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CONSENT TO PARTICIPATE IN RESEARCH – STAFF FORM

Study Title: Scaling Up Science-based Mental Health Interventions in Latin America

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and Lisa A. Marsch, PhD, Dartmouth College, USA

Introduction: You are being asked to take part in a research study. Your participation is completely voluntary.

You are being asked to take part in this study because you work at one of the health care clinics [insert clinic name here] participating in the study and will be implementing a new model of care for patients with depression and/or problematic alcohol use.

Your participation is completely voluntary. Your decision to participate in this study will not affect your employment status at this health care center. You may say “no” to answering any questions. If you agree to participate, you may stop being a participant in the study at any time.

Before you decide to be in this study, please read the following information carefully. Feel free to ask a member of the research team any questions you have about what it means to be in the study. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of this study is to understand your experiences and thoughts on implementing a new way to offer care for depression and problematic alcohol use to patients in primary care health care systems in Colombia. This study will be conducted in multiple health care systems in urban, semi-urban, and rural areas of Colombia. We expect to enroll approximately 30 clinical staff in this study across all participating health care sites in Colombia.

This new model of care will involve training health care providers at this health care site on effective ways to care for depression and problematic alcohol use. This new model may also involve providing patients with medications for depression based on clinical guidelines for treating depression in Colombia. And this will involve providing patients with access to a web-based, computer-based program (called Laddr) that helps them learn new skills and strategies they can use to help change their depression and/or problematic alcohol use. The skills and content offered in this program have been shown to be effective in prior scientific research.

Will you benefit from participating in this study?

There are no direct benefits to your participation. Being a participant in the study and sharing information with us will help us learn more about effective ways to offer care for depression and problematic alcohol use to patients in primary care health care systems. We aim to gather information that may help health care systems like yours in the future.

What does this study involve?

Your participation in this study may last up to one year. You will be asked to answer these questions at the time your health care site first joins the study and every 6 months thereafter as long as the study is being conducted at your health care site.

If you agree to participate in this study, you will be asked to answer questions to help us better understand how helpful this model of care is. For example, you will be asked to answer questions about how well the model of screening and providing resources for depression and problematic alcohol use fits within the workflow of your organization. You will be asked your opinions about the potential benefit of this model of care and its potential impact on the quality and scope of patient care at your health care center.

You will be asked to answer these questions on a computer (or on paper if a computer is not available). It should take about 15-20 minutes to complete these questions each time you are asked to complete them.

What are the options if you do not want to take part in this study?

You do not have to participate in this study. If you elect not to participate in this study, you may continue your work as usual at your place of employment.

If you take part in this study, what activities will be conducted only for research purposes?

If you take part in this study, the answers that you provide (described above) will be collected for research purposes only.

What are the risks involved with taking part in this study?

There are no physical, social or economic risks associated with participation. However, you may find some of the questions uncomfortable. You do not have to answer any questions that make you feel uncomfortable. You may be concerned that your answers will be shared with your co-workers or supervisors. You should understand that you can choose to not answer a question. You can choose to discontinue your participation in the study at any time. We do not plan to share your answers with your co-workers or supervisors in any way that links to your name. Rather, we may share summary feedback from all employees at your health care site who participate in this research with your co-workers or supervisors.

There is a small chance that your private information may be seen by people who are not members of the research team (individuals who are conducting or who oversee the research). We do everything we can to safeguard your information. We describe our efforts to protect your information in the section below called, "How will your privacy be protected?"

Other important items you should know:

- **Leaving the study:** You will have the freedom to withdraw or leave the study at any time, without any penalty and without affecting your employment with the health center.

If you choose to stop taking part in this study, you may cancel permission for the use of your information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

- **New Information:** New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

- **Funding:** The U.S. National Institute of Mental Health at the National Institutes of Health is the sponsor of this research.

One of the Principal Investigators of this project (Dr. Marsch) has an affiliation with Square2 Systems, Inc., the company that developed the Laddr mobile intervention, which is a component of the model of care you are being asked about. Dr. Marsch's affiliation with this company is extensively managed by her academic institution, Dartmouth College in the U.S.

How will your privacy be protected?

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential, except as ruled by law (such as if you express suicidal intent, intent to physically harm another person or indicate that someone is physically harming you).

Your name will never appear in documents, publications, or presentations that come out of the study. The information will be used only for scientific purposes by the persons responsible for this research and will never be shared with your name or other details that may identify you.

The persons responsible for this research include a team of researchers at Javeriana University, Dartmouth College in the U.S. and the National Institute of Mental Health in the U.S.

