Using telehealth to expand treatment access for Veterans with opioid use disorder (CDA 18-008)

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December 13, 2018

Department of Veterans Affairs Research Information Sheet		VAAAHS Research IRB Approved 12/13/2018 
Title of Study:	Using telehealth to expand treatment access for Veterans with opioid use disorder (Provider)	
Principal Investigator:	Lewei (Allison) Lin, MD, MS	**VAMC**: VA Ann Arbor Healthcare System

PURPOSE OF RESEARCH STUDY
The purpose of the study is to learn more about developing an effective telehealth model of medication treatment for Veterans with opioid use disorder (OUD). We are conducting interviews with both patients and providers and the information in this form is for providers. The purpose of this study is to gather various stakeholders' perspectives about use of telehealth in delivering treatment to Veterans with OUD. Telehealth is a way of receiving treatment where patients see and talk with their provider in another location through a screen or computer monitor (rather than in person). You are invited to participate because of your role as a VA healthcare administrator or clinical staff involved in telehealth care for Veterans with OUD.

DESCRIPTION:
We plan to enroll up to 28 administrators and providers from VA hospitals and clinics around the country. If you decide to participate, we will ask you to complete an interview, which will take about 30-40 minutes. The interview will be audio-recorded. There may also be a second person who will be taking notes throughout the interview. You will be asked to share your experiences using telehealth treatment delivery, your views about barriers to and facilitators in using telehealth to deliver OUD treatment, and ways we can improve treatment access for Veterans. Your responses will be combined with responses of staff members from other sites.

RISKS:
The major risk of this study is loss of confidentiality. The researchers will try to minimize this risk by asking you not to give your name or any information that would allow someone to determine your identity in the audio recording. Audio-recordings will be uploaded onto a secure computer server and stored in a password-protected file until they are transcribed. After transcription, audio recordings will be deleted. Any identifying information will then be deleted from the written transcript and this transcript will also be stored in a password-protected file. You will be assigned a unique study ID, and only this ID will be stored with study data. Identifying information will be stored in a separate, password-protected file.

Some participants may feel uncomfortable answering certain questions about the organization at which they are employed. There will be no adverse employment consequences; no supervisors will know who or who is not participating in this study. You may refuse to answer any questions or choose to have the recording device turned off during the course of the interview. You may take a break at any time during the research session and may also stop the session at any time.

We may be required to break confidentiality if we believe that there is a risk of harm to yourself or someone else (for example, you may harm yourself, someone else, or someone is harming you, or in cases of child or elder abuse).

As with any research study, there may be other risks that are unforeseeable at this time.

To help us protect your privacy, we will apply for a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: if you disclose intent to hurt yourself, others, or if you are being hurt.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

BENEFITS:
Your participation in this study may help us to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by participating in this study.

ALTERNATE COURSES OF ACTION:
You do not have to participate in this study. You may withdraw from the study at any time without penalty. Whether or not you choose not to participate in this study, your decision will not affect your employment at the VA.

STATEMENT OF RESEARCH RESULTS:
Research data collected as part of this study will be stored according to the privacy and security guidelines established by the VHA. Data on paper will be stored at the Ann Arbor VAMC in locked filing cabinets. All electronic study data will be kept in restricted access and password protected files and stored on the VA network server at the Ann Arbor VAMC. Only authorized research staff will have access to your research data and research files. Unique ID numbers will be substituted for names for identification purposes to protect your confidentiality in the data file.

Researchers from the VA Ann Arbor Health Care System will analyze the data collected from this study. If the results of this study are reported in medical journals or at meetings, you will not be identified by name or by any other means.

SPECIAL CIRCUMSTANCES:
The investigators of this study may have to end your participation in this study for reasons such as: if it is in your best interest; you do not follow the study plan (e.g., do not complete the interview); the investigator decides that continuation could be harmful to you; other administrative reasons; or other unanticipated circumstances. If you are withdrawn from the study, it will not affect your employment at the VA.

COMPENSATION: The interview will be unpaid with no costs to you.

STUDY CONTACT INFORMATION:
If you have questions, concerns or complaints about the research study, you can contact the principal investigator: Dr. Allison Lin at {PHONE}. The sponsor of this research study is Veterans Administration.

