Document Coversheet

Study Title: Clinical Trial Protocol: Using Practice Facilitation and Operationalizing Referral Information Technology (UP FOR IT) to Increase DSMES Utilization

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/16/2024
NCT Number:	NCT05472142
IRB Number	75928
Coversheet created:	11/19/2024

Cover Letter for REDCap Survey

Hello,

You are receiving this email to invite you to complete a survey as part of the research study Using Practice Facilitation and Operationalizing Referral Information Technology (UP FOR IT) to Increase DSMES Utilization.

Mary Lacy, PhD from the University of Kentucky is leading the research study and you have been selected because of your participation in the (choose one: Diabetes Clinical Quality Improvement Learning Collaborative (DLC) led by the Kentucky Department for Public Health or UP FOR IT practice facilitation study led by Mary Lacy). The survey will ask about your participation in the collaborative and the impact it had on diabetes care in your practice.

Although you will not get personal benefit from taking part in this research study, your responses may help us understand more about increasing referrals to diabetes self-management education services for patients with diabetes in Kentucky.

If you do not want to be in the study, there are no other choices except not to take part in the study.

The survey/questionnaire will take about 15-20 minutes to complete.

There are no known risks to participating in this study.

Your response to the survey is anonymous which means no names, IP addresses, email addresses, or any other identifiable information will be collected with the survey responses. We will not know which responses are yours if you choose to participate.

We hope to receive completed questionnaires from about 15 people, so your answers are important to us. Of course, you have a choice about whether or not to complete the survey/questionnaire, but if you do participate, you are free to skip any questions or discontinue at any time. You will not be penalized in any way for skipping or discontinuing the survey.

Your responses will be collected via REDCap, a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.
To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

If you have questions about the study, please feel free to ask; my contact information is given below.

Thank you in advance for your assistance with this important project. To ensure your responses/opinions will be included, please complete the survey by _____.

Sincerely,
Mary Lacy, PhD
Department of Epidemiology, College of Public Health, University of Kentucky
PHONE: 859-562-1126
E-MAIL: mary.lacy@uky.edu

If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

Using Practice Facilitation and Operationalizing Referral Information Technology (UP FOR IT) to Increase DSMES Utilization

Phone Script for Learning Collaborative

Hello,

My name is _____ and I am contacting you from the University of Kentucky, on behalf of Mary Lacy, PhD.

Researchers at the University of Kentucky are inviting you to take part in a learning collaborative that is focused on improving referrals to diabetes self-management education services. The learning collaborative is a 9-month process by which healthcare organizations come together to learn from one another and from experts in the field and then undertake small tests of change to reach self-identified objectives within their own organization. The goals of this collaborative are to increase patients referrals to DSMES services by improving processes to identify patients who are eligible for DSMES, simplifying the referral mechanism, increasing knowledge of DSMES among providers, and increasing confidence and skills in referring eligible patients to DSMES.

If you agree to take part in this project, the research procedures will be conducted in a virtual or in-person setting, through synchronous meetings and webinars. If you agree to take part in this project, you will attend three learning collaborative meetings over the next 9 months; the first learning collaborative meeting with will be 2 half-day sessions and the second and third learning collaborative meetings will be one half-day session. You will also be asked to participate in data validation meetings virtually at the beginning of the Collaborative and to report monthly progress to our study team for the duration of the Collaborative plus an additional 6 months after the Collaborative ends (a total of 20 meetings, each 30 minutes in duration). The total amount of time you will be asked to volunteer for this study is 22 hours over the next 15 months.

You will not get any personal benefit from taking part in this study. However, we hope that your participation may help you feel more confident in referring patients to DSMES. Additionally, if the intervention results in increased patient referrals to DSMES services, DSMES is associated with better diabetes-related outcomes which would benefit patients. Some volunteers experience satisfaction from knowing they have contributed to research that may possibly benefit others in the future.

You will not receive any rewards or payment for taking part in the study.

There are no reasons why you would not qualify for this study.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

If you do not want to be in the study, there are no other choices except not to take part in the study.

In the course of this study, there are minimal risks related to the project. All identifiable information (e.g., your name, clinical record number, or date of birth) will be removed from the information or samples collected in this study. No identifying information will be used in any report or publication that is produced as part of this study; data will be presented only in the aggregate. No identifying variables for providers or clinic staff will be in the data sets other than a Unique Identifiable Number (UIN). When we write about or share the results from the study, we will write about the combined information.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. No identifying information will be used in any report or publication

that is produced as part of this study; data will be presented only in the aggregate. Everyone with access to the data will participate in all relevant trainings and will adhere to UKY's high standards for ensuring confidentially of all data. All study data will be stored in a password protected, cloud-based database only accessible to study team members.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/. 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 Web site at any time.

If you have questions about the study, please feel free to ask me now or contact the study principal investigator, Dr. Lacy whose contact information is given below.

Do you wish to participate in the study?

{If yes, document name and consent and proceed with call.}
{If no, find out the reason(s) and thank them for their time.}

Contact:
Mary Lacy, PhD
Department of Epidemiology, College of Public Health, University of Kentucky
PHONE: 859-562-1126
E-MAIL: mary.lacy@uky.edu

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