Adverse event form

Travel to Work Study

Adverse Events Form (AE1)

Walking to work is considered a 'low risk' activity but we would like to know if you experience any problems, incidents or accidents as a result of walking to work e.g. aches and pains, blisters, road traffic incidents, street crime or anti-social behaviour. **We hope walking to work will be an enjoyable and healthy experience for you but if you do have any problems we would be grateful if you would let us know as soon as possible by completing this form and returning it to:**

[Insert contact details for local researcher]

In case of a Serious Adverse Event (e.g. an accident resulting in hospitalisation) please telephone the Study Team 0117 928 7284 within 24 hours of your knowledge of the event taking place.

SECTION 1: To be completed by the study participant, Walk to Work promoter or employer

Workplace	
Participant Name	
Location	
Date of event	

Details of event (*Please include what happened and if it was related to the journey to/ from work. Continue overleaf if required*)

Was any action necessary? YES/NO (*If YES please give details below*)

Actions taken	**Action taken by:**	**Date**

Is event on-going: YES/NO **If NO, date resolved:**

For office use only. Participant ID: **Study ID:**

Serious adverse event form

Travel to Work Study

Serious Adverse Events Form (AE2)

This form is to be completed by a member of the research team after receiving a telephone call, email or an AE1 form which indicates that a serious adverse event has taken place and any further information has been gained to assess: whether the event is an SAE, and: whether it is related to study participation. A copy of the relevant AE1 should be attached to this form.

A Serious Adverse Event is an occurrence that results in death, is life-threatening, requires inpatient hospitalisation, may jeopardise the participant, or results in persistent or significant disability or incapacity.

Was this a Serious Adverse Event? YES/NO If yes, please answer the following questions.

Which category was the Serious Adverse Event? *(Please tick one box)*	
Results in the death of the participant	
Is life-threatening	
Requires inpatient hospitalisation or may jeopardise the participant	
Results in persistent or significant disability / incapacity	

Was the Serious Adverse Event related to study participation? *(Please tick one box)*	
Unrelated	
Unlikely to be related	
Possibly related	
Probably related	
Definitely related	

This form should be signed and dated by the researcher (in the box below) and then sent to the Study Manager and Principal Investigator for signature.

	Name	**Signature**	**Date**
Local researcher			
Study Manager			
Principal Investigator			

The Principal Investigator should notify the Chair of the Trial Steering Committee and the Head of School. The Study Manager should send a copy of the form to the **Faculty Research Governance and Ethics Officer:**

[*insert contact details*]

To be completed by Faculty Research Governance and Ethics Officer

Date received	
Date entered on database	
Entered on database by	
Name of reviewer	
Signature of reviewer	
Date of review	
Comments	