the study, the following study activities will take place at enrollment:
1. We will send you educational information about pregnancy, birth control, and kidney disease. This information will be a PDF document sent to your email. We ask you to read that information prior to your appointment with your nephrologist.

At your appointment with your nephrologist, the following study activities will take place:
1. We will provide you with a paper version of the materials you have previously read, which you may review with your nephrologist.
2. During your appointment your nephrologist may review the materials with you and answer any questions.
3. We will ask you complete a short survey about your experience using the materials, your experience about being counseled about pregnancy and birth control during your visit, your willingness use such materials in the future, and about your kidney disease diagnosis.

Reviewing the materials and answering the survey is voluntary. You don't have to answer it if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. It's possible that some of the questions may make you feel uncomfortable. If

a question makes you uncomfortable, you can just skip it and go to the next question. Choosing not to participate won't affect the medical care you might receive at the University of Michigan Health System.

After enrolling you will be assigned a random number, meaning your responses to the survey questions will be kept confidential. This data will be kept in a secure electronic file, which only the researchers will be able to access.

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

The benefits of this study are:

- You may receive information and participate in study measures that ultimately may help you become more informed, activated, and engaged in reproductive health planning and health care in general
- You may receive access to educational materials about pregnancy, birth control, and kidney disease that have been thoughtfully researched and developed
- Possible benefits to society include that this may benefit future patients who have kidney disease plan a pregnancy and choose a birth control option that is safe and fits their needs

Overall expected risks of participating in this study are minimal. However, possible risks include:

- Feeling uncomfortable or distressed reading or reviewing materials about pregnancy, birth control, and kidney disease
- Breach of confidentiality of medical records
- As with any research study, there may be additional risks that are unknown or unexpected

The researchers will try to minimize these risks by keeping all data from this study in locked cabinets and on password protected servers that only members of our study team will be able to access. You are free to skip any survey questions or study measures if you want. If you feel any discomfort or distress from the study materials, you can contact the principal investigator or the study coordinator listed below.

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 choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section "Contact Information" below.

Your collected information may be shared with National Institute of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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.

To thank you for taking part in our study, we'll send you a $20 gift card or check after you complete the study. The University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

A description of this clinical trial may be available on www.ClinicalTrials.gov. 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.

CERTIFICATE OF CONFIDENTIALITY

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

What is a Certificate of Confidentiality?

With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

When are the researchers allowed by the CoC policy to disclose my information?

• If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

• If you have consented to the disclosure, including for your medical treatment. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

• If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

When may the researchers disclose my research information for this study?

• If the NIH, the agency funding this research, requests information to audit or evaluate our procedures.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other information

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- The University of Michigan or a government agency may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, learn more about side effects, or analyze the results of the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

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

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Andrea Oliverio, MD, MSc Mailing Address: 3914 Taubman Center, 1500 E. Medical Center Dr. SPC5364, Ann Arbor, MI 48109 Telephone: 734-647-9342 Email: aoliv@med.umich.edu	Study Coordinator: Kelcie Brophy, BA Mailing Address: North Campus Research Complex, 2800 Plymouth Road, Bldg. 14, G016, Ann Arbor, MI 48109 2800 Telephone: 734-615-0531 Email: kelcieb@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
REDCAP:
By checking the box below you indicate your consent to participate in this study. Thank you!

Check the box to indicate your consent to participate in this research study

Please type your name:_____
Today's Date: _____