**ICONIC Study**

**Completed by Surgery Site, For All ICONIC Surgery patients**

**Surgery Source Data Form Booklet**

* ***Use these Source data forms to record the data entered onto the ICONIC eCRF online database.***
* ***DO NOT return these forms to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

**Contents**

[**1:** **Performance Status Source Data Form** 5](#_Toc22810863)

[**2:** **Biochemistry & Haematology Source Data Form** 6](#_Toc22810864)

[**3:** **Pre Surgery Imaging Source Data Form** 7](#_Toc22810865)

[**4:** **Surgery Source Data Form** 9](#_Toc22810866)

**1: Performance Status Source Data Form** Page **1** of **1**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |
| --- | --- |
| **Trial number:** | **ICO- \_\_\_ \_\_\_ \_\_\_** |
| **Patient name:** |  |
| **Hospital no.:** |  |

|  |  |
| --- | --- |
| **Date of assessment:** | \_\_\_/\_\_\_\_/\_\_\_DDMMYYYY |

|  |
| --- |
| **WHO PS (patients ≥16 at registration)** |
|  [ ]  | **0** | Able to carry out all normal activity without restriction |
|  [ ]  | **1** | Restricted in physically strenuous activity but ambulatory and able to carry out light work |
|  [ ]  | **2** | Ambulatory and capable of all self care but unable to carry out any work; up and about more than 50% of waking hours |
|  [ ]  | **3** | Capable of only limited self care; confined to bed or chair more than 50% of waking hours |
|  [ ]  | **4** | Completely disabled; cannot carry out any self care; totally confined to bed or chair |

|  |
| --- |
| **Lansky PS (patients <16 at registration). n.b. if patient is under 16 when starting on the study, they should remain using the Lansky Score throughout the study.** |
|  [ ]  | **100** | Fully active, normal. |
|  [ ]  | **90** | Minor restrictions in physically strenuous activity. |
|  [ ]  | **80** | Active, but tires more quickly. |
|  [ ]  | **70** | Both greater restriction of, and less time spent in, active play. |
|  [ ]  | **60** | Up and around, but minimal active play; keeps busy with quieter activities. |
|  [ ]  | **50** | Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities. |
|  [ ]  | **40** | Mostly in bed; participates in quiet activities. |
|  [ ]  | **30** | In bed; needs assistance even for quiet play. |
|  [ ]  | **20** | Often sleeping; play entirely limited to very passive activity. |
|  [ ]  | **10** | No play does not get out of bed. Moribund. |
|  [ ]  | **0** | Unresponsive. Dead. |

|  |
| --- |
| Completed by: |
| **Name:** |  | **Signature:** |  | **Date:** |  |

**2: Biochemistry & Haematology Source Data Form** Page **1** of **1**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |
| --- | --- |
| **Trial number:** | **ICO- \_\_\_ \_\_\_ \_\_\_** |
| **Patient name:** |  |
| **Hospital no.:** |  |

|  |  |  |
| --- | --- | --- |
| **Bloods done** | Yes [ ]  | No [ ]  |
| **If not, why not?** |  |
| **Date of sample:**  | **\_\_\_/\_\_\_\_/\_\_\_\_****DD MM YYYY** |

|  |  |  |
| --- | --- | --- |
| **CRP:** |  | mg/L |
|  | Not done: |  [ ]  |
| **Albumin:** |  | g/L |
|  | Not done: |  [ ]  |
| **Alk. Phosphatase (ALP):** |  | IU/l |
|  | Not done: |  [ ]  |
| **LDH:** |  | IU/l |
|  | Not done: |  [ ]  |
| **Creatinine** |  | mmol/L |
|  | Not done: |  [ ]  |
| **Haemoglobin:** |  | g/L |
|  | Not done: |  [ ]  |
| **ANC:** |  | x109/L |
|  | Not done: |  [ ]  |
| **Lymphocytes:** |  | x109/L |
|  | Not done: |  [ ]  |
| **Platelets:** |  |   |
|  | Not done: |  [ ]  |

|  |
| --- |
| Completed by: |
| **Name:** |  | **Signature:** |  | **Date:** |  |

