

## **CONSENT FORM (English)**

### **Title:**

**Impact of esophageal sparing IMRT on patient reported dysphagia outcomes in patients of non-small cell lung cancer treated with radical radiotherapy with or without chemotherapy .**

### **Short Title:**

**Impact of esophageal sparing IMRT on patient reported esophageal adverse effects in lung cancer patients treated with radiotherapy with or without chemotherapy.**

## **Introduction**

We are inviting you to be part of this research study titled “The impact of esophageal sparing IMRT on patient reported dysphagia outcomes in patients of non-small cell lung cancer treated with radical radiotherapy with or without chemotherapy ”. You are being invited to participate in this study as you have been diagnosed with a cancer arising from your lung and will be treated with radiotherapy. The details of this research are presented in this document. Please read this information carefully. Ask questions about anything that you do not understand or want to know more about.

## **Purpose of Research**

When radiotherapy is given for patients who have cancers of the lung, normal organs inside the chest also receive a high dose of radiotherapy. Patients experience several kinds of side effects due to this dose. Esophagus (food pipe) is one among these organs. Because of this, radiation-induced difficulty in swallowing and heartburn are one of the common acute side effects of radiotherapy.

IMRT (Intensity Modulated Radiotherapy) is a modern treatment method where the dose to these organs is reduced with the help of computerized modern planning. With the help of the technique that we are going to use (esophageal sparing IMRT), we will try to avoid exposure to esophagus (food pipe) even more to further decrease these symptoms

During our study, patients undergoing radiation will be assessed on a weekly basis. Both clinician-reported and patient-reported difficulty in swallowing will be recorded every week during radiation in review clinics.

In this study, you will not undergo any additional or new treatment. We will try to find out the rates of patient-reported and clinician-reported radiation-induced moderate to severe difficulty in swallowing in patients treated with concurrent chemoradiotherapy, sequential chemoradiotherapy or radical radiotherapy alone for non-small cell lung cancer. We will also try to find out the time to develop patient-reported moderate to severe difficulty in swallowing during lung cancer radiotherapy. As a part of this study, we would also like to collect more details on the side effects you have during treatment. We will do this in 2 ways-one way will be using a questionnaire that you will be asked to fill every week during treatment and another, which will be filled by the doctor when they are seeing you every week.

### **What will I have to do to participate?**

1. First we will ask you to read and understand this consent form and ask questions you have regarding the procedure.
2. You will undergo radiotherapy planning using a CT scan.
3. We will calculate the best possible dose using computer systems.
4. Each week during radiotherapy, a doctor will ask you about the side effects you are experiencing. You will be given a set of questions in which you will have to answer about the difficulty in swallowing and heartburn that you might feel during the treatment.
- 5 Once your treatment is complete, you will be on follow-up at regular intervals.

### **What are the alternatives to participation?**

You may choose not to participate in the study. Your treatment will not be affected because of this.

**What are the possible risks?**

We do not expect any additional risks in the study.

**What are the costs of participation?**

No extra costs are involved. You will not be asked to pay any extra money to participate in the study.

**Will there be any reimbursement?**

No reimbursement is planned as a part of the study.

**What are the possible benefits?**

This study will help us to identify the incidence, duration and severity of radiation induced difficulty in swallowing with the use of esophageal sparing IMRT which may help in timely assessment and lead to better supportive care and may reduce treatment related toxicity events.

**Will my data be kept confidential?**

Yes. The data that you provide will be stored securely and anonymized at TATA Medical Center, which will only be accessed by doctors and nurses taking care of you. It will not be used to identify you or disclose your identity and will not be disclosed without prior permission.

**Compensation for injury**

As this study does not involve any new intervention, no compensation for side effects will be provided, cost of treatment for side effects will be borne by the patients only.

## Participation

Participation in the research is voluntary. If you do not wish to participate , you may withdraw at any time. You will receive the correct treatment irrespective of your taking part in the study. You will receive a copy of this Participant Information and Consent Form to keep.

## Contact

Tata Medical Center Phone: 033-6605-7000

If you have any questions at any time about the study, you may contact the researchers as below.

Dr Tapes h Bhattacharyya	Dr. Moses Arun Singh	Dr. Urvashi Thakur
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## Address:

Tata Medical Center, 14 MAR (E-W), Newtown Action Area 3 Phone: 033-6605-7000, 033-6605-7404

Tata Medical Center Institutional Review Board (TMC-IRB) can be contacted at 03366057579 for concerns. The Director of TMC is the appellate authority.

## Consent

I understand the above information and agree to participate in the trial.

Patient Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Investigator Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Witness Signature:

\_\_\_\_\_ Name: