Title of research study: Positive Solutions:COPA2
Document Version Date: October 22, 2018
NCT Number: NCT02846350

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Investigators: ***Deborah Jones (PI) at the Department of Psychiatry & Behavioral Sciences, Miller School of Medicine***

Purpose: This research study will test the usefulness and impact of skill-training for doctors to improve HIV care among patients. This study will recruit 420 patients and 36 doctors in 6 clinics in Argentina.

Procedure and Study Visits: If you agree to participate in this study, you will be asked to do the following:

1) Have an audio/video recording at 5 regularly occurring consultations with your doctor, who is also participating in the study.
2) Complete 5 computer assessments. The assessments will ask about general information, any use of drugs or alcohol, psychological issues, your use of medication and your relationship with your doctor.
3) Provide permission for access to your medical records to assess your use of medication and your laboratory results.

Time: We expect that each study visit will be 30 minutes. You will participate for a period of 24 months, when you start being in the study, and every 6 months for a total of 24 months (study start, 6, 12 18, 24 months).

Risks: There is little risk to be expected while you are participating in the study. During the assessment, you may get sad or nervous when discussing HIV/AIDS-related information.

Should you any tell the study staff that you are going to harm yourself, or that you are experiencing anxiety or depression, you will be immediately referred and evaluated by a psychiatrist, psychologist, counselor or other qualified health care provider at your clinic. Following this evaluation, if the provider feels it is important, you will be referred for further assessment and/or hospitalization, or, if not in immediate danger of harming yourself, will be referred for outpatient counseling/treatment. The clinic has licensed psychiatrists, psychologists, physicians and nurses working during all regular clinic hours.

In order to reduce the chance or any risk to your privacy or confidentiality, all study discussions with you will be kept strictly private.

Benefits: We cannot promise any benefits to you or others from your taking part in this research. However, information obtained from this study contribute to knowledge related to engagement and retention in care and medication adherence.

Alternative treatments: You have the alternative choice not to participate in this study. If you do not choose to participate in this study you will still be able to receive your regular medical treatment and your decision will in no way affect the quality of your care.

Compensation: You will be paid $10 (145 pesos) for the visit that includes an assessment to compensate you for your time, effort and transportation expenses.

Compensation for injury: Although risks associated with participating in this study are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

Confidentiality: Your consent to participate in this study includes agreeing to allow the investigators and their assistants to read the results of your interview questions for the study. We will try to limit the use and sharing of your personal information, including research study and medical records, to people who have a need to see your information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB/Ethics Committee and other representatives of this organization.

We will keep a separate record of your address, telephone number and contact person information. When attempting to contact you for follow-up visit reminders, we will not share the reason for the phone call or letter, and the information we share will not identify your health status.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Withdrawal from the study: Participation in this study is voluntary. If you do not wish to participate, you will not lose any benefit that you are entitled to. You are free to withdraw or drop out of the study at any time, and if you do, there will be no penalty for you. If you decide to leave the study, contact the investigator or study staff so that you will not be contacted any further. The investigators also have the right to remove you from the study without your agreement if they feel that it is in the best interest for

you medically, or for administrative reasons. Information that has been collected during your participation in the study prior to your withdrawal will be retained by the investigator.

Questions: We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team.

Helios Salud	**Fundacion Huesped**
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This research has been reviewed and approved by an Institutional Review Board ("IRB"). Please contact the University of Miami Human Subject Research Office at (305) 243-3195 if:

- You wish to talk to someone other than the research staff about your rights as a research subject.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to provide input concerning the research process.

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	IRB Approval Date