**3: PreSurgery Imaging Source Data Form** Page **1** of **2**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |
| --- | --- |
| **Trial number:** | **ICO- \_\_\_ \_\_\_ \_\_\_** |
| **Patient name:** |  |
| **Hospital no.:** |  |

|  |  |  |
| --- | --- | --- |
| **Did patient have presurgery imaging?** | Yes [ ]  | No [ ]  |
| **If no, give reason:** |  |

|  |
| --- |
| **MRI** |
| **Was an MRI performed:** | Yes [ ]  | No [ ]  |
| **If yes, hospital:** |  |
| **Date:** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_DD MM YYYY |
| **MRI Reference:** |  |
| **Disease status:** | 1. | [ ]  | Features consistent with response to treatment |
|  | 2. | [ ]  | no change |
|  | 3. | [ ]  | progressive disease |
|  | 4. | [ ]  | not known |

|  |
| --- |
| **CT chest** |
| **Was a CT chest performed:** | Yes [ ]  | No [ ]  |
| **If yes, hospital:** |  |
| **Date:** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_DD MM YYYY |
| **CT scan Reference:** |  |
| **Disease status:** | 1. | [ ]  | Features consistent with response to treatment |
|  | 2. | [ ]  | no change |
|  | 3. | [ ]  | progressive disease |
|  | 4. | [ ]  | not applicable |
|  | 5. | [ ]  | not known |

**3: PreSurgery Imaging Source Data Form** Page **2** of **2**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |
| --- |
| **Any other imaging, please copy for each one** |
| **Was any other imaging performed presurgery:** | Yes [ ]  | No [ ]  |
| **If yes, please select all that**  | 1. | [ ]  | PET scan |
| **apply:** | 2. | [ ]  | Isotope bone scan |
|  | 3. | [ ]  | WB MRI |
|  | 4. | [ ]  | not known |
|  | 5. | [ ]  | Other, specify: |
| **If yes, hospital:** |  |
| **Presurgery imaging Date:** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_DD MM YYYY |
| **Other presurgery imaging Reference:** |  |
| **Disease status:** | 1. | [ ]  | Features consistent with response to treatment |
|  | 2. | [ ]  | no change |
|  | 3. | [ ]  | progressive disease |
|  | 4. | [ ]  | not known |

|  |
| --- |
| Completed by: |
| **Name:** |  | **Signature:** |  | **Date:** |  |

**4: Surgery Source Data Form** Page **1** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |
| --- | --- |
| **Trial number:** | **ICO- \_\_\_ \_\_\_ \_\_\_** |
| **Patient name:** |  |
| **Hospital no.:** |  |

|  |  |  |
| --- | --- | --- |
| **Did the patient have resection of the primary tumour:** | Yes [ ]  | No [ ]  |
| **Date of primary tumour resection:** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_DD MM YYYY |
| **Name of Hospital where primary tumour resection performed:** |  |
| **Histology report ref. no.:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **If the primary tumour has not**  | 1. | [ ]  | tumour not resectable at presentation. |
| **been resected, state reason:** | 2. | [ ]  | tumour progressed on treatment and has become unresectable |
|  | 3. | [ ]  | for palliative treatment not including resection of primary tumour. |
|  | 4. | [ ]  | patient not fit for surgery. |
|  | 5. | [ ]  | Other, specify: |

|  |  |  |  |
| --- | --- | --- | --- |
| **ASA classification:** | **ASA I:** | [ ]  | A normal healthy patient |
|  | **ASA II:** | [ ]  | A patient with mild systemic disease |
|  | **ASA III:** | [ ]  | A patient with severe systemic disease |
|  | **ASA IV:** | [ ]  | A patient with severe systemic disease that is a constant threat to life |
|  | **ASA V:** | [ ]  | A moribund patient who is not expected to survive without the operation  |

