Improving Emergency Department Discharge Referrals with Automated Text and Phone Messages

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Emergency Medicine Department
Study Protocol, version 4.1
Sponsor: None
IRB#
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Content

A. Introduction

A1. List of Abbreviations

ECRC – Emergency Care Research Core
ED – Emergency Department
EMR – Electronic Medical Record System
HIPAA – Health Insurance Portability and Accountability Act
SMS – Short Message Service (texting)

A2. Protocol Synopsis

This was a prospective randomized open blinded end-point (PROBE) trial that took place at a large urban Emergency Department (ED) to test if a two-way phone messaging system improved patient adherence to referral follow-up visits at outpatient clinics. The primary outcome was patient attendance for follow-up care and the secondary outcome was ED re-admissions within 4 months after initial discharge.

B. Background & Rationale

B1. Background: Adherence to Follow-up Visits After Emergency Department Discharge

Patient adherence to ED follow-up instructions and appointments varies from 26-56% [1]. According to Kangovi et al. (2012), the most common reason a patient gave for readmission to the ED was "feeling unprepared for discharge" after the first visit [2]. The transition from ED to discharge requires the patient to be responsible for following discharge instructions, obtaining prescriptions, and finding time and resources to attend follow-up visits. Readmissions to the ED are not primarily a result of lack of access to services [3], pointing attention toward follow-up communication, which can improve transition to outpatient care [4-6]. ED clinical staff try to sit down with patients after ED visits to review instructions and sometimes schedule follow-up appointments [7]. An outpatient hemodialysis clinic that tried this model found it to be successful initially, but could not afford the extra staff to sustain it.[8]

Time and money could be saved by implementing automated appointment reminders through voice or text messages. No-show patients were reduced by 10% when one primary care clinic began using a text and phone call reminder for appointments, resulting in a positive cost-benefit analysis [9]. A similar improvement in successful follow-up appointments was found in an ED setting with a diverse population [10]. Historically, successful follow-up appointment rates of patients discharged from the Barnes Jewish Hospital Emergency Department (BJH-ED) have ranged from 9% to 37.5%, the highest rate of follow-ups were for next-day appointments [11]. It's difficult to know how much of a difference a simple appointment reminder system would make since a previous study of BJH-ED patients found the major identifiable causes for missing appointments were "other" (34%), no transportation (25%), fear of medical cost (18%), feeling better (13%), and unsure of where to go for the visit (9%) [12]. A sophisticated and robust reminder system may be capable of addressing some of these barriers.. Recently complex modalities of electronic follow-up, such as video conferencing or remote physiological monitoring [13-15] have been introduced, further complicating follow-up care adherence, especially in an ED setting.

A two-way automated SMS system that provides a way for patients to respond has shown promise in improving communication and follow-up care with complex patients, with engagement rates between 80-90% [16]. A pilot study found a two-way system helped dialysis patients improve attendance and had potential to reduce emergency hospitalization [17].

We hypothesize that a bi-directional automated text and phone system which facilitates scheduling follow-up referrals for discharged ED patients will improve follow-up adherence.

B2. Hypotheses

We hypothesize that compared to standard of care, an automated bidirectional phone messaging system will: (1) improve ED patient adherence to follow-up appointments and (2) reduce ED re-admissions.

C. Study Objectives

C1. Specific Aims

The primary objective of this study is to determine whether follow-up appointment adherence is improved within 120 days after an initial discharge from the ED by using an automated bi-directional phone messaging system.

- Specific Aim 1: Did more patients successfully attend follow-up appointments?
- Specific Aim 2: Was there a reduction in ED re-admissions?

C2. Outcomes of Interest

- Primary: Time to attending a follow-up visit with referred primary or specialty care within 120 days post-discharge
- Secondary:
    - Time to re-visit to the ED (BJH or other) within 120 days post-discharge.
- Tertiary:
    - Patient engagement levels with the intervention: number of successful attempts to reach participant, number of successful attempts to schedule a follow-up appointment, length of phone call to schedule an appointment, and number of successful follow-up appointments with a specialist provider versus a primary care provider.

D. Research Team

D1. Key Personnel

PI: Brent Ruoff, MD

D2. Key Personnel Training Certification

All current research team members complete Washington University HIPAA and CITI training courses. They are also registered with the Washington University Human Research Protection Office at myIRB.wusm.wustl.edu and added to the study's research team prior to viewing PHI. The research assistant and medical student are given "View Only" access to the EMR to help with patient chart reviews.

D3. Organization and Participating Centers

Washington University in St. Louis School of Medicine
Barnes Jewish Hospital Emergency Department
Clinical Research and Innovation Student Program at Washington University School of Medicine

D4. Funding Sources and Conflict of Interest

There is no funding being used for this research project and there are no financial conflicts of interest.

E. Data Collection and Analysis

E1. Data Quality Assurance

Brent Ruoff, M.D. is the principal investigator who is the Chief of Division of Emergency Medicine and Associate Professor of Emergency Medicine at Washington University School of Medicine. He is an expert on helping BJC reduce re-admissions and has been doing clinical research since 1990.

E2. Data Analysis, Sample Size Estimation, and Study Power

The sample size from the trial was determined to meet criteria to be sufficiently powered at 90% for a two-sided $\alpha = 0.05$, for a 10% improvement of the primary outcome. We will conduct an Intention-to-Treat analysis to test the impact of the intervention on participant follow-up attendance and ED re-admissions. We will also conduct descriptive statistics regarding user engagement.

We might experience missing outcome data if a participant set up a follow-up appointment with a provider who was not their referral provider and is not a part of the BJH EMR network or Missouri Health Connection. These appointments will not be accessible to our study team and a participant may be labeled as *non-compliant* erroneously; however, since most Missouri health clinics participate in the Missouri Health Connection, this issue will be rare and should apply to both the control and intervention arm equally.

F. General Assurances

The study team agrees to comply with all applicable Washington University policies and procedures, and applicable federal, state and local laws. The research will only be performed by qualified personnel. All persons assisting with the research are adequately informed about the protocol and their research-related duties and functions. We will not implement any changes in the approved IRB application without prior IRB approval.

G. Risks and Benefits

Potential risks include possible breach of confidentiality involving PHI/study data.

Efforts will be dedicated to minimize the risk of breach of privacy. All patient information and study data will be password protected in computer files stored on Box and only shared with research team members. Participants are assigned study ID numbers that will be used to minimize risk of exposure of patient information. Data collected from the Epharmix/CareSignal Intervention Platform are deidentified before being stored in Box.

