# Trauma-Informed Collaborative Care for Low-Income African Americans with PTSD

**NCD03591107**

**September 5, 2018**

**LOUISIANA PUBLIC HEALTH INSTITUTE**
**RAND CORPORATION**

**ViStA-NOLA: Violence and Stress Assessment Project – New Orleans**

**PATIENT INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

You are being asked to take part in a research project. This paper will tell you about the project. The Clinic Recruitment Coordinator will describe the project to you and answer all of your questions. Please read this paper and ask questions about anything you do not understand before deciding if you will take part in this project. It is your choice whether you want to take part in the project. Your medical care will be the same no matter which you choose, though you might get some additional services if you take part in the study.

**What is the purpose of this project?**

The Louisiana Public Health Institute (LPHI) and the RAND Corporation are working together on a project called *The Violence and Stress Assessment Project—New Orleans, or ViStA-NOLA*, to improve the care for patients who have experienced trauma. The project is funded by the National Institute of Mental Health. We are inviting African Americans between the ages of 18 and 65 who may be experiencing symptoms related to trauma, such as community or personal violence, to participate in the project. The symptoms are sometimes called Posttraumatic Stress Disorder or PTSD, but being invited to participate does not mean that you have PTSD. You and your primary care provider can determine if that is the case together. We will include 40 people in the project. Information from this project may help us learn how to improve health care for people who may have had similar trauma experiences.

**How does the project work?**

If you agree to participate, you will be asked to take part in an interview today before you leave the clinic. These additional questions about your health, healthcare experiences, use of medical services, and your background will take about 20 minutes to answer and we will give you $20 for your time.

You will then be randomly assigned (like the toss of a coin) to receive either:

1) Your usual care. You will continue to receive care like you always have had from your primary care provider. We will tell your primary care provider at this clinic that you are eligible for the study because you are experiencing symptoms of stress so that you and your provider can talk about them. If you need treatment for trauma-related problems, your primary care provider will give you the care that this health clinic has available.

**OR**

2) Your usual care plus help from a Care Manager. The Care Manager will work with you and your primary care provider to make sure that you get additional follow-up care for dealing with the trauma you have experienced. After we finish talking, you will be connected with a Care Manager. During this 30-minute visit, you will first meet with your Care Manager (about 30 minutes) who will give you information about problems caused by trauma, answer questions, discuss different ways to handle trauma-related problems, and connect you to needed support before you see your primary care provider. After you see your primary care provider, you will meet briefly (about 10 minutes) with the Care Manager again to review the treatment plan. In addition, the Care Manager may help with your follow-up care by working with a mental health provider and a social service provider, if needed. After the initial face-to-face visit, your Care Manager will schedule a telephone call with you within two weeks and then each month for a total of seven brief, 10-minute follow-up calls over a 6-month period. Some of your interactions with the Care Manager will be audio-recorded. The reason for this is so that our clinical care experts can provide feedback to the Care Manager about how to improve the care that you get. We will destroy the recordings as noted further below.

You will also be asked to take part in another 10-15-minute interview six months after the first interview. You will get $30 for completing that interview.

The last thing that we will ask you to do for this project is to give us permission to look at some of the information that is in your medical record and we will ask you to sign another form for this. ***If you refuse to give permission for sharing your medical record, you will not be able to join our project.***

**What risks do you face if you decide to take part in this project?**

There few risks to you as a participant in the study. However, if your answers to our questions were disclosed, it might be somewhat embarrassing for you. To prevent that, we will keep your interview responses confidential. We will not share your individual interview response with anyone outside of the research team and we will keep your name separate from your interview responses at all times.

Answering some of the questions may upset you, for example, remembering frightening or dangerous events may make you feel anxious, depressed, or uncomfortable. You can skip any question or stop being in the project at any time. If you are feeling extremely upset, you will be referred to a provider in the health clinic.

At the end of the project, LPHI will place general results of the project on its website – www.lphi.org. Your name will not appear on the website or in any publications or presentations about the results of the project.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate may not disclose or use information that may identify you in any legal proceeding, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except:

- if you have consented to the disclosure, including for your medical treatment.
- if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
- if you tell study staff that you are about to harm yourself, or about to harm someone else, they may inform the appropriate authorities to ensure your safety, or the other person's safety.
- If you tell study staff that a child is being abused, they may tell the appropriate authorities about this so that the child is kept out of danger.

You may be concerned that someone may overhear you during the interview(s). We will make sure that the interview is conducted in a private room.

The audio-recordings of your interactions with the Care Manager will be destroyed at the end of the project intervention. All other project records will be kept for 10 years after the end of the project (2030) and then will be destroyed.

**What are the possible benefits to you for taking part in this project?**

You may not benefit from being in this research project. You will receive information about post-traumatic stress disorder. The information may help you or someone you know.

**What are the possible benefits to society for taking part in this project?**

We hope this project will help us learn about the best ways to improve health care for adults who may have experienced trauma.

**What if you are eligible to participate?**

Your participation in this research is **VOLUNTARY**. You don't have to be a part of the project if you do not want to. Your choice about being in this project will not change the relationship with your health care provider or any other services or benefits you may get from your health clinic. Your choice will not affect your right to health care or other services that you can get. If you decide **not** to participate, you will continue to receive your health care as you usually do. If you decide **to** participate, you can skip any question or stop being in the project at any time. If you decide to stop the interview, the medical care your receive at this clinic will not be affected.

**What are the costs of being in this project?**

There is no cost for being in this project.

**Will you be paid to participate in this project?**

If you agree to participate in this research project, you will receive up to $50 more for your time and effort, and for completing two more interviews: $20 for completing a baseline interview today, and $30 for completing another interview six-months later.

**Who can you call when you have questions about this project?**

If you have any questions or concerns about this project, you may call either researcher who is in charge:

Dr. Rebekah Angove of LPHI at 504.301.9857 or Dr. Lisa Meredith of RAND Corporation at 800.447.2631, x7365

If you have questions your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at 866.697.5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Study #2017-0334.

**CONSENT TO PARTICIPATE IN THE ViStA-NOLA PROJECT**

**I have read the above information about the ViStA-NOLA Project. I have asked all of the questions that I have today and they have been answered. I have been told that I can ask other questions at any time. I agree to take part in this research project. I have been given a copy of this form for my own records. I understand that signing this form does not take away any of my legal rights.**

_____

Participant's Name (Print)

_____

Participant's Signature Date

**In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research project.**

_____

Person Obtaining Consent/Title Date