UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

mDAD: Mobile Diabetes Advice for Dads Exploratory Phase

3. Who do you call if you have questions about this research study?

Principal Investigator: Jennifer Elder, PhD, RN: 352-273-6318

Other research staff:

Anastasia Albanese-O'Neill, MSN, RN, CDE, 352-273-9297

Desmond Schatz, MD: 352-273-9270

Susan Schaffer, PhD, ARNP: 352-273-6366

4. Who is paying for this research study?

The University of Florida and the Jonas Foundation for Nursing Research

5. Why is this research study being done?

The purpose of this study is to better understand the educational needs and priorities of fathers and step-fathers of children and youth with type 1 diabetes. The co-investigator, Anastasia Albanese-O'Neill, is building a diabetes educational program that will be available online and via mobile phone/tablet. Your participation will provide information about the diabetes-specific educational needs of fathers and step fathers of children with diabetes, and will help the investigators improve the content and design of the proposed diabetes educational program, Mobile Diabetes Advice for Dads (mDAD).

You are being asked to be in this research study because you are the father or step-father of a child between the ages of 6-17 with type 1 diabetes.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

This study is not related to your clinical care and therefore does not affect your clinical care or your child's clinical care.

7. What will be done only because you are in this research study?

If you choose to participate in the study and sign the informed consent, Anastasia Albanese-O'Neill will contact you to schedule a time to meet that is convenient for you.

At the meeting, you will complete a short demographic (information about your lifestyle and general characteristics) survey about you and your family on a tablet device (like an iPAD) or a laptop computer that will be provided for you. This survey should take about five minutes to complete. To participate in this study, you must be at least 21 years of age and read and speak English, and be the father or step-father of a child ages 6 to 17 years of age with type 1 diabetes.

Next, Anastasia Albanese-O'Neill will interview you about you and your child with type 1 diabetes. This interview will take about 45 minutes to complete and it will be recorded. The interview will take place at a location convenient for you. The interview will include open-ended questions to learn more about your diabetes-specific educational needs. An example of questions that will be asked during this interview include, "Are there parts of diabetes management that you would like to learn more about? If so, what are they?" The recording of this interview will only be available to the research team. It will be downloaded onto encrypted computers in the research lab and copied onto paper. Once the interview has been transferred into written form, the voice recording will be erased.

After the interview, you will be asked to complete a survey to learn more about how you use the Internet and/or your mobile phone to get information about diabetes online. This survey will also ask you about your diabetes-specific educational needs. These needs may include information on how to administer an emergency dose of glucagon when your child has severely low blood glucose, information on how to adjust insulin doses after your child has exercised more than usual, or other educational needs you identify. This survey should take about 30 minutes to complete.

If you have any questions now or at any time during the study, please contact someone who is listed in question 3 of this form.

8. How long will you be in this research study?

The total time required to complete the two surveys and participate in the interview is approximately 1 ½ to 2 hours. The study is expected to last 3-6 months.

9. How many people are expected to take part in this research study?

40 participants

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

There are no anticipated physical risks to study subjects. There is a possibility you may feel discomfort when talking about your child's diabetes. A list of online resources will be provided for fathers/step-fathers who request it. If you choose to participate in the study, you will decide what information to share with researchers about your child with diabetes and you have the right to end your participation at any time.

Researchers will take appropriate steps to protect any information they collect from you. However, there is a slight risk that information about you could be revealed accidentally or inappropriately. Depending on the nature of the information, such a release could upset or embarrass you. Questions 17-21 in this form discuss what information about you will be collected, used, protected and shared.

Your participation in this study is confidential. The survey and interview questions do not ask for information that would identify who the responses belong to. You are being asked to share information to the extent that you are comfortable. All of your information will be kept confidential except for a situation in which there is a legal requirement to disclose (for example, abuse situations).

No identifying information will be requested at any time during the study. The study investigators and the research team will have access to data provided in this study that may be shared with a qualitative data analysis group. If, by chance, you disclose information that could potentially reveal your identity or your child's identity, this information will be removed prior to starting data analysis.

The results of this study will be presented to the co-investigator's (Anastasia Albanese-O'Neill's) doctoral committee at the University of Florida to satisfy requirements for obtaining the degree of Doctor of Philosophy in Nursing. Again, your identity will not be revealed in any presentation that results from this study.

Other possible risks to you may include:

Although unlikely, feelings of discomfort or anxiety may occur when talking about your child with type 1 diabetes.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit to you for participating in this study.

11b. How could others possibly benefit from this study?

A better understanding of the educational needs of fathers and step-fathers of children with type 1 diabetes may help health care providers meet these needs more effectively.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the investigators listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals. The online educational program will be available in the public domain.

12. What other choices do you have if you do not want to be in this study?

Participation in this study is totally voluntary. If you do not want to take part in this study, tell the principal investigator or study staff member and do not sign this consent form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, all information collected up to the time that you withdraw from the study will be used, but no further information will be collected.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

You are unable to complete the study documents due to scheduling difficulties or if you become ill and cannot participate.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No, there is not a cost to you for participating in this study.

15. Will you be paid for taking part in this study?

Upon completion of the two surveys and the in-person interview, you will receive a one-time $40 gift card to offset travel expenses, etc., associated with your participation.

If you are paid for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more, the University must report the amount you received to the Internal Revenue Service (IRS).

16. What if you are injured because of the study?

Please contact the Principal investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

Signature of Person Obtaining Consent | Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting | Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☒ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Jennifer Elder, PhD, RN, or her successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Jennifer Elder has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☒ The following will be **destroyed once the study is closed** (initial next to all that apply):
____ photograph(s) _____ video recording(s) __X__ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

Signature Date