PROTOCOL VIOLATION REPORTING FORM

DO NOT SEND IDENTIFIABLE DATA WITH THIS FORM*

VIOLATION: A deviation that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being.

NB: If the event could NOT potentially have impacted upon (i) patient safety and/or (ii) study outcome, please complete an entry in the Protocol Deviation log (CR010-T01)

1. REPORT DETAILS

Trial Title	**SHORT TITLE**
EudraCT No.	**2015-XXXXXX-XX**
REC No.	**XX/XX/XXXX**
Principal Investigator	**XXX**
Site Name/No.	**Western General Hospital, Edinburgh / 50**
Country Violation Recorded	**UK**
Participant number	**20001**

2. ASSESSMENT TO CONFIRM VIOLATION

Please confirm which of the following may have potentially been impacted by the violation:

		Details:	Sign/Date:
Safety of Participant*	**Yes** ☒ **No** ☐	Potential that participant could have had an allergic reaction to the trial medication if it had been administered.	Person completing form to Sign/Date
Study Outcomes*	**Yes** ☐ **No** ☒	No impact on study outcomes.	Person completing form to Sign/Date

3. DETAILS OF VIOLATION	
Date Occurred:	01MAY16
Description of Violation:	(*Indicate if the event constitutes an urgent safety measure – see SOP SCR005 for details regarding urgent safety measures*) Participant 2001 was randomised into the trial on 01MAY16, and the trial medication dispensed. It was then discovered, on the same date, that the GP record held details of an allergy to IMP.
***Code:**	*THIS WILL BE COMPLETED BY ACCORD (FOR INTENAL PURPOSES ONLY)*
PI Informed: (Sign/date)	Person completing form to sign/date to confirm PI informed
***Violation Codes (ACCORD USE ONLY):** A=Consent Procedure, B=Inclusion/Exclusion Criteria, C=AE Reporting, D=Randomization or Dosing, E=Study Procedures, F=Lab Procedures, G=Visit Schedule, H=Other*	

4. ACTIONS TAKEN		
	Site Actions (see guidance in SOP CR011)	**Sign/Date (when action complete)**
Corrective Action:	*(action taken to correct/document this violation)* The written prescription was scored through, and the drug returned to pharmacy for destruction as per protocol. The patient was advised of this and that they would still be part of the study, and would continue to be followed up (as detailed in the protocol).	Sign/Date to confirm the corrective action is complete
Preventative Action:	*(action taken to prevent this violation occurring again)* Study staff to be advised by Investigator (e-mail) to increase vigilance in checking for allergies before confirming eligibility.	Sign/Date to confirm the preventative action is complete
Conclusion – Justification of Actions: (PI or designee)	Participant to be withdrawn from trial medication. No actual impact on participant safety as IMP was not taken.	PI or designee to Sign/Date
Action Required:	**Participant(s) to remain on trial** ☐ **Participant(s) to be withdrawn from trial** ☒	Sign/Date to confirm the action is complete

5. INFORMATION SOURCE	
Name, Address and Telephone No.: (PI or designee)	**XXX**
Sign/Date: (PI or designee)	**XXX/XXX**
This form must be sent to ACCORD within 3 days of any trial site member becoming aware of violation (Fax +44 (0)131 242 9447 or e-mail (QA@accord.scot)	
Received by ACCORD (Sign/Date): ACCORD WILL SIGN/DATE ON RECEIPT AND PROVIDE COPY TO PI/TRIAL MANAGER	
***Violation Number (ACCORD internal use only):** THIS WILL BE COMPLETED BY ACCORD (FOR INTENAL PURPOSES ONLY)*	