**4: Surgery Source Data Form** Page **2** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |  |
| --- | --- | --- |
| **Central line in situ?** | Yes [ ]  | No [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of primary tumour** | 1. | [ ]  | Amputation |
| **resection performed:** | 2. | [ ]  | Limb salvage |
|  | 3. | [ ]  | Other, specify: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Site of primary resection**  | 1. | [ ]  | L Femur |
| **surgery:** | 2. | [ ]  | R Femur |
|  | 3. | [ ]  | L Tibia |
|  | 4. | [ ]  | R Tibia |
|  | 5. | [ ]  | L Fibula |
|  | 6. | [ ]  | R Fibula |
|  | 7. | [ ]  | L Humerus  |
|  | 8. | [ ]  | R Humerus  |
|  | 9. | [ ]  | L Radius |
|  | 10. | [ ]  | R Radius |
|  | 11. | [ ]  | L Ulna |
|  | 12. | [ ]  | R Ulna |
|  | 13. | [ ]  | Scapula/Clavicle |
|  | 14. | [ ]  | Pelvis/Sacrum |
|  | 15. | [ ]  | Rib |
|  | 16. | [ ]  | Spine |
|  | 17. | [ ]  | Maxilla |
|  | 18. | [ ]  | Mandible |
|  | 19. | [ ]  | Other, specify: |

**4: Surgery Source Data Form** Page **3** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Parts of which segments of**  | 1. | [ ]  | Proximal epiphysis |
| **long bone were resected**  | 2. | [ ]  | Proximal metaphysis |
| **(tick all that apply):** | 3. | [ ]  | Diaphysis |
|  | 4. | [ ]  | Distal Metaphysis (long bone) |
|  | 5. | [ ]  | Distal Epiphysis (long bone) |
|  | 6. | [ ]  | geometric/partial/unicortical excision of bone segment |
|  | 7. | [ ]  | not applicable |

|  |  |  |  |
| --- | --- | --- | --- |
| **If a joint was involved was**  | 1. | [ ]  | Intraarticular resection |
| **this intended to be** | 2. | [ ]  | Extraarticular resection |

|  |  |  |  |
| --- | --- | --- | --- |
| **Pelvic tumours: section** | 1. | [ ]  | **P1 – L** Iliac wing |
| **involved: (tick all that**  | 2. | [ ]  | **P2 – L** Acetabulum |
| **apply)** | 3. | [ ]  | **P3 – L** Anterior pelvis |
|  | 4. | [ ]  | **P1 – R** Iliac wing |
|  | 5. | [ ]  | **P2 – R** Acetabulum |
|  | 6. | [ ]  | **P3 – L** Anterior pelvis |
|  | 7. | [ ]  | **P4** - Sacrum |
|  | 8. | [ ]  | Other, specify: |

|  |  |  |
| --- | --- | --- |
| **Amputation performed:** | Yes [ ]  | No [ ]  |
| **Site of primary resection**  | 1. | [ ]  | Lower limb: Ray amputation only |
| **surgery:** | 2. | [ ]  | Lower limb: Midfoot |
|  | 3. | [ ]  | Lower limb: Through ankle |
|  | 4. | [ ]  | Lower limb: Trans tibial |
|  | 5. | [ ]  | Lower limb: Through knee |
|  | 6. | [ ]  | Lower limb: Transfemoral |
|  | 7. | [ ]  | Lower limb: Hip disarticulation |
|  | 8. | [ ]  | Lower limb: Hindquarter |
|  | 9. | [ ]  | Lower limb: Forequarter |
|  | 10. | [ ]  | Upper limb: Ray amputation only |
|  | 11. | [ ]  | Upper limb: Transradial or below |
|  | 12. | [ ]  | Upper limb: Through elbow |
|  | 13. | [ ]  | Upper limb: Transhumeral |
|  | 14. | [ ]  | Upper limb: Shoulder disarticulation |
|  | 15. | [ ]  | Other, specify: |

