RACER
Robotic Arthroplasty:
A Clinical and cost Effectiveness
Randomised controlled trial

# Unscheduled Events CRF's

If you have any queries please contact the central study team at:
RACER@warwick.ac.uk

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  - **Learning Effect Sub-study**
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- **Protocol Deviation**
- **Adverse Event**
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  - **SAE Continuation**

TRIAL OFFICE USE:

| Received: | Initial: |
|---|---|

| Checked: | Initial: |
|---|---|

# Withdrawal Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

## 1. DATE OF PARTICIPANT WITHDRAWAL:

d d – m o n – y y y y

## 2. RANDOMISATION

a) The participant **HAS** been randomised: No ☐ Yes ☐

## 3. MAIN REASON FOR PARTICIPANT WITHDRAWAL *(please select one option only)*

a) The participant is no longer having surgery ☐
*(please indicate whose decision this was)*

*i. Surgeon's decision:* No ☐ Yes ☐

*ii. Participant's decision:* No ☐ Yes ☐

b) The participant is unfit for surgery ☐

c) The participant no longer wishes to take part (i.e. the participant wants the control procedure, wants treatment outside of the trial, or wants treatment at a different centre) ☐

d) The participant does not wish to take part in follow-up ☐

e) No reason given ☐

f) Other: *(please give details)* ☐

## 4. PARTICIPANT'S TRIAL STATUS (RANDOMISED PARTICIPANTS ONLY) *(Please select one option only)*

a) Participant withdrew from on-site follow-up but is happy to be followed up by the trial team using other methods of follow-up e.g. post, phone, home visits, app, and/or e-mail. ☐

b) Participant has withdrawn completely from the trial and will not be followed up. ☐

**Form completed by (print name):** _____

*(Please note: your name **must** be on the trial delegation log)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

| Received: | Initial: |
|---|---|

| Checked: | Initial: |
|---|---|

# RACER Learning Effects Study Withdrawal Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

## 1. DATE OF PARTICIPANT WITHDRAWAL:

d d – m o n – y y y y

## 2. MAIN REASON FOR PARTICIPANT WITHDRAWAL *(please select one option only)*

a) The participant is no longer having surgery ☐
*(please indicate whose decision this was)*

*i. Surgeon's decision:* No ☐ Yes ☐

*ii. Participant's decision:* No ☐ Yes ☐

b) The participant is unfit for surgery ☐

c) The participant no longer wishes to take part (i.e. the participant wants the control procedure, wants treatment outside of the trial, or wants treatment at a different centre) ☐

d) The participant does not wish to take part in follow-up ☐

e) No reason given ☐

f) Other: *(please give details)* ☐

## 4. PARTICIPANT'S STUDY STATUS *(Please select one option only)*

a) Participant withdrew from on-site follow-up but is happy to be followed up by the trial team using other methods of follow-up e.g. post, phone, home visits, app, and/or e-mail. ☐

b) Participant has withdrawn completely from the study and will not be followed up. ☐

**Form completed by (print name):** _____

*(Please note: your name **must** be on the trial delegation log)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

# Notification of Death

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

1. Date of death: d d – m o n – y y y y

2. Cause/s of death:

***If possible, please give brief details, indicating the reasons for death***

**Reasons for death:**

**Form completed by (print name):** _____

*(Please note: your name must be on the trial delegation log)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

| *Received:* | *Initial:* |
|---|---|

| *Checked:* | *Initial:* |
|---|---|

# File Note

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

**If this is related to a participant, please provide the TNO**

**Form completed by (print name):** .....

**Signature:** ..... **Date completed:** d d - m o n - y y y y

**Trial Office Assessment by (print name):** .....

**Signature:** ..... **Date assessed:** d d - m o n - y y y y

TRIAL OFFICE USE:

| *Received:* | *Initial:* |
|---|---|

| *Checked:* | *Initial:* |
|---|---|

# Protocol Deviation

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

**DETAILS OF EVENT:**

(please give as much information as possible) :

