## ICON - Indian Co-operative Oncology Network



(autonomous body of Indian Society of Medical & Pediatric Oncology)

<u>www.oncologyindia.org</u> email: <u>icon@oncologyindia.org</u> (Registration No: E – 19333 Mumbai, Charity Commissioner, Greater Mumbai Region, Maharashtra State)

INFORMED CONSENT FORM

## ICON TISSUE REPOSITORY

A Tissue Repository or a Bio Bank is an organized bank which collects and preserves tissues and other biological material like components of blood.

You are invited to participate voluntarily and donate your samples to ICON Tissue Repository. These samples will be surplus to the routine samples which will be taken during your surgery as part of your diagnostic work up or treatment. You are being asked to donate blood and/or surgical tissues and/or other biological material.

A small sample of blood (approximately 10 ml or 2 teaspoons) and/or other Biological material will be collected at the time of consenting or at the time of surgery. After your surgery, some of the removed tissue will be used for pathologic diagnosis and the surplus tissue will be used for ICON Tissue Repository Project. There is no potential risk but slight discomfort or bruising may occur while collection of blood as it occurs in any other blood collection.

You are also being asked for your consent to allow the collection of data such as your Medical History and Follow up Medical data (for example: your age, sex, diagnosis, medical treatment for your condition, your family history etc.)

Your donated samples will be kept indefinitely or until they are completely used in Research studies. By signing this Consent Form you are agreeing to allow ICON to keep and preserve these samples and medical information. You also choose to allow us to use them in future for approved Research studies.

If however, you wish to withdraw your permission for storage of the samples and health information in the future, and wish that they be destroyed you may do so at anytime. The withdrawal of your permission has to be performed by writing to the chief administrative officer ICON Tissue Repository (See Contact below). You may withdraw at any time without penalty.

The Research may or may not benefit you directly but it is for improvement in knowledge, for advancement of science and may benefit other patients and community.

Confidentiality and anonymity of all the samples received will be safeguarded. Upon receiving the blood or tissue samples the responsible team at ICON will label the specimen with code that will not use your name or any other identifying information. Linkage of the specimen code to your identification will be stored in a secure database. Researchers will not be able to identify you as the donor. Personal health data and subject linkage codes will be kept securely with permission limited to authorized personnel only who will sign appropriate Confidentiality agreement.

The ICON Tissue Repository will take all reasonable steps and will make all reasonable efforts to preserve the samples received and stored by them till such time the ICON Tissue repository is in existence and operation. The ICON Tissue repository however will not be responsible, if for any reason beyond their control or for reasons including but not limited to force majeure and acts of Nature, they are unable to preserve the samples or the same are destroyed or damaged or otherwise affected in any manner

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I am aware that for correct diagnosis of Cancer, examination of blood or tumor cells of sample is must. These tumor cells/samples are usually evaluated by pathologist by looking under the microscope.

I am aware that many tests on the same tumor sample may provide additional information that helps decide the right treatment or give information about outcome.

I am aware that this project will involve storage of a large number of samples and analysis of the samples from time to time as required.

I am aware that the additional risk and discomfort to me will be that of needle prick for blood collection- wherein not more than 10 ml of my blood will be collected

I am aware that this tissue repository project will make available the samples for testing for specific future projects.

I am aware that this knowledge is of an exploratory nature and the information that will be obtained has the potential to benefit future patients

I am aware that such studies will be conducted following approval by scientific and ethical processes that Investigators, Institutions and tissue repository project will follow.

I am aware that I will not get any direct benefit out of this knowledge nor will it influence in any way the treatment that I am/will be getting.

I am aware that there is no compensation for me.

I am aware that I have the right to withdraw my consent and my sample will be destroyed/handed back to me if I so desire.

I am aware that samples will be preserved for indefinite period of time apart from unforeseen circumstances

Any questions that I had, have been answered adequately by the person taking this consent. I am satisfied with the answers

I give my Consent for my tumor sample and blood sample to be stored and tested to find new information about Cancers and related disease including how they behave.

## Consent to participate in this study

□ Not applicable

Printed name of the subject:	
Signature/Thumb Impression of the subject:	Date:
Printed name of impartial witness:	
Signature of Impartial witness:	Date:
□ Not applicable (Impartial witness is required if the subject is unable to read the consent)	
Printed name of investigator or authorized delegate explaining consent:	
Signature of person explaining Consent- Investigator/Authorized delegate:	Date:
(The Investigator or person designated by the Investigator to conduct the informed consent prothe same time as the subject)	
Printed name of legally acceptable representative	
Signature of legally acceptable representative	Date: