Official Title: The HOP-STEP (Healthy Outcomes in Pregnancy With SLE Through Education of Providers) Intervention: Improving Maternal Health in Women With Lupus Through Improved Pregnancy Prevention and Planning sIRB

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Form
M0345

Duke University Health System

Consent to Participate in a Research Study
ADULT
The HOP-STEP Intervention: Improving Maternal Health in Women with Lupus through Improved Pregnancy Prevention and Planning

KEY INFORMATION SUMMARY

This research study will assess whether the HOP-STEP* Intervention improves rheumatology providers' ability to discuss contraception and pregnancy planning with patients.

You are being asked to take part in this 12-month pilot study because you are a pediatric or adult rheumatology provider at the University of Chicago Medical Center (UCMC). If you agree to participate, you will be randomized into 1 of 2 different groups: half will use the HOP-STEP program and the rest will not. You will be asked to complete surveys and may be invited to an end-of-study interview to understand your experiences. There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality.

If you are interested in learning more about this study, please continue reading below, which may take 5 to 10 minutes to review.

*HOP-STEP stands for Healthy Outcomes in Pregnancy with SLE Through Educating Providers

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Dr. Cuoghi Edens will conduct the study. The study is funded by a grant from the National Institutes of Health. Portions of Dr. Edens and their research team's salaries will be paid by this grant.

Why is this study being done?
The purpose of this study is to improve the reproductive care patients receive in the rheumatology clinic by restructuring care with the HOP-STEP intervention.

We hope that equipping rheumatology providers with the HOP-STEP intervention will increase the frequency that women receive effective pregnancy prevention and planning care.

Up to 20 rheumatology providers at UCMC will take part in this trial.

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IRB NUMBER: Pro00112931
IRB REFERENCE DATE: 02/27/2025
IRB EXPIRATION DATE: 03/27/2026

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What is involved in the study?
If you agree to participate, you will:

- Be randomized to the study intervention group or standard of care control group.
- Complete online surveys at the beginning and end of the study that will include questions about your demographics and confidence in discussing contraception and pregnancy planning with your patients.
- If you are randomized to the intervention group, you will:
    - Receive intervention training in-person and/or virtually.
    - Complete online training surveys and interim surveys at one additional time point.
    - Implement the intervention with applicable patients for 12 months.

- You may also be invited to participate in in-depth interviews at the end of the study.

Data from your applicable patients (female patients between 18-44 years of age) will be collected and analyzed to see if and how the intervention was done as well as its impact. The data collection period will include 6 months prior to and 6 months after the 12-month study period.

How long will I be in this study?
Participation begins at consent when you will take the initial survey and will end with the close-out survey after the 12-month study period. If you are in the intervention group, you will also attend the training and implement of the intervention for 12 months. You may be invited to participate in an interview at the end of the study that will take about 60 minutes.

What are the risks of the study?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Interviews will be conducted by the study partner, Duke University, over secure teleconferencing (e.g., Zoom) and will be audio-recorded for future analysis. The audio-recordings will be destroyed after publication of the study's main findings. If you request that the interview is not recorded, the interviewer will take and maintain notes. These interviews will be transcribed for review by GMR Transcription services. The transcript will not include information, such as your name. Interview files

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will be stored on a Duke encrypted laptop, Box, and/or REDCap and will be available only to authorized study personnel as necessary to review the content of the sessions.

Are there benefits to taking part in the study?
If you agree to take part in this study, you may benefit from additional tools to ensure that women receive effective pregnancy prevention and planning care, resulting in better health outcomes for both mother and baby.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results may be shared with the National Institutes of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of the National Institute of Health
- the Chicago Institutional Review Board
- the Duke University Health System Institutional Review Board

The study results will be retained in your research record for at least six years after the study is completed. This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from. If the data will be stored in a

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controlled access repository include the following: As an additional layer of protection, the repository where the data will be stored requires researchers to formally apply to use the data and obtain approval prior to gaining access.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

> It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
>
> It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.
>
> It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study.

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Will I be paid to be in the study?
If you choose to participate in the post-study interview, you will receive a $100 check. You will not be paid for completing surveys, and intervention providers will not be paid for their intervention activities. To issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Research participant compensation made to a University of Chicago employee at any time during the calendar year will result in a 1099 (Miscellaneous Income) form being issued to the employee and a copy sent to the Internal Revenue Service (IRS) regardless of the total amount paid.

What if I want to withdraw from the study?
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be included in the data analysis.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at the University of Chicago. If you do decide to withdraw, we ask that you contact Dr. Edens in writing and let them know that you are withdrawing from the study. Her address is cedens@bsd.uchicago.edu.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

What if the Consent to Participation is updated?
If study changes occur that impact this Consent to Participation during your participation, you will be recontacted by the study team via phone, email, and/or in-person to review the changes and sign the updated consent.

Whom should I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, For questions about the study or a research-related injury, or if you have problems, concerns, questions or

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suggestions about the research, contact Dr. Cuoghi Edens at 773-702-6169 during regular business hours and after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 and/or the University of Chicago IRB Office at (773) 702-6505 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I understand that I will receive an electronic copy of this consent form after I submit my electronic signature".

Please select one:
❒ I have read the consent document and I wish to participate in the study.
❒ I have read the consent document and I DO NOT wish to participate in the study.