

**Worksite Lifestyle Program for Reducing Diabetes and Cardiovascular Risk in India**

**NCT02813668**

**November 27<sup>th</sup> 2018**

---

## Emory University Consent to be a Research Subject

**Title:** Worksite Lifestyle Program for Reducing Diabetes and Cardiovascular Risk in India

**Principal Investigators:**

K.M. Venkat Narayan, MD, MSc, MBA, Hubert Department of Global Health, Emory University  
Dorairaj Prabhakaran, MD, MSc, Public Health Foundation of India  
V. Mohan, MD, PhD, Madras Diabetes Research Foundation

**Funding Source:** National Heart, Lung, and Blood Institute, National Institutes of Health, U.S.A

**Introduction**

We have come to your workplace to invite you to participate in an interview as part of the study on the INDIA-WORKS program.

This form is designed to tell you everything you need to think about before you decide to consent (agree) to participate in an interview as part of the study or not. **It is entirely your choice. If you decide to take part, you can change your mind later on and not participate in the interview. During the interview, you can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

**Study Overview**

The purpose of the interviews is to learn about ways to make the INDIA-WORKS program better.

**Procedures**

We would like to talk with you one time for about 1 hour. We would like to ask you questions to learn about your experience taking part in the INDIA-WORKS program. Other men and women from your workplace and other workplaces participating in the INDIA-WORKS program will be asked similar questions.

**Benefits**

The interview is not designed to benefit you directly. The interviews are designed to learn more about how to improve the INDIA-WORKS program. The results may be used to help others at your workplace and other workplaces in India and other countries in the future.

**Compensation**

You will not be offered payment for participating in an interview.

**Risks and Discomforts**

We believe there are minimal risks to you from taking part in this interview. Sometimes people are worried about privacy of the information they provide. The risk that your privacy will not be maintained is low.

**Confidentiality**

I want to assure you that we will do everything we can to protect your privacy. We are taking steps to make sure all your answers and your name will be kept private. Certain offices and people other than the researchers may look at your answers. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, and the Emory Office of Research Compliance. The study funder (US National Institutes of Health) may also look at your answers. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records, such as documents with your answers, wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

**Voluntary Participation**

Your decision whether or not to participate in this interview is completely voluntary. You can choose not to participate at all, and if you do agree to participate, you have the right to stop the interview at any time for any reason. There will be no penalty to you if you decide not to participate in an interview. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. Also, after finishing the interview, you can choose to not have your answers included in the study.

**Contact Information**

Contact the Site Investigator or his associate, Dr. V. Mohan, Madras Diabetes Research Foundation, # 4 Conran Smith Road, Gopalapuram. Chennai-600086. Phone No: [REDACTED]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Should you have any questions regarding your rights as a research participant, you may contact Dr. M Balasubramanyam, Member Secretary of Institutional Ethics Committee of MADRAS DIABETES RESEARCH FOUNDATION (MDRF), INDIA. NO: 4, CONRAN SMITH ROAD, GOPALAPURAM. CHENNAI-600086. PHONE NO: + [REDACTED].

**Consent to Participate**

Do you agree to participate in an interview for the INDIA-WORKS study?

Please, print your name and sign below if you agree to participate in an interview. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date          Time

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Date          Time

Thank you for agreeing to talk with us. We are looking forward to talking with you to learn about your experience in the INDIA-WORKS program.

**Consent to Audio-Recording**

Your views and opinions are very valuable to us. So, we want to capture everything you say so that we have all the information we need to make the INDIA-WORKS program better. To help us do that, we would like to record the whole discussion. The reason for recording is so that we don't missing anything you say, and so that the rest of our research team who are not about to join for the discussion can also hear your views and opinions exactly. Please do not worry about this because everything you say will remain confidential. Your name will not be used when we share what we learned in the discussions, so no one can identify you with any answers.

Do you agree to have the discussion recorded?

Please, print your name and sign below if you agree to the audio-recording. By signing, you will not give up any of your legal rights.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date          Time

\_\_\_\_\_  
Signature of Person Conducting Discussion of Consent to Recording

\_\_\_\_\_  
Date          Time