1. Participant did not receive the allocated intervention ☐

Specify the reason

2. Participant received other treatment ☐

Specify the reason

3. Participant deferred intervention ☐

Specify the reason

Please provide the new date of intervention, if known d d - m o n - y y y y

4. Participant has been unblinded ☐

Specify the reason

5. Other Reason ☐

Specify the reason

**Form completed by (print name):** .....

*(Please note: your name **must** be on the trial delegation log)*

**Signature:** ..... **Date signed:** d d - m o n - y y y y

TRIAL OFFICE USE:

| Received: | Initial: | Checked: | Initial: |
|---|---|---|---|

# Adverse Event Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

Please complete one Adverse Event Form per event

**1. Date of AE:** d d – m o n – y y y y

**2. Please tick one event per form:**

- ☐ Injury to teeth, mouth or throat during anaesthetic
- ☐ Urinary retention
- ☐ Chest infection
- ☐ Nerve or vessel injury due to local anaesthetic (i.e. local blocks)
- ☐ Spinal haematoma
- ☐ Exacerbation/persistence of knee pain or restriction in range of motion requiring medical intervention
- ☐ Deep Infection of the knee joint or the implant
- ☐ Wound healing problems
- ☐ Fracture, or ligament or tendon damage or rupture
- ☐ Implant failure, dislocation, or loosening
- ☐ Revision surgery or other corrective surgery
- ☐ Thrombosis
- ☐ Damage to nerves or vessels in the surgical area
- ☐ Persistent muscle soreness or muscle injury
- ☐ Bruising
- ☐ Other *(Please provide as much detail as possible in the box below)*

Please Note if the event meets the criteria listed below:

**Death**
**Life threatening**
**Hospitalisation or prolonged hospitalisation**
**Disability/ incapacity**
**Congenital abnormality/birth defect**

This would no longer be classed as an adverse event and needs to be reported as a serious AE, please complete the SAE form

Please not that medical device related AEs or defects should also be reported to Stryker.

**3. Please add any further details to the box below or write 'Not Applicable' or N/A**

**If you are unable to upload this information directly onto the RACER database, please email to RACER@warwick.ac.uk**
**For queries please call: Tel: 02476 968629**

**Form completed by (print name):** _____

**Signature:** _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE: | *Received:* | *Initial:* | *Checked:* | *Initial:* |

# Serious Adverse Event Form—Initial

**Participant Trial Number:** ☐☐☐☐☐ **Participant initials:** ☐☐☐

**Randomising Site:**

**SAE Reference no.**
*For trial office use only*

***Please email immediately to the RACER Coordinating Centre to wctuqa@warwick.ac.uk***

**1. EVENT TYPE:** *(please confirm 'Yes' or 'No' for each category)*

| | No | Yes |
|---|---|---|
| **1.** Death | ☐ | ☐ |
| **2.** Life-threatening | ☐ | ☐ |
| **3.** Hospitalisation or prolongation of existing hospitalisation | ☐ | ☐ |
| **4.** Persistent or significant disability/incapacity | ☐ | ☐ |
| **5.** Congenital anomaly/birth defect | ☐ | ☐ |
| **6.** Requires medical intervention to prevent one of the above, or it is otherwise medically significant *(please specify below)* | ☐ | ☐ |

**2. DATE OF EVENT:**

**1. Date event deemed serious:** d d – m o n – y y y y

**2. Date site aware of this event:** d d – m o n – y y y y

**3. DETAILS OF EVENT:** *(Please include all **relevant** details of the event, tests performed, associated results, and any **relevant** medical history, concomitant medication and dates of administration)*

*(Please continue on SAE Continuation Form as necessary)*

TRIAL OFFICE USE: | *Received:* | *Initial:* | *Checked:* | *Initial:* |

## 4. CAUSALITY:

**1. Was the event related to administration of the study procedures i.e. the anaesthetic, operation or post-operative care?**

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

**2. Was the event related to the robot?** ***WCTU will ALSO contact STRYKER about any robot related SAEs***

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

## 5. OUTCOME OF EVENT: *(please select one only)*

**1. Resolved—no sequelae** ☐ → **Date of resolution:** d d – m o n – y y y y

**2. Resolved—with sequalae** ☐ → **Details of sequalae:** _____ **Date of resolution:** d d – m o n – y y y y

**3. Unresolved** ☐ → **Please complete the SAE Follow-up Form as appropriate**

**4. Death** ☐ → **Please complete Notification of Death form**

**5. Unresolved at time of death/withdrawal** ☐ → **Please complete Notification of Death/Withdrawal Form as appropriate**

**Clinician assessing causality (print name):** _____

*(Please note: your name **must** be on the trial delegation log with responsibility code J)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

