The Children's Hospital *of* Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: MyDiaText: Texting the Way to Better Diabetes Control

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You or your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are a child 12-18 years old with type 1 diabetes diagnosed more than 1 year ago.

What is the purpose of this research study?

The purpose of this research study is to see if receiving educational text messages improves the diabetes control, self-management skills, and overall health of children with type 1 diabetes

How many people will take part?

About 200 children ages 12 to 18 will take part in this study.

What is involved in the study?

All patients in the study will fill out an online questionnaire every 3 months for 6 months. Half of the patients in the study will receive standard education (which is your regularly scheduled visits with the Certified Diabetes Educator[CDE]), and the other half will get educational text messages once per day. The initial visit will be done at the time of your regular diabetes care appointment. All other correspondence will be via text message. If we cannot get in touch with you by phone, or if any unexpected issues come up (for example, if a payment card is lost and you need a replacement), then we may mail a letter to the home. Hemoglobin A1C measurements will be taken from the medical record.

How long will you be in this study?

If you agree to take part, your participation will last for 6 months and will involve 1 in-person study visit, and 2-4 additional online questionnaires.

What are the study procedures?

The study involves the following tests and procedures.

Review of Medical Record: Demographics, height, weight, BMI, recent hemoglobin A1c, diabetes treatment plan, number of diabetes related admissions

Questionnaires: Self-Care Inventory (14 short questions to identify diabetes self-management skills), Intake Questionnaire (9 demographic and diabetes care questions, Exit Questionnaire (7 questions to evaluate the study). These questions will be administered via a text-message that links to a website where you can fill them out. You do not have to fill it out on paper, and you do not have to spend extra time in clinic after the first screening visit today.

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal.

You will be randomly assigned (like the flip of a coin, or drawing lots) to one of two groups: standard education or text message group. You have a 50% chance of being assigned to either group. If you are in standard education group, you will receive your regularly scheduled education with a CDE as decided by your doctor or nurse practitioner. If you are assigned to the text message group, you will receive daily text messages consisting of a short statement or quiz about diabetes.

Visit Schedule

You will meet study staff at your first Visit. After that, we will primarily communicate with you via text message. We will review the medical record to send out the questionnaires close to your visit, which is when your A1C is drawn. "Check-ins" are when our study team will be contacting you by text message to remind you a questionnaire needs to be filled out

Visit	Purpose	Main Procedures	Duration
Visit 1, Day 0	Screening visit Randomization Start of Study	Self-Care Inventory Questionnaire Intake Questionnaire	30 minutes
Check-in, Day 90	Routine Visit	Self-Care Inventory Questionnaire	10 minutes
Check-in, Day 180	End of Study	Self-Care Inventory Questionnaire Exit Questionnaire	10 minutes

We will send questionnaires out by texting you a link to a website. There you will log in with your MyDiaText username and password that we created at the initial visit and take the questionnaire.

If there are any issues we need to address (an example of this is a child who turns 18 during the course of the study, and needs to sign papers for themselves) we will see you in-person on the day of your visit.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following side effects:

Risks associated with study intervention:

The main risk of the text messaging intervention is cost to the participant if the phone plan for their personal mobile device does not include text messages.

There is also a risk of breach of confidentiality, but many measures will be taken to prevent this including securing all identifying information in locked cabinets or password-protected files.

Are there any benefits to taking part in this study?

You might benefit by improving your diabetes control. You may learn something about diabetes that you didn't know before. You might also develop better self-management skills that will help control your diabetes in the future. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study.

The knowledge gained from this research may help doctors determine if this text messaging intervention can be used together with regular diabetes care to improve the diabetes control in other teenagers.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to follow the study doctor's instructions, keep all study appointments and participate in the text messaging intervention as directed.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- The study is stopped.

- The text messaging intervention is no longer available.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What choices do you have other than this study?

There are options for you other than this study including:

- Receiving your routine diabetes care outside this study.
- Not participation in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and questionnaires. Laboratory test results will appear in your medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Person managing the text messaging program used in the intervention
- National Institute of Health

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed after publication of the study results. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Tara Kaushal
The Children's Hospital of Philadelphia
Division of Endocrinology and Diabetes
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There should be no additional costs to you by taking part in this study. However, if your phone plan does not cover text messages or it changes to not cover text messages, you could have phone charges for receiving these text messages.

Study sponsor is providing financial support and material for this study.

Will you be paid for taking part in this study?

Everyone who takes part will be paid each time they fill out the required questionnaires at each visit to compensate for the time and effort it takes to fill them out. It will be $5 for the first set, $10 for the second, and $15 for the third. Those who were randomly assigned to the text message group may also win $10 at two-week intervals during the study. Only one person will win per two-week period. This person will be picked at random from the set of people with the longest "streak" in text message responses for that two-week period. All payments will be given out via a bank card, given out at the first visit and then re-loaded with money each time a payment is given out.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

We may share your specimens and data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your specimens or data.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

The investigator, Dr. Lipman, is one of the inventors of the MyDiaText tool that will be used in this study. If this invention is ever commercialized by CHOP, Dr. Lipman would be entitled to a share of any royalties CHOP earns. Dr. Lipman's participation in this study was reviewed by CHOP's Conflict of Interest Committee.

Please ask Dr. Tara Kaushal or Dr. Lipman if you have any questions about how this study is funded.

Certificate of Confidentiality

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples could be shared for:

- other scientific research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Tara Kaushal at 267-357-3678 or Dr. Lipman at 215-590-3174. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and, if child is under 18 years of age, you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date