PARITY | Prophylactic Antibiotic Regimens in Tumor Surgery

Screening Instructions for Patients in the PARITY Study

These instructions apply to all patients who present to your clinical site with a primary bone tumor that requires surgery and reconstruction with a large metal implant:

- Introduce the study to the patient.
- Complete a **Screening Form 1.1** (see package) for the patient.
- If the patient does not meet the eligibility criteria, please assign an excluded patient ID using the site number and then the patient number. For example, if your site number is 01 and this is the third patient to be excluded, please write '01 3003' on the Screening Form 1.1.
- If the patient meets all the eligibility criteria, explain the study thoroughly with the patient. If the patient agrees to participate, have him/her sign all necessary copies of the **Consent Form** (see package)**.**
- Give **1 copy** of the consent form to the patient and keep **at least 1 copy** that you will need for your own records.
- Please collect contact information for the patient on **Patient Contact Forms L-1 and L-2** (see package) including two alternate contacts and the family physician.
- Please number the included patient appropriately with the site number followed by the patient number. For example, if your site number is 01 and this is the fifth included patient, please write '01 1005' on the Screening Form 1.1.
- **Please leave the completed Screening Package at:** _____

  _____
- Please complete questions 1-3 on the **Randomization Form 2.1** and then give the form to the Pharmacist after completion.
- Thank you for taking part in the PARITY study. If any problems arise during screening, please feel free to contact the Research Coordinator.

Research Coordinator:_____	**Telephone:** _____
Email:_____	**Pager:**_____

PARITY Study #120 Plate #001 Visit #000

Patient Study ID Number [ ][ ] Centre # [ ][ ][ ][ ] Patient # Patient Initials [ ][ ] F L Date [ ][ ] DD [ ][ ] MM [2][0][ ][ ] YYYY

SCREENING FORM (1 of 1) - FORM 1.1

Please complete this form for all patients with lower extremity tumor to be treated with wide excision and endoprosthetic reconstruction.

For included patients you must answer yes to questions 1-4:	**Yes**	**No**
1. Male or female who is 15 years of age or older?	☐	☐
2. Primary bone tumor of lower extremity with preoperative imaging?	☐	☐
3. Reconstruction with tumor prosthesis planned?	☐	☐
4. Provision of informed consent?	☐	☐
5. Preoperative chemotherapy (non-compulsory)?	☐	☐

If you answered no to any of items 1-4, the patient should be excluded.

For included patients you must answer no to questions 6-16:	**Yes**	**No**
6. Upper extremity tumor?	☐	☐
7. Known allergy to penicillin and/or cephalosporin?	☐	☐
8. Previous local infection of the extremity?	☐	☐
9. Previous local surgery, excluding biopsy?	☐	☐
10. Likely problems, in the judgment of the investigators, with maintaining follow-up?	☐	☐
11. Previous randomization in this study or a competing study?	☐	☐
12. Immunological deficient disease conditions other than recent chemotherapy?	☐	☐
13. Known MRSA colonization?	☐	☐
14. Known VRE colonization?	☐	☐
15. Reconstruction to include allograft?	☐	☐
16. Skeletal immaturity?	☐	☐
17. Other reason: _____	☐	☐

If you answered yes to any of items 6-16, the patient should be excluded.

PATIENT STATUS - See previous page for coding Patient ID #

18. Please indicate the patient's status.

☐ INCLUDED (proceed to the **Randomization Form 2.1**)

☐ EXCLUDED

☐ MISSED (eligible, but was not randomized due to error)

Please do not send Patient Contact Forms L-1 and L-2 to the Methods Centre

PLEASE DO NOT SEND THIS TO THE METHODS CENTRE

Centre # | Patient # | Patient Initials F L

PATIENT CONTACT FORM (1 of 2) - FORM L-1

In order to facilitate follow-up, it is important to collect contact information for you AND 2 alternate contacts that could assist us should you move during the course of the study. This information will not be given to anyone outside of the study.

Patient Contact Information

Patient: (please print)

Last Name _____ First Name _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State (if applicable) _____ Country _____

Home Phone # _____ Work Phone # _____

Family Physician Contact - Clinic Address

Physician: (please print)

Last Name _____ First Name _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State(if applicable) _____ Country _____

Phone # _____

Oncologic Surgeon Contact - Clinic Address

Surgeon: (please print)

Last Name _____ First Name _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State(if applicable) _____ Country _____

Phone # _____

PLEASE DO NOT SEND THIS TO THE METHODS CENTRE

Centre # | Patient # | Patient Initials F L

PATIENT CONTACT FORM (2 of 2) - FORM L-2

Referring Physician Contact - Clinic Address

Physician: (please print)

Last Name _____ First Name _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State(if applicable) _____ Country _____

Phone # _____

<u>Alternate</u> Contact Information

Contact #1: (please print)

Last Name _____ First Names _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State(if applicable) _____ Country _____

Home Phone # _____ Work Phone # _____

Relationship to Patient: _____

Contact #2: (please print)

Last Name _____ First Names _____

Apt. No. _____ Street _____ Postal/Zip Code _____

Town/City _____ Province/State(if applicable) _____ Country _____

Home Phone # _____ Work Phone # _____

Relationship to Patient: _____