**OLIVE VIEW-UCLA MEDICAL CENTER**

EDUCATION & RESEARCH INSTITUTE

**INSTITUTIONAL REVIEW BOARD (IRB)**

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| **CONSENT FORM TO PARTICIPATE IN MEDICAL RESEARCH** |

**LAY TITLE: Emails and Text-Messages for Patients and Staff at Olive View-UCLA**

**OPENING**: You are invited to be part of this research study to help us learn if we can improve your health and experience as an Olive View patient by reducing repeat admissions to the emergency department or hospital. This project will automatically electronically notify your doctors and nurses when you visit the emergency department or are admitted to the hospital and send you a text message after you are discharged from the emergency department or hospital. We will also see if these processes make patients, doctors, nurses, and clinic staff more satisfied and help doctors, nurses, and clinic staff work better. This research will occur at Olive View-UCLA Medical Center(OVMC) with patients who have regular care at an Olive View adult primary care clinic.

Dr. Mark Richman, an emergency physician and adult general medicine physician who has worked at Olive View for 10 years is the Principal Investigator conducting this research study. This study is sponsored, in part, by the Center for Care Innovations and Blue Shield of California Foundation. The sponsors provide funding to pay for the costs of conducting this research study. Neither the investigators nor Olive View has any financial interest in the study.

**BACKGROUND AND PURPOSE OF THE STUDY**

How will we use automated email notifications?

This study is designed to see whether using automated emails to your doctors and nurses about your emergency department visit or inpatient admission reduce repeat emergency visits and hospitalizations by improving communication between doctors and nurses.

You are being asked to participate in this study because you receive or are assigned to receive your primary care medical visits at Olive View. All patients in this study will have had either an emergency department visit or inpatient admission or both. Currently, your primary care team members, such as your doctor or nurses, are not notified of these events. The process we are starting is to automatically notify your primary care team members by email, in real-time, of your emergency department and inpatient visits so they can communicate with the emergency physicians or inpatient physicians and coordinate care. The notifications will be triggered by events in the hospital’s electronic record system, such as registering at the emergency department or being admitted to the hospital. Because we do not know if this email notification process will reduce repeat emergency visits and hospitalizations, some patients will be assigned such that their doctors and nurses will be notified, and some patients will be assigned to usual (current) care (no notification occurs). The assignment to the notification group or usual (current) care group will be random, based on your medical record number. You may be assigned to the usual (current) care group. Approximately 75 patients will be recruited to the email notification group and 75 to the usual (current) care group. Patients will be followed for one year to see how often they visit Olive View. Only your doctors and nurses will receive email notifications about your emergency department or hospital visits.

How will we use text message notifications?

This study is designed to see whether sending patients text messages after their emergency department visit or inpatient admission reduces repeat emergency visits and hospitalizations by improving communication between patients and their doctors and nurses.

Shortly after you are discharged from the emergency department or inpatient visit, we will send patients text messages with their clinic’s phone number and a second text message asking if they already have a scheduled follow-up appointment within 7 days with a primary care provider or specialty care provider and a prescription for enough medications to last until that visit. Patients will be asked to respond to this second message. If they do not have a visit within 7 days or a prescription for enough medications to last until their next appointment, they will be instructed by text message to call their clinic for an appointment. Your doctor or nurse may review your text message replies. If we do not get a response back from you, we will send you another text message in 2 days. If we still do not get a response back from you, we will send you another text message in 2 days. That will be the last text message regarding that emergency department or inpatient visit. If you return to the emergency department or are admitted again to the hospital, the text message process will start over.

Current practice is that patients discharged from the emergency department or hospital ward are not contacted through text messaging. Because we do not know if this text message process will reduce repeat emergency visits and hospitalizations, some patients will be assigned such that they are receive text messages, and some patients will be assigned to usual (current) care ( no text messages from the hospital). The assignment to the text message group or usual (current) care group will be random, based on your medical record number. You may be assigned to the usual (current) care group. Approximately 75 patients will be recruited to the text message group and 75 to the usual (current) care group. Patients will be followed for one year to see how often they visit Olive View. Your doctors and nurses will have access to your text message replies.

A few patients will be contacted after discharge from the emergency department or inpatient visit for an interview to ask about their healthcare experience after discharge.