H. Publication Plan

We will submit a manuscript describing our results within approximately 12 months of finalizing them. Any results published from this study will not contain any participant identifiers.

References

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Protocol from IRB #201504079: Improving medical care in ED discharge referral in patients with electronic interventions based on automated text and phone messages

Content

A. Overview of Study

A1. Study Design Summary

Key elements of study design under 2015040479	
Type of study	PROBE
Total N	~330
Intervention Arm	Automated text and phone messages + Standard of Care
Control Arm	No phone messages + Standard of Care
Power	90%
Hypothesis	Adherence to follow-up visits will improve in intervention arm

Data will be collected regarding scheduling and attendance of follow-up appointments by assessing an automated bi-directional text or phone intervention and reviewing patient charts [see Section C1. Intervention Treatment].

This intervention was an add-on to standard of care with the goal to research the efficacy of an automated two-way phone system in improving follow-up appointment adherence in ED discharge patients.

A2. Epharmix/CareSignal Intervention Builder Summary

An electronic intervention platform was developed by Epharmix/CareSignal, a WUSTL IDEA Labs (ideas.wustl.edu) company, which uses an automated two-way text or phone system for various uses to supplement clinical care, such as tracking patient adherence, collecting additional data, or delivering educational follow-up. The platform is called Epharmix/CareSignal Intervention Builder and is uploaded on Washington University (WU) servers as an application. On this platform our research team has a unique account on which we built a series of messages [see Appendix 5. Pseudocode] to test our hypothesis. Automated text or phone messaging was delivered from this account to intervention participants and participant responses returned directly to this unique account, allowing research team members to supervise responses and have control over the intervention.

Epharmix/CareSignal, Inc. and Epharmix/CareSignal employees are only involved in this project as a service provider, giving WUSTL personnel access to create an account on their platform. One employee, the Chief Developer, assists in aggregating and deidentifying data from our account [see Section D3. Method of Use of Epharmix/CareSignal Intervention Builder].

B. Pre-Enrollment, Screening, Informed Consent & Study Entry

B1. Participant Identification

The trial enrolls any interested adult who is discharged from the Barnes Jewish ED and is recommended to see a referral provider. Discharge instructions have to be complete and the patient needs to be able to use a consistent phone, have a way to understand English communication, and be capable of consenting.

B2. Eligibility Criteria

Inclusion criteria:

1. 18 years and older.
2. Accessible SMS capable mobile phone or residential landline.
3. Able and willing to provide consent and authorize access of participant medical record for study use.
4. Able to read English or have English-speaking family member to assist with phone communications.
5. Supplied a clinical referral with recommended outpatient follow-up timeframe or date within 4 months of discharge.

Exclusion criteria:

1. Unable to be contacted by a phone call and/or SMS text message, or unwilling to provide a phone number.
2. Unwilling to consent and follow the assigned regimen and complete the required follow-up.
3. Non-English speaking.
4. Neurologic, anatomic, or cognitive disorders and thus unable to consent and/or answer text messages/phone calls.
5. Already had a follow-up appointment scheduled before being discharged.

B3. Screening

Enrollment for the trial occurs on a rolling basis for a six-month period. Treating physicians in the ED identify potential participants after completing a patient's discharge and follow-up instructions. The treating physician notifies the Emergency Care Research Core (ECRC) research coordinator with the patient's name and ED room number. While the patient is in their room, the research coordinator approaches the patient to introduce the study and discuss participation.

B4. Informed Consent

The research coordinator identifies him/herself as a research staff member that is separate from clinical care. Follow-up care is not affected by a patient's choice to enroll. The research coordinator reviews the consent form [see Appendix 1. Informed Consent Form] with patients and obtains written consent along with a demographic survey [see Appendix 2. Demographic Survey].

Patients who are unsure about enrollment can take the consent form home with them and decide to join from home, but before they attend a follow-up appointment. A phone number to the study's primary contact is listed at the top of the consent form. Some patients are also contacted by phone by the research coordinator about participating in advance of a scheduled follow-up appointment. When

consent is given over the phone, the research coordinator follows the verbal consent form [see Appendix 3. Verbal Consent Document].

B5. Study Entry

Once a patient provides written consent, they are enrolled as a study participant. After a research coordinator obtains consent, s/he enters a participant's preferred phone number, contact method (text or phone message), and preferred contact times into the research account on the Epharmix/CareSignal Intervention Builder platform via the web portal epx.wustl.edu. They also include the referral clinic name, clinic phone number, and clinic address that the treating ED staff instructs the patient to call for a follow-up appointment. It is possible to include more than one referral clinic if the ED staff provides a second option.

B6. Randomization Method and Blinding

Once a participant is added to the Intervention Builder account, the integrated software independently randomizes participants to either the control or the intervention arm. The software s randomly allocates participants in a 1:1 ratio to intervention and control arms.

Even though participants are not informed if they were enrolled in the intervention or control arm, they are capable of inferring this information (if they did or did not receive a text or phone call).

Treating clinical staff are blinded to arm allocation. They complete treatment before a participant enrolls in the study.

The research team will be blinded to arm allocation whenever possible. EMR review to identify attended follow-up appointments and ED re-visits will be completed before intervention responses are reviewed and analysis commences.

B7. Follow-Up Communication

There was not any follow-up communication in this research study.

B8. Clinical Workflow Precautions

Following discharge from an emergency department (ED), it is standard of care that patients receive written instructions and counseling from ED staff (physicians, nurses and as-needed social workers). Discharged patients are not normally contacted by ED staff after leaving the ED. The intervention is considered an add-on to this standard of care by facilitating communication to the participant's designated provider for their follow-up appointment.

In the event that a discharged patient begins showing new signs or symptoms that required clinical evaluation before leaving the ED, the patient is required to start the standard clinical care process over again in compliance with ED guidelines and the Emergency Medical Treatment and Labor Act. Depending on the outcome of the subsequent evaluation, the patient may or may not meet research criteria, which is determined by the patient's final disposition.

If a participant's ED visit results in scheduling a follow-up appointment at the time of their discharge, such as for a specialist consultation or social worker visit, they are not included in the study.

B9. Participant Withdrawal

If any participant wants to withdraw from the #201504079 study they may call the number listed at the top of the written consent form and ask the project lead or principal investigator to send a copy of a withdrawal letter to fill out, or they could follow instructions in the consent form to go to the Human Research Protection Office website and print off their own copy of a withdrawal letter. They would mail the letter to the address given at the top of the consent form [see Appendix 1. Written Consent Form].