Collected digital data (audio recordings) will be securely stored on a data server at Javeriana University. The Direction of Information Technology at Javeriana University follows all national and international safety standards for data protection, including assistance in security informatics related to research projects. The procedures of the Direction of Information Technology are available at: <http://www.javeriana.edu.co/dir-tecnologias-de-informacion/asistencia-de-seguridad-informatica>. The protection of personal data collected in this project will follow the Colombian regulation laws on data protection: Law 1581 of 2012 and the regulation 1377 of 2013.

Analog data (notes from the interviews) will be kept in a locked facility inside the Department of Epidemiology and Biostatistics in the Javeriana University Hospital Universitario San Ignacio building. Only the facilitator and members of the qualitative research team will have the code to access the analog information. Notes taken during the interviews will be digitized and stored with the audio recordings. The transcribed notes of interviews will contain no information that could identify you.

We will keep all information you give us in our secure, encrypted databases under a study number, not your name. The name-number code will also be kept secure so that no one outside of the research team can find out how you answered the questions. We will NOT disclose the information you provide to anyone outside the research team.

Your information will be transferred in encrypted form to the researchers at Javeriana University. This information will not include your name, and will be sent via secure electronic data transfer to protect your privacy.

The information collected for this study will be used only for the purposes of research as stated earlier in this form.

There may be other times when we cannot keep your information private. If we determine that you or someone else is in danger, we will tell someone who can help. If we think that a child or adult who cannot care for themselves is being exploited, abused, or neglected, we will tell someone who can help.

This study is reviewed every year by groups that are dedicated to the safety of the participants in research studies and also to ensure the study is being conducted correctly. These groups are permitted to review your private information (if needed). In this study, those groups or agencies are:

- Javeriana University's Institutional Review Board
- Dartmouth College Committee for the Protection of Human Subjects
- U.S. National Institute of Mental Health's Data and Safety Monitoring Board

To help us keep your information private, we will request a special certificate. It is called a Certificate of Confidentiality. It comes from the National Institutes of Health in the United States (U.S.) and can be used to legally refuse to disclose information that may identify you in any proceedings of the U.S. government (federal, state, or civil, criminal, administrative, legislative, or other proceedings). We will use the Certificate to further help keep your information private. A Certificate of Confidentiality only protects data stored in the United States.

Who may use or see your health information?

This study will not collect information on your personal health.

To help us keep the information you give us private, we will request a special certificate. It is called a Certificate of Confidentiality. It comes from the National Institutes of Health in the United States (U.S.). We will use the Certificate to further help keep your information private. A Certificate of Confidentiality only protects data stored in the United States.

Data Sharing: Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that information like your name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental health more quickly than before.

During and after the study, the researchers will send deidentified information from your participation in this research to NDA. Other researchers in the U.S. can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental health challenges so that they have better outcomes. NIMH will also report to U.S. Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who are conducting this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available online at <http://data-archive.nimh.gov>.

Whom should you call about this study?

In case of any situation that prevents you from continuing to participate in the study, please contact the individuals responsible for this study: Dr. Sergio Castro at 320-8320 ext. 2812 or sergiomariocastro@gmail.com and/or Dr. Magda Cepeda at 57-301-362-1356 or by email at mccepedag@gmail.com.

If neither Dr. Castro nor Dr. Cepeda are, other members of the research team will be available to answer your questions during normal business hours at 320-8320 ext. 2827.

If you have questions, concerns, complaints, or suggestions about human research at Javeriana, you may call the Institutional Review Board at 571 5946161 Ext 2741 or +571 2879227 during normal business hours.

What about the costs of this study?

There is no cost to you for participating in this study.

Will you be paid to take part in this study?

You will not be provided any additional compensation for participating in this study.

What happens if you get sick or hurt from taking part in this study?

This study is being conducted by researchers at Javeriana University and Dartmouth College (U.S.) with funds from the U.S. National Institute of Mental Health at the National Institutes of Health. The researchers do not anticipate that you will get sick or hurt from taking part in this study, as none of the research being conducted is considered harmful to you.

If you are injured or become ill as a result of this research, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment:

- Your health care clinic
- U.S. National Institute of Mental Health
- Javeriana University
- Dartmouth College

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

SIGNATURE OF INFORMED CONSENT

I have read the above information about “Scaling Up Science-based Mental Health Interventions in Latin America” and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this consent form.

Participant's Signature and Date

PRINTED NAME

Researcher or Designee Signature and Date

PRINTED NAME

Witness Signature and Date

/

PRINTED NAME

Witness Relationship to Participant

/

Witness Address