SAINT LOUIS UNIVERSITY

Institutional Review Board
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NOTICE OF INSTITUTIONAL REVIEW BOARD APPROVAL

Date:	November 21, 2016
To:	Broom, Matthew, Pediatrics
	Wilmott, Robert, Pediatrics
From:	Kisselev, Oleg,Chairperson, Associate Professor, Minimal Risk #1
Protocol Number:	25160
Protocol Title:	Evaluation of text messaging as an educational method to improve healthcare utilization

Sponsor Protocol Version Number and Version Date : Not Applicable

The above-listed protocol was reviewed and approved by the Saint Louis University Institutional Review Board.
Assurance No: FWA00005304

Below are specifics of approval:

Form Type:	CONTINUING REVIEW
Level of Review:	EXPEDITED #5, #7
Form Approval Date:	November 18, 2016
Protocol Expiry Date:	December 18, 2017
HIPAA Compliance:	HIPAA Authorization
Waiver of Consent:	Consent

The Saint Louis University Institutional Review Board complies with the regulations outlined in 45 CFR 46, 45 CFR 164, 21 CFR 50 and 21 CFR 56 and has determined the specific components above to be in compliance with these regulations, as applicable.

Approved Study Documents Include: newest vital signs.pdf; demographic questionnaire.doc; text post-test.docx; data collection.xlsx; DPBABY Sign.pdf; ESoC.pdf; Codebook.docx; enrollment checklist.docx; message schedule.xlsx; text post-test - Version 2.docx; Approved_data collection.pdf; Approved_Codebook.pdf; Approved_enrollment checklist.pdf; Approved_ESoC.pdf; Approved_message schedule.pdf; Approved_newest vital signs.pdf; Approved_demographic questionnaire.pdf; Approved_text post-test - Version 2.pdf; Approved_DPBABY Sign.pdf; SSM RBR Approval Letter.Broom #25160.pdf; Approved_Codebook - Version 2.pdf; Approved_data collection - Version 2.pdf; Approved_Informed_Consent_-_Version_3.pdf; HIPAA - 120914.doc; Approved_HIPAA - Version 2.pdf; HIPAA - Version 2.doc

SAINT LOUIS UNIVERSITY
SSM Cardinal Glennon Children's Medical Center

Research Study Consent Form

STUDY TITLE:	Evaluation of text messaging as an educational method to improve healthcare utilization.

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – it is <u>your choice</u>.**
- **If you choose to join this study, you may <u>stop at any time</u>.**
- **<u>No</u> <u>one</u> can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant _____ **IRB Number** 25160

Principal Investigator (PI) Matthew Broom, MD **Contact Phone #** 314-268-4150
First Last Credentials

Title of Project: Evaluation of text messaging as an educational method to improve healthcare utilization.

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Matthew Broom and colleagues because you have a baby less than two (2) months of age who receives primary care at Danis Pediatrics.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

The way health care providers deliver information has been shown to make a difference in how new parents use different health resources. Understanding how families use different kinds of health care services – like their primary care office and the emergency room – is important to doctors, patients, insurance companies, as well as state and local governments. This research is being done to learn if different ways of providing information about infant health, safety, growth, and development, change how parents use health care resources.

This study will enroll as many as 260 families at Saint Louis University.

2. WHAT AM I BEING ASKED TO DO?

No research procedures will be done until you agree to be in this study and sign this form.

If you agree to participate in this research study, you will receive additional information about infant health and development until your child is six (6) months old. Everyone in this study will receive handouts at routine well-child visits; half of the participants in the study will receive text messages 4 times per week until their child is six months old. You have a 50/50 chance of receiving text messages. The messages will be about different aspects of infant health, care, and growth. If you are selected to receive text messages, you will receive no more than 104 text messages from the research team. Neither you nor your doctor can decide if you will receive text messages or not, this is decided randomly, like flipping a coin.

At the **first visit**, a member of the research team will explain this study, and you will fill out some short surveys about you, how you feel about taking care of your baby, and your understanding of health information. At this first visit, the researcher will give you some information to take home about taking care of a new baby. This first meeting with the researcher should take no more than 30 minutes.

You will meet briefly with a member of the research team at every well-baby visit until your child is six (6) months old; well child visits are recommended at 1, 2, 4, and 6 months of age. At each of these visits a member of the research team will provide you with information to take home about infant health, growth, and development, in addition to the regular standard of care you receive as a patient at Danis Pediatrics.

