NHS
Health Research Authority

REPORT OF SERIOUS ADVERSE EVENT (SAE)
(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	Professor Phyo Myint
Address:	Professor of Medicine of Old Age Room 4.013 Polwarth Building Foresterhill Aberdeen AB25 2ZD
Telephone:	01224 437841
Email:	phyo.myint@abdn.ac.uk

2. Details of study

Full title of study:	RAndomised IroN Deficiency anaemia management Pilot
Name of main REC:	North of Scotland REC 1
Main REC reference number:	18/NS/0064
Research sponsor:	University of Aberdeen & Grampian Health Board Ref: 3.023.18
Sponsor's reference for this report: (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate options:

Death ☐	Life threatening ☐	Hospitalisation or prolongation of existing hospitalisation ☐
Persistent or significant disability or incapacity ☐	Congenital anomaly or birth defect ☐	Other ☐

4. Circumstances of event

<table>
<tr><td>Date of SAE:</td><td></td></tr>
<tr><td>Location:</td><td></td></tr>
<tr><td>Describe the circumstances of the event:

(Attach copy of detailed report if necessary)</td><td>Date reported to Investigator team:

Diagnosis / Adverse Event Description:</td></tr>
<tr><td>What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?</td><td>
1. Severity:
Mild ☐ Moderate ☐ Severe ☐

2. Relationship to study intervention:
Unrelated☐ Possible ☐ Probable ☐ Definite ☐

3. Unblinding completed? Yes ☐ (if yes complete below) No ☐
<table>
<tr><th>Study Intervention</th><th>Start Date</th><th>End Date
OR Tick if ongoing</th><th>Date of Last Dose</th></tr>
<tr><td>☐ Continue Oral Iron
☐ Stop Oral Iron
☐ IV iron</td><td></td><td>☐</td><td></td></tr>
</table>
4. Action Taken:
☐ None
☐ Hospitalisation
☐ Intervention stopped
☐ Concomitant medication commenced
☐ Other :
_____

5. Expectedness:
☐ Expected (in-line with study intervention)
☐ Unexpected (not listed in protocol or SmPC)
Rationale for expectedness assessment:
_____

6. Outcome:
Recovered: ☐ Recovered with Sequelae: ☐

Ongoing ☐ Disability or Incapacity ☐ Death ☐ Unknown ☐

Date of Recovery/Date of Death:

7. Narrative:
Additional information regarding circumstances, sequence, diagnosis and treatment of the event(s) not otherwise on this form.
</td></tr>
</table>

5. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

6. Acknowledgement of receipt by main REC:

The North of Scotland (1) Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back to Chief Investigator (or other person submitting report)
Copy to be kept for information by main REC.