ProFHER Trial: Adverse Event Reporting Form

Participant ID number: | | | | |

This form should be completed for patients who have had an **adverse event:** i.e. any undesirable experience occurring to a patient, whether or not considered related to the treatments being compared in the trial.

Date of assessment (dd/mm/yy):

Name of Principal Investigator:

Name of person reporting the adverse event:

Q1. Please record **date of adverse event** (dd/mm/yy):

Q2. **Nature of adverse event**:

Please provide as much information as possible in the box below about the adverse event including investigations and treatment given.

Please continue form overleaf

Q3. **Type of adverse event***:

Please categorise this adverse event, crossing all appropriate options:

	Yes	No
a. Resulted in Death	☐	☐
b. Is life-threatening	☐	☐
c. Required hospitalisation or prolongation of existing hospitalisation	☐	☐
d. Resulted in persistent significant disability or incapacity	☐	☐
e. Consists of a congenital anomaly or birth defect	☐	☐
f. Is otherwise considered medically significant by the investigator	☐	☐
g. Other (please describe):	☐	☐

Q4a. In your opinion, is the adverse event **related** to the patient taking part in the ProFHER Trial? **Yes** ☐ **No** ☐

Q4b. Is it an **expected** ☐ or **unexpected** ☐ adverse event?

Please explain your responses to 4a and 4b in the box below:

***** If the answer to any parts of a-f for Question 3 is 'Yes', this is a **serious adverse event** and must be reported to the ProFHER Trial Co-ordinator **within 24 hours** of the local investigator becoming aware of it.

If the only answer to Question 3 is 'Yes' to part g. this is a **non-serious adverse event** and must be reported to the ProFHER Trial Co-ordinator **within 5 days** of the local investigator becoming aware of it.

Please fax this form to the ProFHER Trial Co-ordinator on 01904 [redacted] for the attention of Dr Stephen Brealey. Before you fax the form, please ring Stephen Brealey on 01904 [redacted] to inform him that the fax is on its way. If Stephen is unavailable then please ring Ms Sarah Gardner, ProFHER Trial Secretary, on 01904 [redacted].

Thank you for completing this form