

Patient Information Leaflet and Consent form

What is NDLI CHAVI?

CHAVI is an acronym for Comprehensive Digital Archive of Cancer Imaging and it is a “bank” of all medical images (like CT Scans, MRI Scans, PET scans or scans of any of your investigations) obtained for patients diagnosed with cancer. CHAVI is thus a biobank of all images and patient information associated with the images. This project is being developed as a part of the National Digital Library of India (NDLI)

Giving your consent for this research is completely voluntary and no new treatment will be given as a part of this research.

Purpose of such a biobank?

We are asking for help in our research efforts to gain a better understanding of how cancer spreads, how it responds to treatment and how it comes back. All cancer patients undergo many imaging investigations during the course of their treatment as well as follow up. Some of the examples of such imaging investigations include CT scans, PET CT scans, MRI Scans, Endoscopy, Mammograms etc. The imaging biobank will store all such images in a single site and use information from these images to gain better understanding for this disease

You can help us by allowing us to store your images in the CHAVI biobank and allow us to use the information in these images. We will be using the images to:

- Gain an understanding of how cancer spreads in the body
- Explore imaging features which can predict a better outcome
- Explore imaging features which can allow us to forecast which patients may respond to treatment
- Understand how cancer biology relates to the imaging information

Some of procedures your images will be used for are:

- Explore common imaging features of cancers for a specific cancer type in a

large number of patients

- Understand and extract information regarding the shapes, sizes of tumors
- Explore the difference between normal tissue and tissues harbouring cancer
- Studying the effect of various treatments on the imaging appearance of the cancer

What are the benefits?

The benefits of any such imaging biobank is that it allows use to learn more about how the cancers actually behave in a large series of patients. The information may be of immense value in preventing and treating this dreaded disease. While there are many benefits that the society may have you may not gain any benefit directly from this research. Allowing us to store your images is unlikely to result in any harm to you.

What are the risks?

Your consent involves less than minimal risk in relation to the use of your personal information. All your information and images will be held in the CHAVI biobank in the strictest confidence with careful controls and supervision. Within limits imposed by technology and law every effort will be made to maintain the confidentiality of your information. No identifiable information about the participants will be available to anyone outside TMC and IIT Kharagpur.

Your images are already stored in the hospital database for use during follow up and treatment. This storage will be an additional storage and will not interfere with your existing images already stored in our database.

How will my information be kept confidential?

We have put in place several measures to protect your confidentiality. First of all images kept in the CHAVI biobank will be identified through a unique ID number which will be different from your hospital ID number. Thus no user of the CHAVI biobank will know that this is your image. The computers that will house these images will be securely located in Indian Institute of Technology Kharagpur, which

has a strong and secure IT infrastructure to prevent unauthorized access. Access to the image biobank will be restricted to researchers from TMC, IIT Kharagpur and its research partners. All staff will have to sign study specific agreements to ensure confidentiality. All image data stored in the database will not have personal identifying details. The record number in the CHAVI biobank will be linked to your hospital ID through a secure key which will be stored in a secure location under the supervision of a designated data protection office.

This will prevent any identifiable information from being used - accidentally or deliberately - for any purpose other than research.

Who will be able to use the images in CHAVI biobank?

Information and images available in the CHAVI biobank will be available only for researchers who have relevant scientific and institutional review board approval for an ethically planned research study. This may include researchers working in TMC, IIT Kharagpur as well as researchers from the rest of the country and outside India as well as those working in commercial companies. The aim of such research studies will be many and may include research into ways to detect and treat this disease in various stages. We will ensure that all research originating from the images stored in the CHAVI biobank are published in scientific fora so that other researchers and public may benefit from the information.

Insurance companies and employers will not be given any individual's information, images and results from the banked images. Your images may be reviewed to ensure that the image quality meets standards. These reviewers may include representatives of the institutional review board or the department of biotechnology, Government of India.

Will I receive reimbursement?

No reimbursement will be allowed for your consent to store your images in the CHAVI biobank.

Possible commercial products?

All images stored in the CHAVI biobank are important and no research is undertaken with a motive for profit. However, if a commercial product is developed as a result of a research done on the CHAVI biobank, you will not profit financially from such a product.

Alternatives to participation?

You may choose not to give your consent for this study and your consent will not influence your treatment at the hospital.

Important Contacts.

Dr Sanjoy Chatterjee Senior Consultant Radiation Oncologist Tata Medical Center, Kolkata Telephone: 03366057406	Dr Santam Chakrabarty Consultant Radiation Oncologist Tata Medical center Kolkata 03366057406	Prof Jayanta Mukhopadhyay Department of Computer Science and Technology Indian Institute of Technology Kharagpur
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Tata Medical Center Institutional Review Board (TMC-IRB) can be contacted on 03366057579 if you have any concerns about the project. The director TMC is the appellate authority in case you have issues with the IRB decision on your concern.

I understand the above information and agree to participate in the CHAVI project.

Patient

Signed:

Print Name:

Date:

Witness

Signed:

Print Name:

Date:

Investigator

Signed:

Print Name:

Date: