Reporting Adverse Events in FEMuR

Instructions

1. Upon becoming aware of an adverse event (AE) involving a participant or carer, record it on the attached form in part A. There is no need for you to determine whether it is "serious" as this will be done by the chief investigator (CI) of the study once it has been reported.

An AE is an untoward occurrence experienced by either a participant or carer which:

a) exacerbates a pre-existing illness; (e.g. something that causes an acute asthma attack necessitating a change in medication use or visit to the hospital for someone who has asthma).
b) increases in frequency or intensity a pre-existing episodic condition (e.g. an increased frequency of angina episodes necessitating taking medication or other health service intervention – these may or may not be directly as a result of the study (e.g.directly related might be: following practice of physiotherapy extercises);
c) is a condition detected after the start of the study (even though it may have been present prior to the start of the study) (e.g. a new diagnosis of Parkinson's disease after recruitment to the study)
d) is a continuous persistent disease or symptoms present at baseline that worsen during the study (e.g. periferal vascular disease present at baseline with intermittent claudication symptoms provoked by shorter distances walked);
e) results in a fall or repeat fracture;
f) requires hospitalisation (e.g. a myocardial infarction that happended at home resulting in a hopsitialisation)or prolongs existing hospitalisation (whilst recovering from hip fracture surgery the patient constracts an infection requiring inpatient IV medication);
g) results in persistent or significant disability or incapacity (e.g. a stroke resulting in hemiplegia that doesn't resolve completly as might happen with a TIA);
h) is otherwise considered medically significant and based upon appropriate medical judgement, may jeopardise the participant and require medical or suirgical intervention;
i) is life-threatening;
j) results in death.

In addition, any cases where action has been taken for the protection of vunerable adults (dealing with suspected abuse or neglect of participants) should be reported to Bangor using this procedure.

It should be noted that all AE should be reported to Bangor University, even if initially there may be no obvious connection to the trial. In particular:

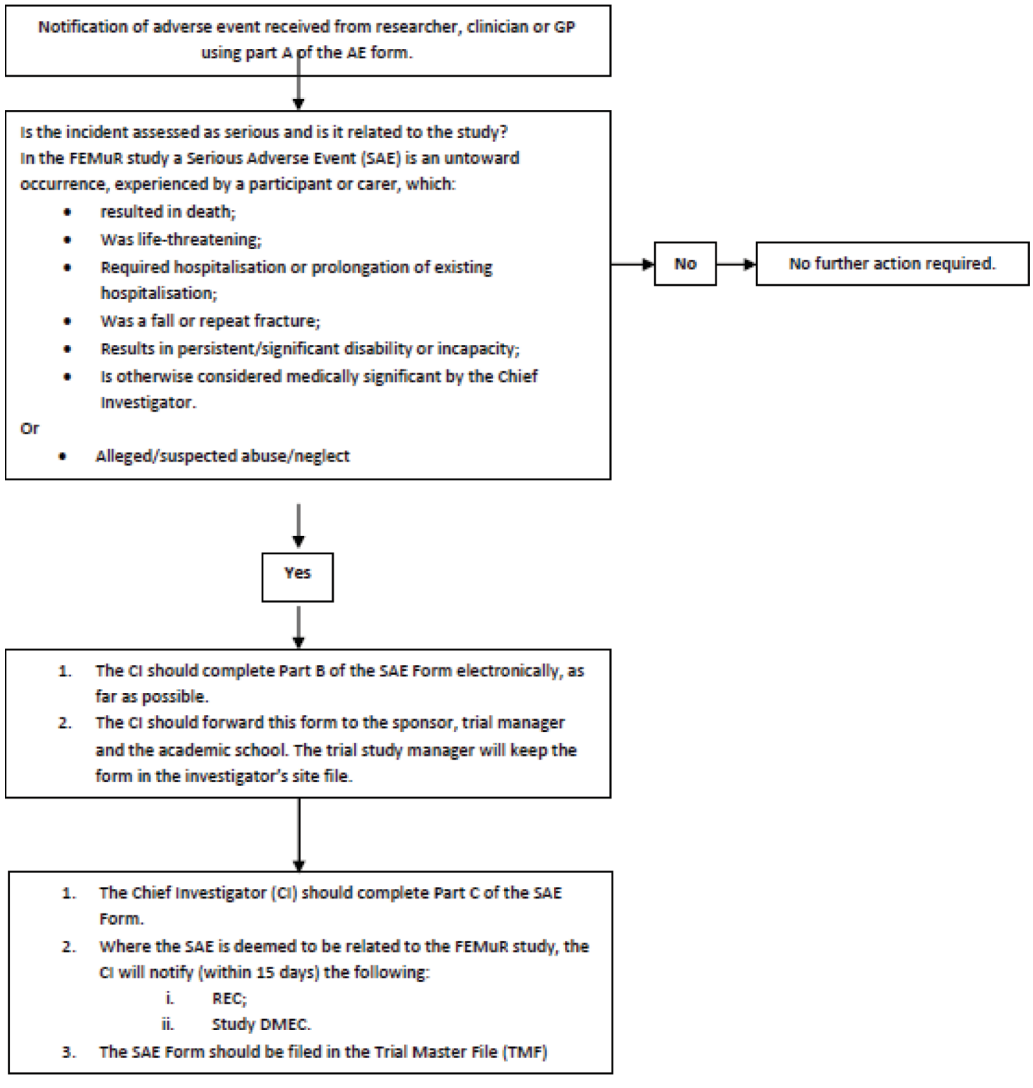
- All deaths of participants and carers should be reported to Bangor University.

