**THE UNIVERSITY OF THE WEST INDIES**
ST. AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES
**CAMPUS ETHICS COMMITTEE**

# CONSENT TO PARTICIPATE IN RESEARCH

**Phone: 645-3232 Ext: 5021 Email: campusethics@sta.uwi.edu**

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|---|---|
| **Complete Protocol Title** | Prevalence of Depression amongst patients with Cardiovascular disease in Trinidad |
| **Principal Investigator** | Dr. Naveen Seecheran MBBS (MD), MSc, FACC, FESC |
| **Co-Investigators** | Dr. Cathy-Lee Jagdeo BSc, MBBS |
| **Research Site(s)** | Eric Williams Medical Sciences Complex, Mount Hope. |
| **Sponsors** | Not Applicable |

Why is this research being done?

This research is being done as coronary artery disease as well as depression are both highly prevalent diseases. Both of them cause a significant decrease in quality of life for the patient and impose a significant economic burden on society. The evidence is growing that depression per se is an independent risk factor to suffer a cardiac event and thus, if physicians become more aware of the prevalence of depression, this can impact on treating the condition and overall reduce the rate of mobidity/motality in these patients.

What is the duration of taking part in the study (for each subject)?

The duration of taking part in the study for each subject is approximately 10- 15 minutes. This will be the time approximated for each subject to sign the attached consent form and complete the questionnaire.

What will happen to me?

Each subject will be approached by an investigator of this study in which they will be informed of the study being conducted along with its purpose. The initial informed consent will be conducted by one of the investigators of this study in the outpatient cardiology clinic at EWMSC on the same day as the patient's scheduled appointment. The participant will be asked to sign the campus research ethics committee approved informed consent form once they agree to participate. Afterwards, the questionnaire will be given to the subject to be completed.

What is in in for me?

The score from the Patient Heath Questionnaire-9 will be communicated by the secondary researcher to the patient. If permission is given from the patient, then the cardiology doctor will be informed of the patient's score at the time of their visit; in which routine medical care will be carried out. Patients will be screened for depression in which they can be referred

What will happen if I drop out of the study early?

Participation in this study is completely optional and there will be no consequence if a subject drops out of the study. The subject's decision will be accepted and respected.

What are my responsibilities if I join and what about confidentiality?

The responsibilities of each participant in the study include reading and signing the informed consent form and filling out the questionnaire attached to the study. The de-identified data (names and dates of birth will not be recorded) will then be entered

What if I get hurt in the study?

There are no identifiable risks in this study to the patient. However, if the occurrence of any adverse event, the patient is in a tertiary institution (EWMSC) where there is an easily accessible emergency department whereby routine medical care and

**CONSENT**

I have read and understood this explanation. The researcher has also explained the study to me. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel like I had to take part.

I have read the attached experimental Subject's Rights, which contain some important information about research studies. I have also read the Authorisation to use my Private Health Information**. I must sign this Consent Form, the Experimental Subject's Rights and the Authorisation to use my Private Health Information. I will be given a signed copy of each to keep.**

Print Name of Subject | Signature of Subject | Date

Signature of Person conducting the informed consent discussion | Date

Role of person named above in the research project

Signature of Second Witness | Date

**This document was approved by Campus Ethics Committee on:**

September 4 2018

**By Chairman:**

**This document expires on:**

September 3 2019

THE UNIVERSITY OF THE WEST INDIES
Chairman
CAMPUS ETHICS
COMMITTEE
ST. AUGUSTINE

## EXPERIMENTAL SUBJECT'S RIGHTS

**If I am asked to consent to participate as a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:**

1. *Learn the nature and purpose of the experiment (also called "study" or "clinical trial").*
2. *Receive an explanation of the procedures to be followed in the study, and any drug or device used.*
3. *Receive a description of any discomforts and risks that I could experience from the study.*
4. *Receive an explanation of any benefits I might expect form the study.*
5. *Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me.*
6. *Learn what medical treatment will be made available to me if I should be injured as a result of this study.*
7. *Ask any questions about the study or the procedures involved.*
8. *Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.*
9. *Receive a copy of the signed and dated consent form.*
10. *Decide to consent or not to consent to a study without feeling forced or obligated.*

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Principal Investigator, The University of the West Indies at:

*By signing this document, I agree that I have ready and received a copy of this document.*

**Signature of Subject or Legal Representative** **Date**

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## REQUEST FOR PERMISSION TO USE AN INDIVIDUAL'S PRIVATE HEALTH INFORMATION

**Name of Study:**

Prevalence of Depression amongst patients with Cardiovascular disease in Trinidad

**Investigators:**

Dr. Naveen Seecheran, Dr. Cathy-Lee Jagdeo

**What is private health information?**

Private health information is any information that can be traced back to you. We need your permission to use your private health information in this research study. The type of private health information that will be used and shared for this study includes:
- Your past and present physical and mental health information
- Information that can be used to contact you
- Results of your medical tests and DNA
- Questionnaires and information on your drug/alcohol usage and that of your family.

**Who else will see my information?**

Information will be shared amongst researchers of this study along with the named data analysis collaborator in the study. Patients will be identified by registration number and not by name

**How long will the investigators use and share my information?**

The study will be conducted for approximately 1 year. Data will be stored on a password protected computer device of the principal investigator at the Department of Clinical Medical Sciences, FMS, UWI at EWMSC. No personal devices will be used

**What if I change my mind about sharing my research information?**

Participation in this study is completely optional and there will be no consequence if a subject drops out of the study. The subject's decision will be accepted and respected.

**Do I have the right to see and copy my research information?**

Yes, the results of Patient Health Questionnaire-9 will be communicated to the patients and their respective cardiology doctors (if the patient agrees) in the cardiology outpatient clinics where appropriate routine care will be carried out.

If you agree to share your information, you should sign this form below. You will receive a copy of this form.

**I agree to share my information as described in this form**

| **Print Name** | **Signature** | **Date** |
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If you have questions or concerns about your privacy and the use of your personal medical information, please contact the investigator at the telephone number listed in the consent form.