Permission to Take Part in a Human Research Study

Title of research study: A clinical trial to validate an automated online language interpreting tool with Hispanic patients who have limited English proficiency – Phase Two.

Investigator: Peter Yellowlees, M.B.B.S, M.D.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are 18 or older, Hispanic, primarily Spanish-speaking, and have been referred by your primary healthcare provider to have an evaluation by a psychiatrist.

What should I know about a research study?
(Experimental Subject's Bill of Rights)
• Someone will explain this research study to you, including:
- The nature and purpose of the research study.
- The procedures to be followed.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.

• Whether or not you take part is up to you.
• You can choose without force, fraud, deceit, duress, coercion, or undue influence.
• You can choose not to take part.
• You can agree to take part now and later change your mind.
• Whatever you decide it will not be held against you.
• You can ask all the questions you want before you decide.
• If you agree to take part, you will be given a signed and dated copy of this document.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:
Michelle Burke Parish, Project Manager (916) 703-5577
Peter Yellowlees, Principal Investigator (916) 734-8581(day)

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011. The TDD line for hearing or speech impaired is 916-451-1974),, tell the Operator you are participating in a research study and you wish to talk to Dr. Peter Yellowlees in the Department of Psychiatry. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand research is on-line at

http://www.research.ucdavis.edu/IRBAdmin.You may talk to a IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

Through conducting this research, we hope to learn more about new approaches to providing psychiatric consultations to Spanish-speaking populations.

How long will the research last?

We expect that you will be in this research study for approximately half a day.

How many people will be studied?

We expect about 100 people will be in this research study.

What happens if I say yes, I want to be in this research?

Screening and enrollment*:*

- You will be interviewed in Spanish by a researcher to see if you will be considered as a candidate for this study. The appointment will consist of a mental health assessment telephone or in-person interview which will take approximately half an hour. You are to answer the questions asked in the interview as accurately as possible and should feel free to ask the researcher any questions that you wish or to decline to answer any question you do not wish to answer.
- Based on your answers to the interview questions, the researcher will determine if you will be selected for participation in this study.
- After the interview, if the researcher determines that you are not to be included in the study, you will no longer be contacting about participation.

Participation:

- Once included in the study, your treatment group will be assigned and explained to you by the psychologist of researcher under his/her direct supervision.
- You will be scheduled for your half-day research appointment.
- You will receive two psychiatric interviews, the order of which is determined by which group you are randomized in to, and both of which will be video-recorded. The two psychiatric interviews include: Method A (conventional in-person interview with a psychiatrist and a human interpreter) and Method B (asynchronous telepsychiatry — that is, a video-recorded interview with a non-psychiatrist mental health professional that is subsequently processed with automated speech recognition and machine translation technologies).

• Group enrollment is randomly chosen and pre-determined. Participants will not be able to request placement in a particular treatment group.
• You will also be asked by the clinician or researcher to complete several survey assessments in Spanish or English and to respond to a semi-structured interview in Spanish
• There will be a total of 1 study assessment appointment that will last approximately 4-5 hours, after which you will be compensated for your time.
The video-recordings of the interviews will be analyzed by the researchers to compare the quality and effectiveness of the interviews and the interpretations and translations and will be kept securely in accordance with IRB requirements.

Please note that your participation in this study is purely voluntary and we expect that you will participate during the entire time but, should some unforeseen set of circumstances arise, please notify the researcher to discuss this matter with them as soon as possible.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:
• Complete the study assessment as scheduled

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can take you out of the study.

Is there any way being in this study could be bad for me?

Potential risks include ensuring the participant's ability to consent, the collection of sensitive mental health information, stigmatization in being involved in a psychiatric research project, and the time required to complete procedures. Overall, the risks are minimal with the use of the proposed study procedures. Use of technology: There are no significant risks in the technical procedures as subjects will only be involved in interviews which will be recorded, all transfer of data electronically will be in accord with HIPAA requirements.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improvement in mental health symptoms for you, and improvement in mental health services for others.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise

complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

The sponsor, monitors, auditors, the IRB, and the National Institutes of Health will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in this research. If you have given your consent for an insurer or employer to obtain information about you, the Researcher may not withhold this information. Confidentiality also does not prevent a Researcher from disclosing information about you to prevent serious harm to yourself or others, such as reporting to the authorities' incidents of child abuse, elder abuse or spousal abuse.

Can I be removed from the research without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to complete the study obligations or inappropriate conduct with study staff of other participants.

What else do I need to know?

This research is being funded by the Agency for Healthcare Research & Quality **(**AHRQ**)**, also called the sponsor. Sponsors may change or be added. There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department. Only the costs of the research related evaluations conducted by research staff and the psychiatric consultations will be covered by the study.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

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It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

If you agree to take part in this research study, we will compensate you in one of two options. The first is a $75 check that will be mailed to you after filling out our compensation form along with a W-9 form. The second option is a gift card for $75 dollars towards Amazon.com. This will either be handed to you directly after the study session has concluded or will be sent in an electronic format via email. Both require you to fill out our compensation form. You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional. (initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is:

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Document Revision Date: July 12, 2013

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1131922	November 14, 2017

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