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

Data Analysis_25160

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.