Your **final visit** takes place when your baby comes to Danis Pediatrics for their six month well child visit. At this visit, you will again meet with a doctor and receive the regular standard of care offered at Danis Pediatrics, and a member of the research team will give you additional information about your baby's growth and development. You will also fill out a brief survey about what you thought of the text messages you may have received if you were selected to receive messages. This final meeting with the research team will take no more than 15 minutes.

The research team will periodically review your baby's SSM electronic medical record until they are one year old. The research team will look at the number and type of outpatient and emergency room visits, as well as phone calls to and from Danis Pediatrics.

If you choose to participate in this study, you will not have to make any extra visits to Danis Pediatrics. Being in this study will not change the way the doctors at Danis Pediatrics take care of your baby

If at any time you choose to withdraw from the study, you will be asked to have a final follow-up visit in Danis Pediatrics. You will be asked to fill out a brief survey. While the research team would like you to attend this final meeting, if you withdraw, you may withdraw from the study without returning for this final visit.

OPTIONAL PARTS OF THE STUDY

Future recruitment for research studies

May a member of the research team contact you to invite your participation in future research studies? Please initial next to your decision below.

_____Yes _____No

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you may spend in this research study is until your baby is one (1) year old.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study.

Though the risks are minimal in this study, some of the text messages you receive from the research team may offend you. Similarly, some questions in the surveys may make you feel uncomfortable or seem intrusive. You may choose not to answer any questions with which you feel uncomfortable. The research team will try to minimize these risks by designing questionnaires that are as neutral and as un-offensive as possible. Special care will also be taken to create text messages that will not make you uncomfortable.

Every effort will be made to protect your research study data. There is, however, always the possibility of a breach of confidentiality.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may not benefit from this research study. The possible benefits to you are a greater knowledge of infant health, safety, growth, and development.

Even though you may not receive any benefit, society may benefit in the future because of what the researchers learn from this research study. If the project is a success, society will benefit by being made aware of how text messages can influence how people use different kinds of health care resources.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study. If you choose not to be in this research study, you can still receive primary care at Danis Pediatrics. If you choose to participate, you may withdraw from this research study at any time.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published, but your name or identity will not be revealed and your record will remain private. In order to protect your information, the research team will collect all survey and medical record information using a confidential participant number. Participant names and numbers will be kept in a separate file protected by a password and accessible only by members of the research team. All computer files will be kept on a secure university network that requires password access.

All paper surveys will be kept in a locked filing cabinet, in a locked office at Cardinal Glennon. These paper surveys will only contain your participant number, and not your name, in order to protect your privacy. Only the researcher will have access to these files.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research), other University officials, and Cardinal Glennon Children's Medical Center representatives may review your research study records. State laws or court orders may also require that information from your research records be released.

8. WHAT ARE THE COSTS AND PAYMENTS?

The cost of receiving text messages from the research team will be your responsibility. The cost of receiving text messages is standard according to your personal mobile phone plan. Routine medical care, including visits to the emergency room and Danis Pediatrics, etc. are ordinarily covered by insurance carriers. You should check with your insurance company to verify that they cover standard of care procedures. You will be responsible for any costs not covered by your health insurance company.

You will not receive any payment or incentive for participating in this study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call Dr. Matthew Broom at 314-268-4150. If you have questions after hours, please call 314-388-6275 and request to speak with Dr. Matthew Broom or a member of his research team.

If you have any questions about your rights as a research participant or if you believe you have suffered an injury as a result of taking part in the research, you may contact the Chairperson of the Saint Louis University Institutional Review Board (314-977-7744), who will discuss your questions with you or will be able to refer you to someone else who will review the matter with you, identify other resources that may be available to you, and provide further information as how to proceed.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

Please note that you will not be able to withdraw from this study by replying to the text messages. Please contact Dr. Matthew Broom at 314-268-4150 directly if you no longer want to participate in this study.

The investigator may take you out of the research study without your consent when you are unable to participate as instructed, you are unable to keep scheduled appointments, you choose not to receive primary care at Danis Pediatrics, or if, in the researcher's judgment, it is in your best interest to do so.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

I have read this consent document and agree to allow my child to be in this research study with the understanding that I may withdraw him/her at any time.

_____ _____

Consent Signature of Research Participant **Date**

_____

Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #: 25160
Approved: 12-19-14
Expires: 12-18-15
Changes Approved: 07-23-15
Board #: 1
Saint Louis University

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.