**4: Surgery Source Data Form** Page **4** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |  |
| --- | --- | --- |
| **Limb sparing surgery performed:** | Yes [ ]  | No [ ]  |
| **If yes, reconstruction types:**  | 1. | [ ]  | Type of Implant – custom |
| **(tick all that apply)** | 2. | [ ]  | Type of implant - modular |
|  | 3. | [ ]  | Coating - silver |
|  | 4. | [ ]  | Coating - other (please specify): |
|  | 5. | [ ]  | Fixation - Cemented |
|  | 6. | [ ]  | Fixation - Uncemented |
|  | 7. | [ ]  | Collar – HA coated |
|  | 8. | [ ]  | Collar – other (please specify) |
|  | 9. | [ ]  | Biological reconstruction - Allograft |
|  | 10. | [ ]  | Biological reconstruction - Autograft |
|  | 11. | [ ]  | Biological reconstruction – other (please specify): |
|  | 12. | [ ]  | Other reconstruction, specify: |
| **Implant manufacturer:** |  |

|  |  |
| --- | --- |
| **Which Anatomical structures were removed? (please list)** |  |
| **Surgeon assessment of**  | 1. | [ ]  | Negative |
| **margin** | 2. | [ ]  | planned positive |
|  | 3. | [ ]  | unintentionally positive |
|  | 4. | [ ]  | intralesional - piecemeal |

|  |  |  |  |
| --- | --- | --- | --- |
| **Histological subtype of**  | 1. | [ ]  | Osteoblastic osteosarcoma |
| **resected tissue:** | 2. | [ ]  | Chondroblastic osteosarcoma |
|  | 3. | [ ]  | Fibroblastic osteosarcoma |
|  | 4. | [ ]  | Telangiectatic  |
|  | 5. | [ ]  | Small cell |
|  | 6. | [ ]  | High grade surface |
|  | 7. | [ ]  | Periosteal |
|  | 8. | [ ]  | Low Grade Surface |
|  | 9. | [ ]  | Parosteal |
|  | 10. | [ ]  | Type not specified |
|  | 11. | [ ]  | Other, specify: |

**4: Surgery Source Data Form** Page **5** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |  |
| --- | --- | --- |
| **Did the patient require antibiotics:** | Yes [ ]  | No [ ]  |
| **If yes, provide details:** |  |

|  |  |  |
| --- | --- | --- |
| **Estimated blood loss (mls)** | Yes [ ]  | No [ ]  |

|  |  |  |
| --- | --- | --- |
| **Did the patient have any post-op complications:** | Yes [ ]  | No [ ]  |
| **If yes, provide details:** | 1. | [ ]  | Wound complications requiring return to theatre |
|  | 2. | [ ]  | Superficial infection |
|  | 3. | [ ]  | deep Infection |
|  | 4. | [ ]  | deep venous thrombosis |
|  | 5. | [ ]  | pulmonary embolism |
|  | 6. | [ ]  | Other, specify: |

|  |
| --- |
| **Resection pathology** |
| **Length maximum resection dimension (mm)** |  | mm |
| **Width maximum resection dimension (mm)** |  | mm |
| **Depth maximum resection dimension (mm)** |  | mm |
| **Resection margins:** **Narrowest bone margin (mm)** |  | mm |

**4: Surgery Source Data Form** Page **6** of **6**

* ***Use this Source data form to record the data entered onto the eCRF.***
* ***DO NOT return this form to UCL CTC.***
* ***On completion, print off, sign and file this form with the patient notes.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Resection margins:** | 1. | [ ]  | Tumour at surface of specimen |
| **Narrowest margin (mm)** | 2. | [ ]  | <1 mm |
|  | 3. | [ ]  | <2 mm |
|  | 4. | [ ]  | <3 mm |
|  | 5. | [ ]  | <4 mm |
|  | 6. | [ ]  | <5 mm |
|  | 7. | [ ]  | ≥5 mm |
|  | 8. | [ ]  | not stated |

|  |  |  |  |
| --- | --- | --- | --- |
| **Covered by intact periosteum?** | Yes [ ]  | No [ ]  | Not stated [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Lymphovascular invasion:** | Yes [ ]  | No [ ]  | Not stated [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Response to chemotherapy: percentage necrosis:** |  | **%** | Not applicable [ ]  |

|  |  |  |
| --- | --- | --- |
| **Was a snap frozen specimen stored:** | Yes [ ]  | No [ ]  |
| **If yes, hospital where snap frozen specimen stored:** |  |
| **If no, provide reason:** |  |

|  |
| --- |
| Completed by: |
| **Name:** |  | **Signature:** |  | **Date:** |  |