PARTICIPANT INFORMED CONSENT FORM (PICF)

Participant identification number for this trial: _____

Title of project: **Preoperative Embolization of Bone Tumors**

Name of Principal Investigator: Dr Raushon Kumar Jha

The Contents of the information sheet dated …….. that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:

(Signatures / Left Thumb Impression) Place:

Name of the Participant: _____

Son / Daughter / Spouse of:_____

Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator Date:

Place:

1) Witness – 1

Signatures

Name:

Address:

2) Witness – 2

Signatures

Name

Address:

PATIENT INFORMATION SHEET

Title of Thesis: Preoperative Embolization of Bone Tumors.

We would like to invite you to take part in our study to investigate the role of Preoperative embolization of bone tumors. Aim of the study is to determine the benefits of preoperative embolization of resectable primary and secondary bone tumors by assessing perioperative blood loss with comparison to degree of embolization, by assessing the perioperative blood transfusion volume and by assessing surgical time. Preoperative embolization leads to decreased perioperative blood loss, decreased perioperative blood transfusion volume and decrease in surgical time.

Voluntary Participation:

Your participation in this study is voluntary. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician. On inclusion in the project, you will be embolized once you will be admitted for surgery. Embolization will be done 24-48 hrs prior to your surgery. You will be monitored regularly during the procedure of angiography and embolization and up to 48 hrs of postoperative period for the outcome and any surgical or procedure-related complications. Any additional expense for the project, other than your regular expenses, will not be charged from you. All your records will be kept confidential.

Methodology:

A detailed history regarding your symptoms would be obtained. X-ray, CT/MRI and biopsy of the lesion (whenever required) would be obtained. You would be admitted and preoperative embolization of the bone tumor would be performed under local anaesthesia. You would be observed in orthopaedic ward for procedure related complications. You would be under follow up during surgery for assessing the effects of preoperative embolization on blood loss, blood transfusion volume and surgical time. You would be under follow up for next 24 hrs for assessing blood loss and blood transfusion requirement and would be under follow up for 48 hrs for any procedure related or surgery related complications.

Benefits of preoperative embolization of bone tumors:

Benefits expected of preoperative embolization include decrease in perioperative blood loss, decrease in perioperative blood transfusion volume and decrease in surgical time and also reduction in other surgical complications.

Risks of preoperative embolization of bone tumors:

Complications expected of preoperative embolization include pain in the immediate post procedure period, post embolization syndrome (low grade fever, myalgia, and malaise), infection, hemorrhage, neurological complications etc.

No part of the expense for any research related injury will be charged from you.

Confidentiality:

Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.

Your rights:

Your participation in the study is optional and voluntary. The copy of the results of the investigations, treatment performed will be provided to you for your record.

For further information and to report any side effects/complications, kindly contact:

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