WOLLF Serious Adverse Event Form

Wound Management of Open Lower Limb Fractures

Please report any SAEs which occur following initial discharge

Please fax immediately to the WOLLF Coordinating Centre on 02476 150 549

Centre ID: ☐☐☐ **Participant ID:** ☐☐☐☐ **Participant Initials:** ☐☐☐ **Date of Birth:** ☐☐-☐☐-☐☐☐☐

Initial or Follow Up? **Initial:** ☐ **Follow Up:** ☐

1. EVENT TYPE:

	Yes
i. Death	☐
ii. Life-threatening	☐
iii. Hospitalisation or prolongation of existing hospitalisation	☐
iv. Persistent or significant disability/incapacity	☐
v. Required medical intervention to prevent one of the above	☐
vi. Otherwise considered medically significant	☐

2. EVENT DETAILS:

i. Date event deemed serious: ☐☐-☐☐-☐☐☐☐

ii. Details of Event:

Please include all **relevant** details of the event, any tests performed and associated results:

3. CAUSALITY: **In the opinion of the Principal Investigator was the event related to the trial**

Related: ☐ Unrelated: ☐

4. EXPECTEDNESS:

Expected: ☐ Unexpected: ☐

5. OUTCOME OF EVENT:

Resolved ☐ Ongoing ☐

Principal Investigator Signature: _____

Date signed: ☐☐-☐☐-☐☐☐☐

Office use only:

Is the event related to the intervention? **No** ☐

Yes ☐

Is it Unexpected? **No** ☐

Yes ☐

Date report sent to MREC/Sponsor (within 15 days of WOLLF team receiving report) ☐☐-☐☐-☐☐☐☐

Chief Investigator Signature: _____

Date signed: ☐☐-☐☐-☐☐☐☐