SAINT LOUIS UNIVERSITY

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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

Title

Evaluation of text messaging as an educational method to improve healthcare utilization

1. Background

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

a) Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. *?HELP?*

Health care utilization is a issue germane to health care providers, insurers, and patients alike. Reducing non-urgent visits to the emergency department (ED) and primary care providers can improve both the quality and cost of care. There are barriers, however, to educating patients about more appropriate health care utilization. Low health literacy is one such barrier, particularly for caregivers of pediatric patients. Research reveals that up to half of caregivers seeking treatment at the ED have low levels of health literacy; levels that can make it more difficult to not only make sound decisions, but also provide effective follow-up care. Moreover, low levels of literacy perpetuate a cycle of seeking care for non-urgent conditions. Education initiatives designed to counteract the effects of low health literacy on health care utilization have been shown to reduce non-urgent ED visits by as much as 80%. These education interventions, while effective, are complex, costly, or time-intensive. For example, home visits by a nurse, parenting classes, and video tools are all shown to reduce non-urgent ED use, but each poses a unique problem for implementation in high volume, urban, pediatric primary care clinic. To date, no study has examined the effectiveness of text messaging as a possible avenue for educating caregivers about issues related to health care utilization. Text messaging has been shown to support behavioral change, and represents a fast and cost-effective alternative to more labor-intensive and expensive alternatives.

Danis Pediatrics, the pediatric practice of Saint Louis University physicians within SSM Cardinal Glennon Children's Medical Center (CGCMC), serves as a medical home to primarily urban, low-income patients. In the first half of 2014 alone, there were 5259 visits to the ED by caregivers of patients < 13 months of age. Of those, 520 Danis Pediatrics patients accounted for 919 of those visits. In short, just under 1 in 5 visits to the CGCMC ED is a Danis patient, and Danis patients visit the ED approximately 2 times in the first year. Previous studies of patients at Danis Pediatrics suggest that this population has access to text messaging and is interested in receiving healthcare-related information from their pediatric provider.

b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.

NA

2. Purpose of the study

a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

Our overall goal is to assess the feasibility and effectiveness of using text messages as an educational tool in order to improve health care utilization among the parents and caregivers of newborns; in particular, we seek to understand how educational text messages counteract the effects of low health literacy as it relates to non-urgent visits to the emergency department.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

b) List your research objectives (specific aims & hypotheses of the study).

Research Objectives
1) Evaluate the feasibility of sending educational text messages to the caregivers of newborns through 6 months of age.
2) Assess how text messaging affects urgent and non-urgent health care utilization across caregivers with varying levels of health literacy.

Hypotheses
1) Text messaging is a feasible and welcomed educational tool for caregivers of newborns.
2) Receiving educational text messages reduces the number of non-urgent visits to the ED for caregivers across all levels of health literacy.

c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.

We propose a prospective, randomized, single-blind experiment assessing the effectiveness of receiving educational text messages on health care utilization at caregivers of newborns across varying levels of health literacy.

All caregivers of newborns less than 2 months of age will be approached for enrollment during regular clinic visits to Danis Pediatrics in Cardinal Glennon Children's Medical Center. Enrollment will take place following their visit with a provider; we anticipate this process will take no more than 15 minutes. Subjects will receive educational text messages four times per week until the child is 6 months of age. The research team will conduct a review of the child's medical records until the child is one year old. We will enroll up to 260 participants, and we anticipate the study continuing for an additional 18 months - including time for analysis - beyond the date when the final subject is enrolled.

d) If subjects will be given placebo, please justify placebo use. *Error! Hyperlink reference not valid.*

NA

3. Study Procedures

a) **Yes** **No** **Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?**

Yes **No** **Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.**

Yes **No** **Will the SLU site be participating in all parts/procedures/arms of the study?**

If No, explain what SLU will NOT participate in:

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

b) Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).

Any caregiver of a newborn, aged 0-2 months, that receives primary care at Danis Pediatrics, has reliable cellular and text messaging service, and speaks English will be approached for enrollment. If the caregiver is interested in receiving educational text messages about their new baby, they will meet with a member of the research team.

At enrollment, caregivers will complete a brief demographic survey and be given a researcher-administered health literacy test. We anticipate enrollment will take no longer than 15 minutes. Following enrollment, participants will be randomly assigned to either the group that receives only enhanced standard of care documents, or receives text messages in addition to enhanced standard of care documents.

As a part of the regular standard of care at Danis Pediatrics, at all routine well-child exams, caregivers receive anticipatory guidance, as well as information related to their child's growth and development in the form of Bright Futures handouts. Bright Futures is a series of informative, age-specific, handouts produced by the American Academy of Pediatrics (AAP) for use by providers as a tool to educate patients on growth, development, and safety. All subjects will receive a condensed version of the Bright Futures content at their scheduled 1, 2, 4, and 6 month well child exams. This enhanced standard of care document (ESoC) is designed to be more readable, digestible, and more directly address the most common causes of non-urgent ED visits, than the Bright Futures handouts received as a part of the regular discharge process at Danis Pediatrics.

