

Teachers College, Columbia University
525 West 120th Street
New York NY 10027
212 678 3000

Verbal Consent Exempt Survey, Interview, or Focus Group Research

Protocol Title: Measurement-based care to engage racial and ethnic minority youth in mental health treatment for depressive disorders: A pilot study

Principal Investigator: Dr. Perna G. Arora, Ph.D., Teachers College 212-678-3086,
pa2542@tc.columbia.edu

INTRODUCTION

You are being invited to participate in this research study called “Measurement-based care to engage racial and ethnic minority youth in mental health treatment for depressive disorders: A pilot study.” You have qualified to take part in this research study because you are a licensed mental health professional OR are supervised by a licensed mental health professional to provide outpatient depression treatment for a caseload of 50% or more racial or ethnic minority youth (for example, youth that identify as Black or African American, American Indian or Alaska Native, Asian American, Native Hawaiian or Other Pacific Islander, Hispanic or Latinx) and you are fluent in English. Approximately ten clinicians will participate in this study and it will take one hour of your time to complete.

WHY IS THIS STUDY BEING DONE?

The aim of the study is to improve depression treatment for racial and ethnic minority teens. Our goal is to find treatment practices that therapists can use to help racial and ethnic minority teens stay in treatment and get the individualized help they deserve.

WHAT WILL I BE ASKED TO DO IF I AGREE TO TAKE PART IN THIS STUDY?

If you decide to participate, you will participate in one confidential phone interview with a member of the research team. You will hear or read scenarios of therapists, teens, and their parents in treatment. The scenarios involve therapists working with the teen and parent to fill out and use surveys about the teen’s depression and other issues they want to work on in therapy. The interviewer will then ask you questions about each of these scenarios. The interviewer will read the scenarios aloud to you, but also provide you with a written copy of the scenario. You can choose whether you want to receive a copy of the scenarios and questions by google voice text, email, or mail. This interview will be audio-recorded. After the audio-recording is written down the audio-recording will be deleted. If you do not wish to be audio-recorded, you will not be able to participate. The interview will take approximately one hour and will be conducted over the phone or via zoom.

Do you have any questions so far?

WHAT POSSIBLE RISKS OR DISCOMFORTS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Teachers College, Columbia University
Institutional Review Board

Protocol Number: 20-414
Consent Form Approved Until: No Expiration Date

This is a minimal risk study, which means the harms or discomforts that you may experience are not greater than you would ordinarily encounter in daily life while taking routine physical or psychological examinations or tests. However, there are some risks to consider. You might feel discomfort if any of the scenarios remind you of a challenging moment you have experienced or are experiencing with one of your clients. However, you may choose not to answer any questions you do not wish to answer and you can end the interview at any time.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

There is no direct benefit to you for participating in this study. Participation may benefit depression treatment for racial and ethnic minority teens.

WILL I BE PAID FOR BEING IN THIS STUDY?

You will be paid with a \$30 amazon gift card for your participation. There are no costs to you for taking part in this study.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

The study is over when you have completed the interview. However, you can leave the study at any time even if you haven't finished. You will not be paid if you are unable to finish the interview.

PROTECTION OF YOUR CONFIDENTIALITY

We, the research team, are taking precautions to keep your information confidential and prevent anyone from discovering or guessing your identity, such as using an ID number on all written materials instead of your name and keeping all information on a password protected computer and locked in a file drawer.

This study is voluntary. You do not have to be in this study. And if you decide to be in this study and want to stop part way, you can do so, without penalty. You can choose to skip any question you do not wish to answer.

HOW WILL THE RESULTS BE USED?

The results of this study will be published in journals and presented at academic conferences. The results will also be presented in aggregate to the site administrators to inform continuous quality improvement. Your identity will be removed from any data you provide before publication or presentation.

CONSENT FOR AUDIO RECORDING

Audio recording is part of this research study. You can choose whether to give permission to be recorded. If you decide that you don't wish to be recorded, you will not be able to participate in this research study.

Would you like to be audio recorded?

The researchers or someone hired by the researchers will listen to the recording and write down what people said during the interview. The written copy of an audio recording will be saved, but

the recording will be destroyed. No information that could identify you will be included in the written copy of the audio recording. Your data will be kept for 1 year.

If you have any questions about taking part in this research study, you should contact the primary researchers, Dr. Prerna G. Arora at 212-678-3086 or at pa2542@tc.columbia.edu, or Dr. Elizabeth Connors at elizabeth.connors@yale.edu. You can also contact the research assistant, Kayla Parr, by email at kmp2182@tc.columbia.edu or by phone/text at 732-836-8020.

Being in this study is optional, and you can tell me if you want to stop being in the study at any time.

1. Do you have any questions about the study?
2. Do you have any concerns about the study?
3. Would you like me to repeat anything?
4. Would you like to participate?

REVIEW OF INFORMED CONSENT

There may be some words or phrases or requirements above that you do not understand. Please ask me any questions you have now and I will take the time to explain. Before we proceed, could you share your thoughts on the following questions:

- What is the aim of this study?
- What is asked of you if you participate in this study?

PARTICIPANT'S RIGHTS QUESTIONS AND SUMMARY

- Have you had enough time to discuss the informed consent with me the research assistant?
- Have you had ample opportunity to ask questions about the purposes, procedures, risks and benefits regarding this research study?
- Do you understand that your participation is voluntary?
- Do you know that you may refuse to participate or withdraw participation at any time without penalty?
- If, during the course of the study, significant new information that has been developed becomes available which may relate to your willingness to continue your participation, the researcher will provide you with this information.
- Do you understand that any information derived from the research study that personally identifies me will not be voluntarily released or disclosed without my separate consent, except as specifically required by law.
- Identifiers will be removed from the data. De-identifiable data may be used for future research studies.
- You can receive a copy of the Informed Consent document, if you would like one.

Before I proceed with the study, I want to be sure that you (the participant) understand what is being asked of you. An informed consent is a process, so I want to be sure to check in with you (the participant) to ensure you want to continue with the study.

Please acknowledge verbally with a “yes,” or “no,” response to this question. Would you like to participate in this study?

_____ **“Yes, I agree to be in this study.”**

_____ **“No, I do not agree to be in this study.”**

Investigator’s Verification of Explanation

I certify that I have carefully explained the purpose and nature of this research to _____ (participant name) in a culturally sensitive and age-appropriate way. He/she/they has the opportunity to discuss the study with me and knows that they can stop participating at any time. I have answered all of their questions and this adult has provided the verbal agreement to participate in this research study.

Principal Investigator’s Signature _____

Date _____