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)

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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 **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). **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). **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.