You may contact the VA Human Studies coordinator at {PHONE} to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

Department of Veterans Affairs Research Information Sheet

Title of Study:	Using telehealth to expand treatment access for Veterans with opioid use disorder (Patient)	
Principal Investigator:	Lewei (Allison) Lin, MD, MS	**VAMC**: VA Ann Arbor Healthcare System

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?
The purpose of the study is to learn about ways to improve treatment programs for Veterans with opioid use disorder (OUD) and other substance use disorders (SUDs). We are conducting interviews with patients and providers to gather views about using telehealth in treatments. The information in this form is for patients.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?
We plan to enroll up to 70 patients from VA hospitals and clinics around the country. If you decide to take part in the study, we will ask you to complete one telephone interview, which will take about 30-40 minutes.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Taking part in this study may help us to improve services for Veterans in the future. However, we cannot and do not guarantee or promise that you will benefit by taking part in this study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
You may feel uncomfortable when answering questions, such as questions about your experiences with a SUD. This type of discomfort is expected to be temporary. You may refuse to answer any questions that make you uncomfortable or that you do not wish to answer. You may take a break at any time during the interview and may also stop at any time.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Allison Lin of the VA Ann Arbor Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: {PHONE}

RESEARCH DETAILS

You are being asked to participate in a research study conducted by Dr. Allison Lin at the VA Ann Arbor Healthcare System. We are conducting a study to learn about ways to improve treatment programs for Veterans with opioid use disorders (OUD) and other substance use disorders (SUDs). Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?
We are conducting a research study to gather views about using telehealth in treatments. Telehealth is a way of receiving treatment where you see and talk with your provider in another location through a screen or computer monitor (rather than in person). We would like to speak with Veterans to better understand experiences they have had with treatment for OUD and other SUDs. You have been invited to participate in this research study because you may have received this type of treatment from the VA or can provide thoughts to help inform this type of treatment.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?
If you agree to participate, we will ask you to complete one telephone interview, which will take about 30-40 minutes. The interview will be audio-recorded. There may also be a second person who will be taking notes throughout the interview. During the interview we will ask about topics such as your opinions on treatment you have received, decisions and attitudes about seeking treatment, your views on telehealth treatment, and your ideas about what could make treatment better for other Veterans. Your responses will be combined with responses of patients at other sites to help us understand how to make OUD and other SUD treatment better.

ARE THERE ANY RISKS OR DISCOMFORTS?
As part of the interview, you will be asked about your personal experiences related to OUD and other SUD treatment. However, you will not be expected to discuss any topics that make you uncomfortable or that you do not wish to discuss. You can also leave the interview at any time. The interview will be audio-recorded so that it can be transcribed into written form and analyzed later. The researchers will take many steps to be sure your information remains confidential. As with any research study, there may be other risks that are unforeseeable at this time.

ARE THERE ANY BENEFITS?
You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers understanding of improving treatments for patients with SUDs.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?
The information collected for this study will be kept confidential. We have taken many steps to prevent breaches of confidentiality, including storing your name separately from study data and keeping all data in a locked cabinet and on a secure computer server in a limited access protected file. We will ask you to not to give your name or any information that would allow someone to know who you are in the audio recording. Because your identity might be determined from your voice, audio-recordings will be transferred onto a secure computer server and stored in a password protected file until they are transcribed into written form. Any identifying information will then be removed from the written transcript. This transcript will also be stored in a password protected file.

We may be required to breach confidentiality if we believe that there is a risk of harm to yourself or someone else (ex. you harming yourself or someone else or someone else is harming you). We may be required to inform your regular care providers or other authorities to protect you or others. If you are having thoughts about harming yourself, you can call the Veteran's Crisis Line at 1-800-273-8255 and press 1.

To help us protect your privacy, we will apply for a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: if you disclose intent to hurt yourself, others, or if you are being hurt.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Research data collected as part of this study will be stored according to the privacy and security guidelines established by the VHA. Data on paper will be stored at the Ann Arbor VAMC in locked filing cabinets. All electronic study data will be kept in restricted access and password protected files and stored on the VA network server at the Ann Arbor VAMC. Only authorized research staff will have access to your research data and research files. Unique ID numbers will be substituted for names for identification purposes to protect your confidentiality in the data file.

SPECIAL CIRCUMSTANCES: The investigators of this study may have to end your participation in this study for reasons such as: if it is in your best interest; you do not follow the study plan (e.g., do not complete the interview); the investigator decides that continuation could be harmful to you; the study is canceled; other administrative reasons; or other unanticipated circumstances. If you are withdrawn from the study, it will not affect your treatment from your providers at the VA.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?
You will receive a $25 gift card for your time to complete the interview.

WHO CAN I TALK TO ABOUT THE STUDY?
If you have questions, concerns or complaints about the research study, you can contact the principal investigator: Dr. Allison Lin at {PHONE}. The sponsor of this research study is Veterans Administration.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA IRB Coordinator at {PHONE}.