Only people who choose to take part in the interview will be included in the research study. Your participation in this study is entirely voluntary. Choosing not to participate in the interviews will not affect your care or your ability to access care at Olive View. You should read the information below and ask questions about anything you do not understand before deciding to participate.

**PROCEDURES**

If you choose to volunteer for the interviews, we will do the following:

* + Call you to arrange a convenient time to interview you at Olive View
  + Interviews should take about 30 minutes. However, some patients may want to describe their situations in more detail. Therefore, you should allocate 1 hour for interview time.
  + Keep your personal identification information (for example, name, medical record number) anonymous in all communications outside of those who need to use it for clinical care or to study the effect of this new process on your health and experience at Olive View.

**When will the study start and end?**

The automated email notifications, and the text messaging, will start between January and June 2014. Patients may be called for an interview as early as spring of 2014 and as late as summer of 2015. The interview part of the study will begin once you sign the consent form.

**RISKS AND DISCOMFORTS**

**What risks could happen if you agree to be in this study?**

This is to inform you of the risks and discomfort that you may reasonably expect as a part of the study.

* Your health information will be secured. However, it is possible, but unlikely, that someone might obtain information about you who does not have permission.

**POTENTIAL BENEFITS TO PARTICIPANTS AND SOCIETY**

**What do you get from the study? (Benefits)**

The potential benefits from participating in the study may include:

* You may express concerns about the coordination or your care that could lead to changes in how the hospital coordinates care such that if you return to the emergency department or are admitted again to the hospital, the care coordination will be improved

**ALTERNATIVES TO PARTICIPATION**

**If you choose not to participate:**

You will receive usual care. Your participation in this study will in no way influence the care received by you or your family at any LAC DHS facility.

**PAYMENT FOR PARTICIPATION**

**Do you get paid for being part of the study?**

No. You will not receive any money for taking part of this study.

**FINANCIAL OBLIGATION**

**Do you have to pay for any procedures done as part of the study?**

No procedures are part of this study. You will have to pay for the original care that you seek. You may have to pay for each text message if your plan with your cell phone company does not already cover text messages. We will not be responsible for any text-message related charges.

**PRIVACY AND CONFIDENTIALITY**

**How will we keep your information private?**

The only people who will know that you are participating are members of Olive View’s clinical staff (for example, doctors and nurses), the research team, and our text message providers. For those patients who are contacted for an interview, the doctors and nurses will not know this, or whether you agreed to the interview, or the interview content linked to your specific name or medical record number. No information about you, or provided by you, during the research will be disclosed to others without your written permission except:

* If necessary to protect your rights or welfare (for example, if you are injured or need emergency care)
* Or—if required by law

When the results of this study are published or discussed in conferences, no information will be included that would reveal your identity.

We need to share information with the sponsor of the study, the Center for Care Innovations, but what we give to them will not have your name or other specific information on it.

**PARTICIPATION AND WITHDRAWAL**

**Taking part in the study is up to you**

Your participation in this research is VOLUNTARY. If you choose not to participate, it will not affect your relationship with Olive View-UCLA ERI, Olive View-UCLA Medical Center, or Los Angeles County, or your right to health care or other services to which you are entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at Olive View-UCLA Medical Center.

**WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The investigator, Dr, Mark Richman, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

**NEW FINDINGS**

During the course of the study, you will be informed of any important new findings (either good or bad), such as changes in the risks or benefits from participation in the research, or new alternatives to participation. If new information is provided to you, your consent to continue participating will be re-obtained.

**IDENTIFICATION OF INVESTIGATORS**

**Who answers your questions about the study?**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact the Principal Investigator, Dr. Mark Richman, at Olive View-UCLA Medical Center at 818-364-3205 or Research Assistant Khathy Hoang at 818-364-3568.

**RIGHTS OF RESEARCH PARTICIPANTS**

**What are your rights as a research participant?**

You may withdraw your consent to participate in this research study at any time without penalty and you will receive the current standard of care. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, you may contact the OV-UCLA Education and Research Institute, Research Administration Office, 14445 Olive View Drive, Sylmar, CA 91342-1495, 818-364-3434.

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| **SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE** |

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Participant's Bill of Rights.

**BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.**

Name of Participant Signature of Participant

Name of Legal Representative (if applicable) Signature of Legal Representative

Date

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| **SIGNATURE OF PERSON OBTAINING CONSENT** |

I have explained the research to the participant or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Name Position

Signature Date