Contact: Dr Nefyn Williams Tel: [redacted] E-mail: [redacted]

- All incidents of hosptialisation (and prolonging of hospitalisation) for participants and carers should be reported to Bangor (even when the illness or condition being treated has no obvious connection to the trial).

2. If an AE is deemed to have taken place, therapists, clinicians and researchers should complete the attached form part A and forward it to the StudyManager as soon as possible and within 24 hours, where possible, of discovering and AE has taken palce. The contact details are given at the end of part A.
3. The Study Manager will liase with the study CI who will determine whether it is serious or not and whether it is realated to the study or not.
4. The CI will report and SAEs to the DMEC chair and the CI and DMEC Chair will determine whether they are related to the study. If the AE is determined to be both serious and related to the study, the CI will report it to the sponsor and to the academic school (Schools of Medical and Healthcare Sciences, College of Health and Behavioural Science) within 24 hours. They will also be reported to the Research Ethics Committee.

Figure 1 – Flow chart of FEMuR Serious Adverse Event Reporting Procedure



Contact: Dr Nefyn Williams Tel: [redacted] E-mail: [redacted]

FEMuR Serious Adverse Event Reporting Form

PART A (to be completed by Researcher, Therapist or GP)

A1. Centre Name: **BCUHB**

Completed by: _____

A2. Date form completed: | | | | | | | | | (d d m m y y y y)

A3. Participant Identity | | | | | | | Number:

A4. How did you become aware of this incident?

A5. Was this AE suffered by the participant or carer? *Place an **"x"** in **one** box only.*

Participant ☐

Carer ☐

A6. Are you reporting a death? Place an "x" in one box only.

Yes ☐ **Please proceed to Question A8**

No ☐ **Please proceed to Question A7**

A7. Please categorise this event, by placing an "x" in all appropriate boxes.

☐ Life threatening

☐ Hospitalisation or prolongation of existing hospitalisation

☐ Persistent or significant disability or incapacity

☐ Otherwise considered medically significant

A8. Date of SAE | | | | | | | | | (d d m m y y y y)

Contact: Dr Nefyn Williams Tel: [redacted] E-mail: [redacted]

A9. Location of SAE _____

A10.	Describe the circumstances of the event. Is there any evidence that participation in the trial may have been a contributing factor? (attach further sheet if necessary)	

After signing, please send by post, or email to the address below and retain a copy for your records. You can also contact the Study Manager by phone during office hours.

[redacted]
Tel: [redacted]

PART B (to be completed by Chief Investigator)

B1. In your opinion, is this reported AE assessed as serious according to the FEMuR protocol?

Yes ☐

No ☐

B2. In your opinion, did this AE arise as a result of the participant's or carer's involvement in the Femur Study? Place an "x" in one box only.

Yes ☐

No ☐

B3. Please add any comments regarding the SAE

Please print and sign a copy of this form and return to Dr Claire Hawkes for the investigator's Site File.

Contact: Dr Nefyn Williams Tel: [redacted] E-mail: [redacted]

PART C (to be completed by Chief Investigator)

C1.	Action taken	
C2.	Name of CI	Dr Nefyn Williams
C3.	Signature of CI	
C4.	Date of signature	d d m m y y y y

Contact: Dr Nefyn Williams Tel: [redacted] E-mail: [redacted]