The research coordinator reviews this process with the participant at the time of their written consent. Participant data collected up to the time of withdrawal will still be analyzed. If the participant was still receiving automated messages when the research team received a withdrawal letter, the project lead located the participant's information in the Epharmix/CareSignal Intervention Builder and discontinues the intervention from the research account.

C. Study Procedure

C1. Intervention Treatment

After providing written informed consent, participants in the intervention arm begin receiving text or voice messages to help them schedule a follow-up appointment with the referral provider per the pseudocode template attached [see Appendix 5. Pseudocode]. By default, participants receive automated messages starting one hour following discharge if it is normal business hours (Monday through Friday 0900 to 1700), or at 1000 the next business day if they are discharged outside of normal business hours. Automated messages are sent up to three days in a row or until the participant responded or the participant opted out, whichever occurs first. The participant is able to respond to all messages by either using alphanumeric (1-3) or binary answers (Yes or No). The primary goal of the intervention is to connect the participant directly to the referral provider's office to schedule an appointment. Once the participant hangs up with the office, the intervention asks if they were successful with scheduling an appointment.

If the participant fails to respond to the intervention, the intervention leaves a voicemail detailing instructions on how to reach the referral provider's office via a toll-free phone number. This toll-free number is the same number that showed up on the participant's cell phone or landline caller ID when the intervention reached out to them. If the participant calls the toll-free number, the intervention works as it normally would.

Once an appointment is made, the system sends reminders at 14 days, 7 days, 3 days, and 1 day before the appointment date. The day after the appointment, the intervention contacts the participant to see if they attended it. If the participant did attend, the intervention stops. If the participant did not attend and needs to reschedule, the intervention resets and starts over again.

Participants can voluntarily opt-out of receiving any further messages at any time if they text STOP or if they press * on the keypad during an automated phone message.

Participants in the control arm do not receive any messages.

C2. Participant Education on Research vs Clinical Care

At the time of written consent the research coordinator will advise participants that the messages they may receive are not coming from their treating physicians or clinical staff, but from an automated system that is separate from their medical care because it is only part of a research study. Participants

are advised that if they have any health concerns, the automated system would not be able to help them and they need to reach out to their doctor or the emergency room as they normally would. If the participant feels they are having a health concern related to the study, they are encouraged to call the phone number to the main study contact at the top of their consent form. If the research team is notified, they willfollow reporting procedures for an adverse event [see Section F2. Reporting of Adverse Events].

C3. Changes to Standard of Care

No automated clinical judgements are included in this study. The purpose of utilizing the Epharmix/CareSignal Intervention Builder in this study was purely to facilitate follow-up visits to referral providers.

D. SMS and Phone Application

D1. Epharmix/CareSignal

This study under umbrella IRB 201504079 uses the Epharmix/CareSignal Intervention Builder platform to develop an automated outreach that facilitates patient follow-up visits with referral providers and collects appointment follow-up rates. The platform utilizes two-way text messaging or automated phone calls to acquire data from participants, at intervals set by the principal investigator. The research team's unique account on the Epharmix/CareSignal Intervention Builder collected follow-up appointment data. Only one Epharmix/CareSignal employee, the Chief Developer, had access to the Intervention Builder platform in order to provide routine maintenance. This employee had updated HIPAA and CITI training. The Epharmix/CareSignal Intervention Builder was not a phone application; participants did not need to download or install anything on their phones in order to receive the research texts or phone messages. Participant phone responses were automatically stored on the Epharmix/CareSignal Intervention Builder site, epx.wustl.edu, in the specific research account that is password protected. Epharmix/CareSignal, Inc does not have access to this password. In addition, the site is SSL-encrypted, ensuring password safety in transmission.

D2. Regulatory Status

The FDA has not made an assessment of risk with regard to this study, and as a communication tool we are not requesting to conduct this study under FDA NSR requirements. Epharmix/CareSignal Intervention Builder is not an implant and does not present a potential for serious risk, does not support or sustain human life, and is not of substantial importance in diagnosing, curing, mitigating, or treating disease, and does not have serious risk for health, safety, or welfare of a subject.

D3. Method of Use of Epharmix/CareSignal Intervention Builder

After enrollment, the research coordinator will initiate use of the research account's intervention that was built on the Epharmix/CareSignal Intervention Builder. The research account will send an initial text message or phone call as described in Section C1. Intervention Treatment. Since patients discharged from the ED do not have any further contact with ED providers, this intervention is not designed to sustain communication between the clinical provider and the participant. This intervention is instead fully automated to connect participants to a referral provider or service. It does not request health information from participants nor deliver any health information to them. The pseudocode responds to a participant's success in setting up a follow-up appointment and provides alternate choices if a follow-up appointment could not be made [see Appendix 5. Pseudocode].

Once the intervention is completed with the last enrolled participant, the project lead will request that the Epharmix/CareSignal Chief Developer aggregate and extract a raw data file (.csv) from the research account that the study manager encrypted so that the data is unviewable by the Chief Developer. The Chief Developer places this encrypted data file on an encrypted flash drive that is handed off to the project lead. The project lead uploads the encrypted file onto a secure database on box.wustl.edu.

D4. Alert Management

No alerts were used as a part of the intervention.

E. Follow-up Visit Schedule

No additional follow-up visits were required for this study. Participants followed up with their referral providers as they normally would.

F. Data Collection and Analysis

F1. Outcome Assessments

The outcomes of interest are:

- Primary: Participant follow-up attendance to a referral clinic or provider (compliant / non-compliant).
- Secondary:
    - Number of re-admissions to the ED (BJH or other) within 30 days and again within four months post-discharge.
- Tertiary:
    - Patient engagement levels with the intervention: number of successful attempts to reach participant, number of successful attempts to schedule a follow-up appointment, length of phone call to schedule an appointment, and number of successful follow-up appointments with a specialist provider versus a primary care provider.

To minimize bias, all clinical staff and research team members conducting patient chart reviews will be blinded to participant arm allocation [see Section B6. Randomization Method and Blinding]. We anticipate the study will have no impact on clinical workflow since the intervention will take place during a gap in clinical care when a participant is transferred between providers and we will only be completing patient chart assessments and data analysis to finalize the study.

F2. Confidentiality and Security

The Epharmix/CareSignal Intervention Builder has been evaluated by WU IT security before and approved for other studies [see Appendix 7. Security Clearance]. Participant responses to the intervention are stored on a HIPAA compliant WU server at epx.wustl.edu that has both encryption and penetration testing. Data was exported upon request after being de-identified in a .csv file and uploaded to Box [see D3. Methods of Use of Epharmix/CareSignal Intervention Builder].