**Form completed by (print name):** _____

*(Please note: your name **must** be on the trial delegation log with responsibility code K)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

| *Received:* | *Initial:* | *Checked:* | *Initial:* |
|---|---|---|---|

# Completion Guidelines for RACER Serious Adverse Event Form

| | |
|---|---|
| Form dates: | Use format: 0 6 - J U N - 1 9 5 6 |
| Date deemed Serious | This is the date when an adverse event is considered to be serious i.e. date the AE fitted one of the event types in box 1. |
| Date site became aware of the event | Date the investigator team at site first became aware of this event—this may be different from the date the event was deemed to be serious. **N.B. GCP requires that investigators report all SAEs to the trial sponsor 'immediately' or at least within 24 hours of their first knowledge of the event** |
| Was the event related to administration of the study procedures i.e. the anaesthetic, operation, or preoperative care? | **Unrelated:** There is no evidence of any causal relationship<br>**Unlikely:** There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the patient's clinical condition, other concomitant medications).<br>**Possibly:** There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant medications).<br>**Probably:** There is evidence to suggest a causal relationship and the influence of other factors is unlikely.<br>**Definitely:** There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. |

**If an SAE Continuation Form is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.**

TRIAL OFFICE USE:

| Received: | Initial: | Checked: | Initial: |
|---|---|---|---|
| | | | |

# Serious Adverse Event Form—Follow-up

**Participant Trial Number:** ☐☐☐☐☐ **Participant Initials:** ☐☐☐

**Randomising Site:**

**SAE Reference No.**
For trial office use only

***Please email immediately to the RACER Coordinating Centre to wctuqa@warwick.ac.uk***

**1. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON:** d d – m o n – y y y y

(Date must match to that stated in Section 2 of Initial Report)

## 2. FURTHER DETAILS OF EVENT:

**1. Have there been any additional serious adverse event symptoms or worsening in grade of the event symptoms reported on the initial report?**

**Yes** ☐ **No** ☐ → *Please continue to next page.*

*Please complete section below with any new or updated information.*

**Please include all relevant further details of the event, any additional tests performed, updated results and treatment:**

*(Please continue on SAE Continuation Form as necessary)*

TRIAL OFFICE USE: | *Received:* | *Initial:* | *Checked:* | *Initial:*

## 3. CAUSALITY:

**1. Was the event related to administration of the study procedures i.e. the anaesthetic, operation or post-operative care?**

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

**2. Was the event related to the robot?** ***WCTU will ALSO contact STRYKER about any robot related SAEs***

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

## 4. OUTCOME OF EVENT: *(please select one only)*

**1. Resolved—no sequelae** ☐ → **Date of resolution:** d d – m o n – y y y y

**2. Resolved—with sequelae** ☐ → **Details of sequelae:** _____ **Date of resolution:** d d – m o n – y y y y

**3. Unresolved** ☐ → **Please complete the SAE Follow-up Form as appropriate**

**4. Death** ☐ → **Please complete Notification of Death form**

**5. Unresolved at time of death/withdrawal** ☐ → **Please complete Notification of Death/Withdrawal Form as appropriate**

**Clinician assessing causality (print name):** _____

*(Please note: your name **must** be on the trial delegation log with responsibility code J)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

**Form completed by (print name):** _____

*(Please note: your name **must** be on the trial delegation log with responsibility code K)*

**Signature:** _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

| *Received:* | *Initial:* | *Checked:* | *Initial:* |
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## Completion Guidelines for RACER Serious Adverse Event Form—Follow-up report

Form dates: Use format: 0 6 - J U N - 1 9 5 6

Further details of event: Please add any additional **relevant** information that has come to light since the initial report

Was the event related to administration of the study procedures i.e. the anaesthetic, operation, or post-operative care?

| | |
|---|---|
| **Unrelated:** | There is no evidence of any causal relationship |
| **Unlikely:** | There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the participant's clinical condition, other concomitant medications). |
| **Possibly:** | There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant medications). |
| **Probably:** | There is evidence to suggest a causal relationship and the influence of other factors is unlikely. |
| **Definitely:** | There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. |

**If an SAE Continuation Form is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.**

# Serious Adverse Event Continuation Form

Participant Trial Number: | | | | | | Participant Initials: | | | |

Randomising Site:_____

**SAE Reference No:** | | | | | | | | | | |

**Please Scan Immediately to the RACER Coordinating Centre: RACER@warwick.ac.uk**

Is there additional SAE information available relevant to this SAE report? Yes ☐ No ☐

*(If Yes please complete below)*

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*(Please note your name **must** be on the trial delegation log to sign this form)*

**Clinician assessing causality (print name):**_____

**Signature:** _____**Date Signed:** d d – m o n – y y y y

**Form completed by (print name):**_____

**Signature:** _____**Date Signed:** d d – m o n – y y y y