Following enrollment and assignment into one of the two experimental groups, subjects assigned to the text messaging intervention group will receive four educational messages per week until their child is 6 months of age. Subjects will receive no more than 104 messages during the study period. The text messages directly reflect the Bright Futures and ESoC content, addressing infant development, safety, care, and the most

common causes of non-urgent visits in the first year. Again, all participants will receive ESoC documents from the research team at scheduled 1, 2, 4, and 6 month well child exams.

Upon completion of text messaging and distribution of ESoC handouts, the research team will review the child's electronic medical record, documenting the volume and type of health care utilization until the child is one year old. The research team will type and count visits to the emergency department and Danis Pediatrics, as well as call volume.

c) If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.

NA

d) Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.

The sample size for the study was estimated to achieve 80% statistical power, assuming a non-directional test and a critical level for significance of alpha = .05, based on the primary outcome variable of emergency department (ED) use. The study was powered on the latter variable because it is expected to yield the smallest intervention effect. Danis Pediatric Center patients <13 months of age have a six-month incidence rate of presentation at the Cardinal Glennon Children's Hospital ED of 41% (clinic data). This rate was assumed as the baserate behavior for the Control group in the proposed research. Assuming an incidence rate in the Intervention group of 20-25% (difference from baserate behavior of 16-21%), sample sizes ranging from 84-147/group would yield adequate statistical power. Because this is a first-time study of this intervention in relation to ED use, a 23% effect size was targeted, requiring 115 subjects/group or 230 subjects total. Danis Pediatric Center encounters with study eligible patients average ~25 patients/week (conservative estimate); thus, with a 67% response rate (consistent with other research of this type in the Department of Pediatrics), the study will require 12-14 weeks to enroll this target number.

The primary outcome of 6-month ED use (no vs. yes) will be compared between study groups, Intervention vs. Control, using the chi-squared test of association. Other categorical outcome variables (e.g., keeping well child appointments, keeping immunization appointments) will also be analyzed this way. Multivariate analyses of dichotomous outcomes, including multiple logistic regression, will be conducted with Group as the independent variable and covariates like patient age, race, gender, etc., included as control variables. Time-to-event data (e.g., time to first ED visit after study entry) may be evaluated using a Cox proportional hazards regression model with Kaplan-Meier curves.

Because this study rests on the assumption that text messages are both delivered and read, this study has several validity checks in place. First, to assure messages are delivered, the company (TeleVox) that will service text messaging for this study provides daily reports regarding

message status. That is, we can see - within 24 hours - whether or not a message has been successfully sent to a subject. In this regard, we can then address any message failures with subjects by phone, or at subsequent visits. While we can track whether or not a message has been received, knowing if a message has been read or understood is a more difficult. We've included questions on our post-test that inquire about message use and subject involvement. These questions will serve as a statistical covariates in the analysis, such that the treatment effect would be stratified by the levels of self-reported use of and involvement with the texts.

8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).

Subjects are likely between 15 and 65 years of age (age of caretakers including parents and guardians).

b) Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI). up to 260

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

c) Number of evaluable subjects to be accrued study wide. *?HELP?* up to 260

d) If applicable, state the rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, economically and educationally disadvantaged, or decisionally impaired individuals. Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects.

In this study, for those participants less than 18 years of age, though minors, they will have given birth and are therefore considered emancipated minors who may consent for themselves.

Because of clinic demographics, this study may involve subjects who are economically and educationally disadvantaged with low levels of health literacy. The research team will take special care to engage in culturally competent communication with subjects. In particular, all team members will be trained in the neutral administration of the health literacy test.

e) If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. *?HELP?*

Participation is limited to English-speaking parents and/or guardians because of cost and communication barriers.

f) If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects.

g) Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#16). Important to remember: potential subjects cannot be contacted before IRB approval. NOTE: The use of SLU owned websites in an approved SLU format (e.g., Cancer Center website, etc.) are always approved methods of recruitment.

Parents and/or guardians of all newborns between 0 and 2 months of age will be recruited at scheduled visits to Danis Pediatrics in Cardinal Glennon Children's Medical Center. Subjects will be identified by their child's pediatric provider, including nurses. In addition, flyers will be placed in exam rooms so that caregivers may inquire about participation. No additional recruitment of subjects will be required beyond serving those already part of the medical home.

8. Subject Population (continued)

Page numbers from a sponsor's protocol/grant may be referenced in 8h.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

All English-speaking parents and/or guardians of newborns, aged 0 to 2 months, who receive primary care at Danis Pediatrics will be considered for participation. In addition, they must have reliable mobile phone service and be able to receive text messages.

Identify exclusion criteria.

Non-English speaking caregivers and those without reliable text messaging service will be excluded from this study.

i) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.

Subjects will not be compensated for participation.

j) Describe who will cover study related costs. Explain any costs that will be charged to the subject.

The cost of receiving the text messages will be the responsibility of the participant, which will be explained prior to enrollment. This generally amounts to no more than ten cents per message, but many individuals have a specific number of text messages per month that are included in their plan. The cost of messages being sent to participants, will be covered by Danis Pediatrics.

All medical care costs related to the care of the child will be covered by the child's caregiver and their insurance. No additional visits to Danis Pediatrics will be required for this study beyond what is recommended as a part of the newborn standard of care at Danis Pediatrics.