

Tata Medical Center

14, Major Arterial Road (EW)
New Town, Rajarhat
Kolkata – 700 156



To
The Chairperson
Institutional Review Board
Tata Medical Center, Kolkata

Date:

Subject: Letter seeking approval for conducting prospective study

We are herewith submitting the study proposal titled **“A Prospective Multicentre Observational Post-Market Surveillance Study and Performance Evaluation Study to Assess the Safety, Real-World Diagnostic Performance, and Clinical Utility of the Electrical Impedance-Based BIRADx System (BDS) for Breast Tumour Evaluation before Biopsy or during Breast Cancer Surgery”**

This study aims to differentiate lesions with a higher likelihood of malignancy from those that are likely benign with the use of the BIRADx System (BDS), which is a novel, minimally invasive, impedance-based diagnostic device designed to evaluate breast lesions in real time under ultrasound guidance. It will include 30 patients being treated at Tata Medical Center.

Please find the prerequisite documents required by the IRB for the above mentioned study for your kind perusal and conducting the same upon obtaining your approval.

Thanking You,

Sincerely,

Dr. Abhishek Sharma

Signature of Principal Investigator

I, acknowledge the receipt of above mentioned document(s) on behalf of the Ethics Committee

Date

Received Signature

Name of the Personnel