Hard copies of consent forms and demographic surveys will be kept in a research binder in a locked cabinet in a locked office at the ECRC by the research coordinator until digitally archived. All patient identifiers will be destroyed at the earliest time possible.

F3. Data Quality Assurance
An interim patient chart assessment and analysis of intervention responses will be performed four months after enrollment of the 85th participant. The principal investigator is responsible for monitoring participant responses.

F4. Data Analysis, Sample Size Estimation, and Study Power
As detailed in Section A.2 Pilot Data, we calculated that we need to recruit at least 333 participants to have a power of 90% for a two-sided $\alpha = 0.05$, to detect a 10% improvement of the primary outcome. As a Phase II study, we are attempting to identify the effect size of the intervention.

We obtained the estimated improvement in the primary outcome from our pilot study. The number of eligible patients in the ED over a 6-month period were approximately 21% of admitted patients. We needed a sample size of 266 patients, and anticipated that roughly 20% of participants would be lost to follow-up, which means we needed to recruit 333 participants. We calculated our sample size using the G*Power3 program.

G. Safety and Adverse Events

G1. Definitions
Adverse Events (AE) would include a data breach in this study.

Serious Adverse Events (SAE) are defined as any medical occurrence that results in death, is life threatening, requires inpatient hospitalization, results in persistent or significant disability, is a congenital anomaly or birth defect, or is an event requiring medical intervention to prevent any of these examples of an SAE. SAEs may be mild (transient, easily tolerated by participant), moderate (causes discomfort or interrupts the study or the participant's usual activities), or severe (causes considerable interference with usual activities).

G2. Reporting of Adverse Events
In the study, all adverse events, whether expected or unexpected, will be reported to Washington University's Human Research Protection Office (HRPO) [see Appendix 6. Adverse Events Log]. The HRPO office will be notified of any serious adverse experience within ten working days of the occurrence. If the event is fatal or life threatening, HRPO will be notified immediately, but not more than twenty-four hours after occurrence. Other adverse events will be reported to HRPO in annual reports. Adverse events will be reported from the time of participant enrollment to four months post-enrollment.

In the case of a data breach, Information Security (IS) will be notified immediately and the IS security date and number will be recorded. Participants will be notified by a phone call from the research coordinator.

G3. Data Collection Procedures for Adverse Events
In cases where the principal investigator deems it necessary for a participant to stop receiving the intervention prior to end point (e.g. change in health rendering patient unable to participate), data will be included up to the date of the event.

G4. Follow-up of Serious Adverse Events
All SAEs will be followed until resolution, permanent outcome of the event or until stabilization. Some SAEs will require study discontinuation. For example, participants will discontinue the study if they are unable to tolerate study participation. These participants will continue to undergo follow-up evaluation by the investigator, direct consultation between the investigators and the treating physicians and establishment of ongoing care plans before being discharged from the study. For participants experiencing an SAE that does not require study discontinuation, continuing study participation will require discussions of the potential risks and benefits of continuing participation, involving the participant and their treatment team, the investigators and the participant's treating physicians.

H. Risks and Benefits

Potential risks include possible breach of confidentiality involving PHI/study data and possible risk of annoyance by the subject due to repetition of messages.

Efforts will be dedicated to minimize the risk of breach of privacy. All patient information and study data will be password protected in computer files and all paper forms will be kept in a secure locked office within a locked suite, controlled by the research staff. Additionally each patient will be assigned a study ID number to minimize risk of exposure of patient information. The ID number will be used to code all the data assigned to each patient as they are included sequentially into the study. This number will be used for the electronic spreadsheet and placed on the paper documents (if created) and a list of the assigned numbers will be maintained in a password-protected electronic spreadsheet.

Communication via phone and text are unsecured and potentially non-confidential. Additionally the information stored on a patient's phone is outside the control of the study investigator. The patient was informed of these risks and was required to consent to exchange potential Protected Health Information (PHI) via these communication lines to participate in the study. To prevent the accidental disclosure of PHI from pop-up phone notifications, the text message read: "Confidential message" and the content began 3 lines later, which was not seen on an automatic notification preview [see Appendix 8. Text Message Example Screenshots].

The major side-effect of this intervention is potential annoyance and disruption to patient lives. To reduce these risks, text messages and phone calls are reduced to the minimum possible to meet reminder or patient communication guidelines. In addition, efforts are made to ensure that the text message and phone calls are kind, courteous, respectful, and timely. Patients are also given the opportunity to opt out at any time via a "STOP" message or the * dial key.

I. Study Administration

I1. Key Personnel
PI: Brent Ruoff, MD

I2. Key Personnel Training Certification
All research team members complete Washington University HIPAA and CITI training courses. They are also registered with the Washington University Human Research Protection Office at myIRB.wusm.wustl.edu and added to the study's research team prior to viewing PHI.

I3. Funding Source and Conflicts of Interest

This study was supported by the NIH/National Center for Advancing Translational Sciences (NCAT), grant ULI TR000448. Epharmix/CareSignal, Inc is also providing in kind services that allows us to create a free account for this study on the Epharmix/CareSignal Intervention Builder platform where we can design and build our own unique intervention. Automated phone or text messages that we send out from our account are free of charge to the study, as well as the phone responses that participants send back to our account. Phone companies may still charge participants for their responses based on participants' individual data and phone plans. These charges are outside of our control.

I4. Subject Stipends or Payments

No payment or reimbursement is offered for this study.

Appendix

1. Informed Consent Document

Washington University Physicians®
Washington University School of Medicine in St. Louis

Authorization for Release of Health Record Information

I hereby authorize **Washington University Physicians** to transfer, release or obtain information on:

_____ _____ _____
(Name of Patient) (Date of Birth) (Last 4 digits of Social Security #)

OBTAIN FROM: (DO NOT LEAVE BLANK)	**DISCLOSE TO: (DO NOT LEAVE BLANK)**
☐ Dr(s). _____	Dr. Brent Ruoff, Washington University in St. Louis (Physician/Institution/Patient)
☐ Specialty _____	Robert Mattson Peters (Attention)
☐ All Washington University Physicians	660 S. Euclid Ave. (Address)
☐ Non Washington University Physician	Campus Box 8121 (Address)
(Please complete section below)	St. Louis, MO 63110 (City, State, Zip)
_____ (Physician/Institution)	314-273-1397 (Phone) _____ (Fax)
_____ (Address)	robert.m.peters@wustl.edu (E-mail address)
_____ (Address)	Select Delivery Method: ☑ E-Delivery ☐ Mail
_____ (City, State, Zip)	
_____ (Phone) _____ (Fax)	

For the purpose of:

- ☐ Continuing Medical Care
- ☐ Insurance
- ☐ School
- ☐ Military
- ☑ Other (specify) Washington University Research Study: IRB# 201504079
- ☐ Legal Purposes
- ☐ Social Security/Disability
- ☐ Patient's Request

Date(s) of Treatment: ☐ Specific Dates: _____thru_____ ☑ All dates

Please Check Specific Information Requested

- ☐ All Records
- ☑ Abstract Record **(Office Notes, Procedures & Test Results Only)**
- ☐ Medication Records
- ☑ Other (specify) Verification of appointment dates scheduled and if attended
- ☐ Laboratory/Pathology Reports
- ☐ Radiology Reports
- ☐ Verbal Communication Only **(No Records will be Released)**
- ☑ Office/Progress Notes
- ☐ Operative Report/Notes
- ☑ Discharge Summary
- ☑ Nurses Notes

Questions regarding Billing Records should be directed to Physician's Billing Services (Phone: 314-273-0763)
Questions regarding Radiology Films should be directed to the Radiology Film Library (Phone: 314-362-2850)

Psychotherapy Notes: This authorization does not include permission to release outpatient Psychotherapy Notes. Psychotherapy Notes are defined as notes that document private, joint, group, or family counseling sessions that are separated from the rest of a patient's medical record.

Release of Psychotherapy Notes requires a separate authorization.

**** PLEASE ALLOW UP TO 30 DAYS FOR REQUEST TO BE PROCESSED. IF RECORDS ARE NEEDED SOONER, PLEASE CONTACT OUR OFFICE AT 314-273-0453. ****

I understand that my records may contain but are not limited to: history, diagnosis, and/or treatment of HIV (AIDs virus), other sexually transmitted diseases, drug and/or alcohol abuse, mental illness, psychiatric treatment, or genetic counseling. I give my specific authorization for these records to be released.

☐ ____**Yes**, I consent to the release of this information Initial ☐ ____**No**, I do not consent to the release of this information Initial

- This request is a free and voluntary act by me. I understand that I may revoke this authorization at any time by sending a written notice of revocation to:

  Washington University
  Health Information—Release Services
  Campus Box 1219
  4240 Duncan Ave., Suite 301
  St. Louis, MO 63110
  Office Phone: 314-273-0453 Fax: 844.868.1435

- The revocation will not apply to information already released in response to this authorization.
- I understand that if I choose not to give this permission or if I cancel my permission, I will still be able to receive any treatment or benefits that I am entitled to, as long as this information is not needed to determine if I am eligible for services or to pay for the services that I receive.
- I understand that once my information is used and/or disclosed pursuant to this authorization, it may no longer be protected by federal privacy regulations and may be subject to re-disclosure by the recipient(s).
- **I understand that a reasonable fee may be charged unless copies are sent to another physician or healthcare facility. This fee is based on the cost of the labor and supplies involved in copying the requested health information. Copies sent to other recipients (i.e. attorney, insurance companies) are subject to fees as provided by state law.**

Authorization is valid either for 90 days from the date of signature (if not otherwise specified) OR as specified by selecting one of these options:

☑ **This authorization expires on the following date** End of study - 8/19/2020

☐ **This authorization expires due to the following event or special condition** _____

I have read and understand this consent and I have signed it voluntarily.

_____ _____
(Signature of Patient or Parent/Legal Representative) (Date)

_____
(Relationship to Patient-if not the patient)

_____ _____
(Witness) (Date)

_____ _____
(Patient's Address, City, State, Zip) (Patient's Phone)

(Certified copy of appointment of legal guardian or personal representative and death certificate of deceased patient must be attached)

INFORMED CONSENT DOCUMENT

Project Title: Improving medical care with electronic interventions based on automated text and phone messages

Principal Investigator: Brent Ruoff

Research Team Contact: Robert Peters
robert.m.peters@wustl.edu
314-273-1397

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because your health care provider has recommended that you would be a good candidate for a research study we are conducting on an automated phone and text messaging service to try and improve your health care. Your name was obtained from your health care provider's contact list.

The purpose of the study is to look at the effectiveness of phone or text-based communication.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, you will be randomized (like the flip of a coin) to one of two groups. About 50% of participants in this research will be in the first group and about 50% of participants will be in the second group. For the first group, over the following weeks we will ask you about your symptoms, signs, or medically related events that have occurred relating to your medical condition through automated voice calls or texts directly to your personal phone. This information will then be shared with

your health care provider for the purpose making prompt management decisions and of improving your health.

For the second group, over the following weeks, you will may receive fewer texts, or phone calls where we may ask you about events that may have occurred related to your medical condition.

At the end of study period, you will be placed in the opposite group then you were and will then either receive more or less messages.

No matter which group you are in, you will first provide your best contact phone number for receiving texts or phone calls, as well as potentially the best time to reach you. During and at the end of the study we will look over your medical records to collect data about how your condition changed during the study. These data are collected as part of your standard medical care. You will not be asked to attend any additional appointments or undergo tests.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 5000 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for as little as 1 month to as long as 5 years, depending on the duration of your medical condition and at what point you enroll in the study. The research team will review data from your medical record for that equal duration of up to 5 years.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

We want to make sure you know that unencrypted text messages are not secure communications, and that we are not able to encrypt text messages, i.e. make them unreadable to others. Voice calls, however, are considered secure, and are an option for the study. Text messages or the voice calls may become part of your clinical record and be available to your clinical staff as needed. It is possible that someone else could become aware of your health information.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because health care providers and centers will be able to provide services for better clinical care.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

Epharmix is funding this research study by providing in kind services (the text messages or phone calls) for free.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will assign an ID code number on all survey material, instead of your name, so that any information you provide us will be separated from your name and identifying information about you. Your phone number will be on a protected electronic server and will not be used for any other purposes besides providing health-related information to you. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The research team will send study results to Epharmix. Information sent to Epharmix will not be identifiable. In the future, Epharmix may continue to use your health information that is collected as part of this study. For example, Epharmix may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the SMS/Voice messages, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Epharmix, may also share information from the study with regulatory agencies in foreign countries.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"
Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- ☐ You authorize the use of your PHI for this research
- ☐ This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - ☐ To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - ○ **If you revoke your authorization:**
      - ♣ The research team may only use and share information already collected for the study.
      - ♣ Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - ♣ You will not be allowed to continue to participate in the study

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Robert Peters, robert.m.peters@wustl.edu, 314-273-1397, or Will Ross, rossw@wusm.wustl.edu. If you experience a research-related injury, please contact: Robert Peters, robert.m.peters@wustl.edu, 314-273-1397, or Will Ross, rossw@wusm.wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.

To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Do not sign this form if today's date is after EXPIRATION DATE: 08/17/16.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)

2. Demographic Survey

Interview occurred: ☐ In person ☐ Over the phone

Date: _____

Demographics

Name: _____

Date of birth(MM/DD/YYYY): _____

Gender (check): ☐ Male ☐ Female

Race (check all that apply):

- ☐ White
- ☐ Black of African American
- ☐ Asian
- ☐ American Indian or Alaskan Native
- ☐ Native Hawaiian or Pacific Islander
- ☐ Other _____
- ☐ I decline to answer

Ethnicity:

- ☐ Hispanic or Latino
- ☐ Not Hispanic of Latino
- ☐ I decline to answer

What is your highest level of education?

- ☐ No formal education
- ☐ Grade school
- ☐ Some high school
- ☐ High school graduate or GED
- ☐ Some college
- ☐ College graduate or associate's degree
- ☐ Some graduate school
- ☐ Graduate degree or professional degree
- ☐ I decline to answer

Marital status:

- ☐ Never married
- ☐ Married
- ☐ Domestic partnership
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ I decline to answer

Physical health

Do you have any other medical problems? Please check all the apply:

- ☐ Diabetes mellitus
- ☐ Hypertension/high blood pressure
- ☐ Heart disease (heart attack, coronary artery disease, arrhythmias, valve disease)
- ☐ Neurological disease (including previous stroke, seizures, fainting)
- ☐ Lung disease (COPD, emphysema)
- ☐ Thyroid disease
- ☐ Cancer
- ☐ Other: _____
- ☐ I decline to answer

3. Verbal Consent Document

Verbal consent with Health Care Provider: May occur over the phone
A health care provider will discuss at length with the patients the direct benefits and risks of each electronic intervention as specific for disease subtype. In particular the provider will explain the transmission of protected health information via phone and text, and get verbal consent to the process. Phone numbers to reach about the study will also be specific to condition or disease subtype.

Verbal consent will be documented by the health care provider in an Allscripts clinic or call note.

Consent for all patients will use the following phone script with the following components, describing the study.

- Introduction Message
- Verification of patient's identity
- Explanation of Study + Benefits
  - Disclosure that this is research and completely voluntary
  - Purpose of research
  - Description of procedure
  - Forseeable risks or discomforts
  - Any Benefits
- Duration of study
- Consent to PHI disclosure
  - Text vs phone communication security
  - Statement about confidentiality of records
  - Who to talk to if any questions, and directions to HRPO website.
- Opt-out procedures

Phone script

Hello, is this Mr/Ms. _____? I am calling on behalf of {{Health care provider name}} from {{Washington University School of Medicine or Barnes Jewish Hospital}}. {{Health care provider name}} recommended you would be a good candidate for a research study we are conducting on , an automated phone and text messaging service to try and improve health care. The purpose of the study is to look at the effectiveness of phone or text-based communication. Approximately 5000 people will take part in this study at Washington University.

If you agree to participate, we will ask you about your {{medical condition or health management, eg. Asthma, wound healing}} via automated voice calls or texts directly to your personal phone for anywhere between 1 month and 5 years depending on your condition and when you enter the study. There is no cost to the study, and you will not be paid for participating. We will also review your medical records to collect data about how your condition changed during the study.

As part of the study, you will be placed in either the treatment or control groups. Treatments groups will get more messages, while control groups will receive less. At the end of study period, you will be placed in the opposite group then you were and will then either receive more or less messages.

The potential benefit of this service is to keep you informed and help your doctor take better care of you.

We want to make sure you know that unencrypted text messages are not secure communications, and that we are not able to encrypt text messages, i.e. make them unreadable to others. Voice calls, however, are considered secure, and are an option for the study. Text messages or the voice calls may become part of your clinical record and be available to your

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Robert Peters at 314-273-1397. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Do you have any questions?

If you have any other questions, please call us at [Appropriate Nurse Phone Number], at any time, or visit hrpo.wustl.edu.

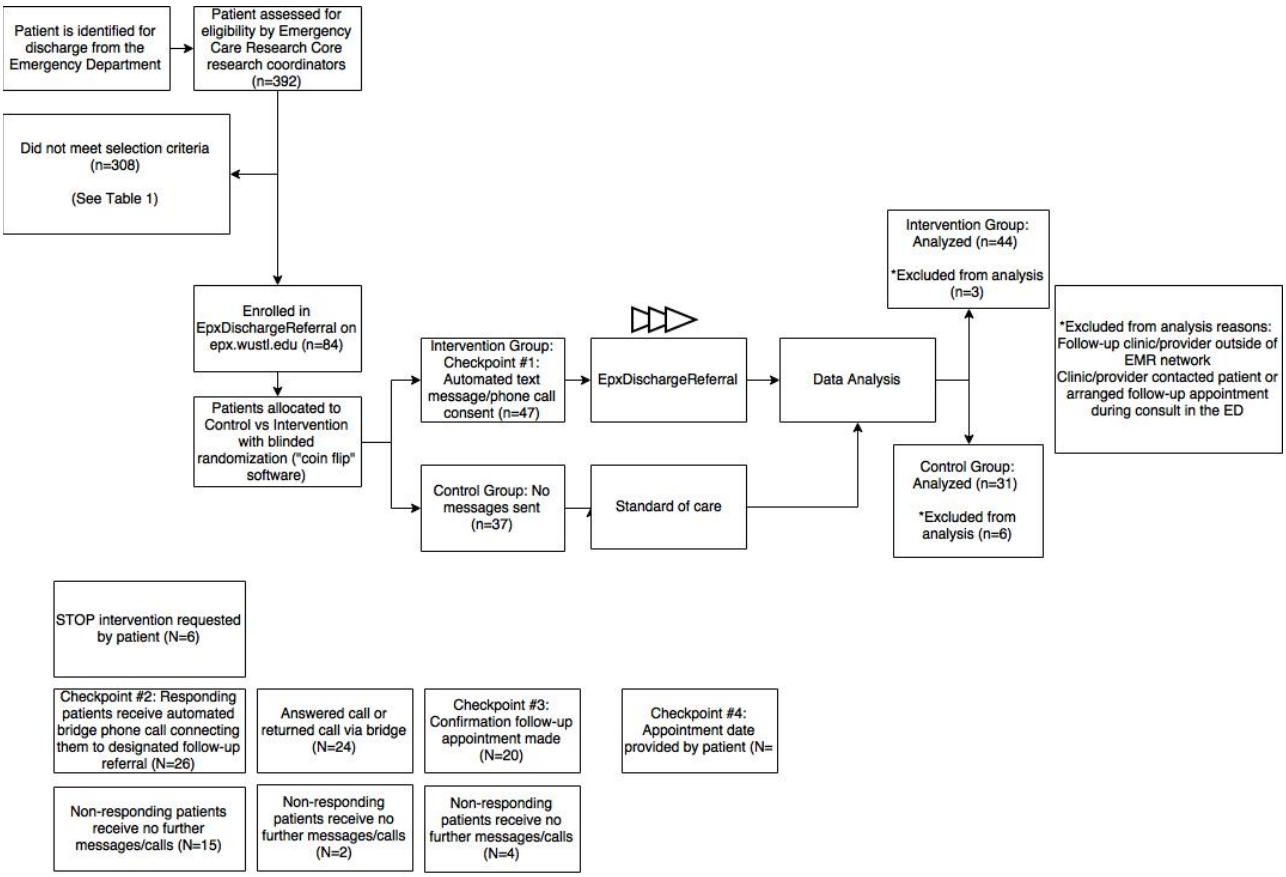
Do you agree to participate in this study?
If yes then:

Thank you! You will begin receiving messages or calls shortly.

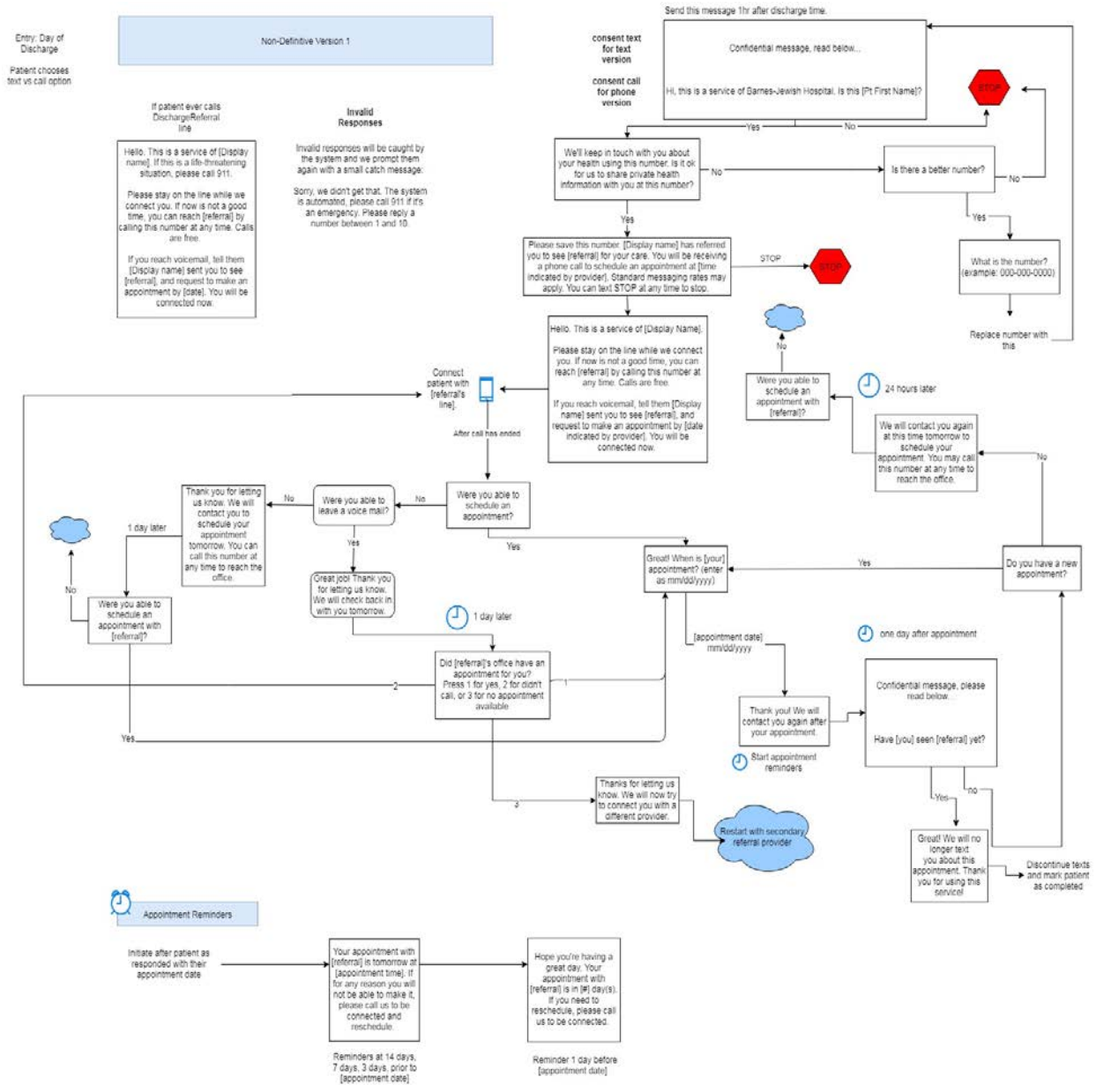
If no then:

Thank you. You will not receive any future messages or calls.

4. Pilot Study Timeline



5. Pseudocode



6. Adverse Events Log

Adverse Event Log

HRPO#: _____ Short Title: _____

Site Number: _____ Site: Washington University

Participant ID#: _____

This form is cumulative and captures adverse events of a single participant throughout the study.

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious Adverse Event (SAE)
1 = Mild 2 = Moderate 3 = Severe 4 = Life-Threatening	0 = Not related 1 = Unlikely related 2 = Possibly related 3 = Probably related 4 = Definitely related	0 = None 1 = Dose modification 2 = Medical Intervention 3 = Hospitalization 4 = Intervention discontinued 5 = Other	1 = Resolved 2 = Recovered with minor sequelae 3 = Recovered with major sequelae 4 = Ongoing/Continuing treatment 5 = Condition worsening 6 = Death 7 = Unknown	1 = Yes 2 = No	1 = Yes 2 = No (if yes, complete SAE form)

At end of study only: Check this box if participant had no adverse events ☐ None

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome of AE	Expected?	SAE?	Entered in Data-base?
									☐
									☐
									☐
									☐
									☐
									☐
									☐
									☐
									☐
									☐
									☐

7. Security Clearance

Information Security Office
IRB Study Security Report

*** IRB Study Security Report ***			
Date:	06/09/2015	**Security Event ID:**	20140131-01
Protocol:	IRB ID #: 201504079 Title: E-interventions and medical care		
Risk Rating:	☒Low ☐Med ☐ High ☐ Critical ☐ Not Yet Rated		
Requested By:	Avik Som		
Status:	Approved		

Event Handler Contact Information			
Name:	Denise Woodward	**Title:**	Information Security Manager
Phone:	314-362-0735	**Email:**	woodwardd@wusm.wustl.edu

Event Type		
☐ Transmission of PHI	☐ Third Party Review	☐
☒ Secure Storage	☐ Social Media Review	☐ Other (explain below)
☐ Process Review	☐	Other:

Review Notes	
Background	In addition to the scan we will need the following information to begin the assessment: 1. Study Number and/or Name (IRB ID #: 201504079 Title: E-interventions and medical care) 2. Identify what ePHI (electronic protected health information) data elements you will be collecting, storing or transmitting We will be collecting and storing name and phone number. These will not be transmitted. 3. Identify where the ePHI will be created, stored or

Information Security Office
IRB Study Security Report

	transmitted (network share, workstation, laptop, USB drive, external site) On the network server at epx.wustl.edu. 4. How is the ePHI protected (password protected document, encrypted USB Drive, Secure Transmission) Password protected site at epx.wustl.edu 5. Are you using social media for outreach No. 6. Will the information be stored on a WUSM supported device Epx.wustl.edu is hosted on WU servers In addition the database will store the date and time patients respond to outgoing automated phone call and text messages (using messages that have no PHI per review by Sondra Hornsey, WU HIPAA compliance officer). The system will store their responses, which can only be numerical or binary, but relate to health events, such as pain, glucose, or blood pressure measurements. This information won't be transmitted but should be stored in an encrypted fashion on the server. The password in the database is hashed and encrypted using the blowfish algorithm, so that it's not reversible. In addition the

Information Security Office
IRB Study Security Report

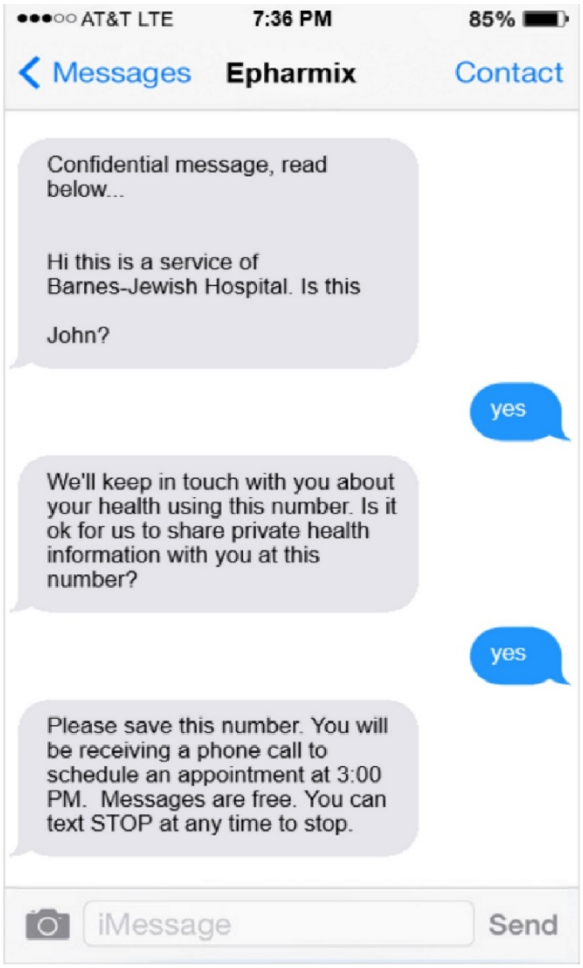
	connections to the site are SSL-encrypted, ensuring password safety in transmission.
Describe any risks	Low Risk

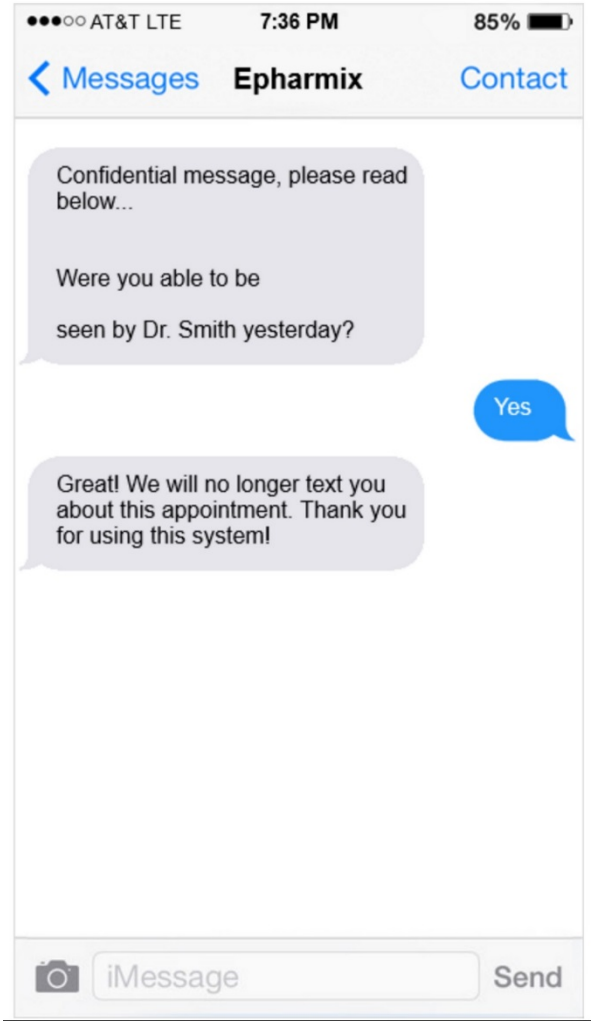
Additional Information
Protected Health Information must be encrypted in all locations or transmissions. PHI is defined as: patient name, date of birth, date of service, MRN, invoice number, social security number, address, email address, facial photos or other identifying photos or numbers. • Password protecting Microsoft Office Documents also encrypts those documents. • Large File Transfer and WUSTL Dropbox are approved methods for transmission. Business Associates Agreements may be required. We will contact the HIPAA Privacy Office for confirmation.

Recommendations
Annual scan of system and website.

Assessment
The review status is based upon data provided to the Information Security Office. If any changes occur, please resubmit for security review.

8. Text Message Example Screenshots




●●●○○ AT&T LTE
7:36 PM
85%
Messages
Epharmix
Contact
Confidential message, please read below...
Were you able to be
seen by Dr. Smith yesterday?
Yes
Great! We will no longer text you about this appointment. Thank you for using this system!
iMessage
Send