PARITY | PROPHYLACTIC ANTIBIOTIC REGIMENS IN TUMOR SURGERY

Study Screening Package

STUDY TITLE: Prophylactic Antibiotic Regimens in Tumor Surgery (PARITY): A Multi-Center Randomized Controlled Study Comparing Alternative Antibiotic Regimens in Patients Undergoing Tumor Resections with Endoprosthetic Replacements

STUDY SYNOPSIS:
The PARITY Trial is a multi-center, blinded, randomized controlled trial, using a parallel two-arm design, to investigate whether post-operative antibiotic regimens (24 hours vs. 5 days) will decrease the rate of infection among patients being surgically treated for a lower extremity bone tumor or soft-tissue sarcoma which has invaded the bone. The rationale for this study is fuelled by: 1) increased infection rate outcomes in bone tumor surgery compared to general arthroplasty; 2) a lack of consensus among Orthopaedic Oncologists regarding the most effective prophylactic antibiotic regimen; 3) a lack of randomized controlled trial (RCT) evidence; and 4) extensive investigator support for the proposed trial.

These instructions apply to all patients who present to your clinical site with a primary bone tumor, or soft-tissue sarcoma which has invaded the bone, of the lower extremity that requires surgery and reconstruction with a large metal implant.

- Introduce the study to the patient.
- Complete a **Screening Form (1)** for the patient (enclosed).
- If the patient does not meet the eligibility criteria (both inclusion and exclusion), assign an excluded Patient ID using your Site Number and then the unique Patient Number. For example, if your Site Number is 01 and this is the third patient to be excluded, please use *01 3003* as the Patient ID on the **Screening Form (1)**.
- If the patient meets all the eligibility criteria (both inclusion and exclusion), please explain the study thoroughly with the patient. If the patient agrees to participate, have him/her sign all necessary copies of your ethics committee approved **Informed Consent Form**.
- Give one (1) copy of the **Informed Consent Form** to the patient and keep at least one (1) copy for your site's own records.
- Collect the patient's contact information on the **Patient Contact Form (L)** (enclosed), including two (2) alternate contacts and the patient's family physician.
- Assign the appropriate included Patient ID using your Site Number and then the unique Patient Number. For example, if your Site Number is 01 and this is the fifth included patient, please use *01 1005* as the Patient ID on the **Screening Form (1)** and all other study CRFs.
- Please complete the top half of the **Randomization Form (2)** before providing the form to the Research Pharmacist for completion at the time of randomization.

This completed Screening Package can be left at: _____

Thank you for taking part in the PARITY Trial. If any problems arise during the screening process, please contact the Research Coordinator.

Site Research Coordinator Contact Information	
Name: _____	**Telephone No**.: _____
Email: _____	**Pager No.**: _____