INFORMED CONSENT FORM TO BE A RESEARCH PARTICIPANT

TITLE OF RESEARCH:
Implementation of Home-Based Palliative Care in limited Resource Settings.

Population group: Indian cancer subjects referred for home-based palliative care

Site Name & Address: Tata Medical Center, 14 MAR (EW), Newtown, Rajarhat, Kolkata-700156
Principal Investigator: Dr Gaurav Kumar, +91-8376030761

Sponsor: National Institutes of Health, USA, 6701 Rockledge Drive MSC 7768 Bethesda, MD 20892-7768

Introduction

This consent form may contain words that you might not understand. Please ask the study physician or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study at the Tata Medical Center (TMC), Kolkata India in collaboration with the Medical University of South Carolina, USA because a) you have been recently referred for palliative care services after being diagnosed with cancer b) you reside in North or South 24 Parganas and c) you are equal to or above 18 years of age. "Palliative care" is specialized medical care for people with serious illnesses. It focuses on providing patients with relief from the physical, psychological and spiritual symptoms and stress of a serious illness. The goal is to improve quality of life for both the patient and the family.

Eighty percent of patients who need palliative care live in limited resource countries (e.g. India); however, only 10% of these patients have access to this service. In this study, we will compare a **home-based** palliative care intervention delivered by community health workers (CHWs) under the guidance of the cancer center oncologists and palliative care consultants, to the standard cancer-center based palliative care.

The CHWs can help you and your family with managing your physical and emotional symptoms, assist with accessing your oncologists and work with you and your family on overcoming your pain and other barriers. CHWs will also assist you in obtaining pain medications including morphine and provide awareness and education regarding your symptoms. Your satisfaction, symptoms and pain control, palliative care needs, quality of life for you and your caregiver, patient care experience are some of measures that we will assess.

This site for this research study is the Tata Medical Center (TMC), Kolkata, India in collaboration with the Medical University of South Carolina (MUSC). Approximately 90 volunteers will be enrolled. The National Cancer Institute (NCI/NIH) sponsors this study. The investigator in charge at TMC is Dr. Gaurav Kumar and the primary investigator at MUSC is Dr. Suparna Qanungo.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will be randomly assigned to one of the groups, like drawing numbers from a hat. There will be two groups **Control** (receive "usual care" palliative services in which the patient or caregiver (by proxy) must visit the cancer center for care) and **Pal-Care Intervention** (receive home-visit from CHW).

2. If you are in the "Control" you will receive TMC services including consultation with a multi-disciplinary team, a weekly 7-day morphine supply, basic training on medication, catheter and wound care and psychological counseling. Patients are also provided a 24/7 emergency hotline.

3. If you are in the "Pal-Care Intervention", the CHW will visit your home 1+ times/ week for 6 months. During these visits, The CHW will 1) monitor condition of patient/caregiver, 2) provide basic palliative care (e.g. medication administration, wound care, catheter care, psychological support), 3) teach caregivers to deliver care, 4) assist with pain and symptom control, and 5) assist patients to contact their oncologist or other resources when needed. To facilitate timely communication between CHW and the clinical team, a simple telehealth platform will be used. After completion of 6months of study period, you may transition to cancer – center based care or continue receiving supportive services from the CHWs for a reasonably small fee per visit.

4. The CHW will collect your health and other feedback information provide by you throughout the study and send it to Dr. Gaurav Kumar, the site investigator/oncologist.

5. Your information will then be entered into a secure computer database where it will be assigned a unique number and that will be available for analysis by the TMC and the MUSC team in USA so that we can study it.

C. DURATION

Participation in the study will take about 24-28 visits over a period of approximately 6 months.

D. RISKS AND DISCOMFORTS

Risks are minimal, however may exist as described below.
When someone participates in a research study, there is a risk for loss of confidentiality. It is possible but unlikely that some of the survey questions could pose minor psychological discomfort. The researchers will adopt all possible measures to prevent that the participant's health information and all data remains confidential and is not disclosed to anyone outside the research group.

E. BENEFITS

There will be no direct benefit to participating in this study. However, it is hoped that the information gained from the study will help develop a model of home-based palliative care in India and which shall likely be adaptable for use with other life-threatening diseases beyond cancer in resource limited settings in other countries.

F. COSTS

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated approximately $15 (exact to be given is Rs.1000) for each survey data collection time (baseline, 1, 3, 6 months = Rs. 4000) that you may use towards paying for your travel expenses.

H. ALTERNATIVES

Your alternative is to not participate in this study.

Will any confidential information be obtained from me?

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing

this document, you will be allowing the research team investigators, other study personnel, sponsors, institutional ethics committee and any person or agency required by law like the Licensing Authority in India to view your data, if required.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible. The investigators associated with this study, the sponsor, and Institutional Review Board at TMC, Kolkata and the MUSC Institutional Review Board for Human Research will have access to identifying information.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to participate in this research study will not affect your medical care. Your physician will still take care of you and you will not lose any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Research Participant's Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, I may contact the TMC lead investigator Dr. Kumar at the contact information provided below
I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ Signature of Person Obtaining Consent

_____ Date

_____ Signature of Participant

_____ Date

_____ Signature of Legal Guardian (if applicable)

_____ Date

For further information/questions, you and/or your nominee can contact any of the following for the purposes mentioned below:

A. For queries related to the study		
Role in the study	Name	Contact details
Principal Investigator	Dr Gaurav Kumar Consultant, Palliative Care Tata Medical Center, Newtown, Kolkata	+91-8376030761 +91-6260675620
B. For queries related to your rights as a participant in the study		
Chairperson, Ethics Committee		
Member Secretary, Ethics Committee		
C. For queries related to sponsor		
Principal Investigator	Dr Suparna Qanungo Assistant Professor and Director, Telehealth Research Medical University of South Carolina Charleston USA	+001-8438761125