

General Medical Council

Fitness to Practise Panel

Session beginning 3 January 2012

St James's Buildings, 79 Oxford Street, Manchester, M1 6FQ

New case of impairment by reason of misconduct.

The Panel will inquire into the following allegation against Dr Iain Stephenson, BChir 1993 University of Cambridge.

"That being registered under the Medical Act 1983, as amended:

1. During 2010 you held the post of Honorary Consultant Physician at The University Hospital of Leicester NHS Trust; **Admitted and Found Proved**
2. You were the Principle Investigator in the study; 'Evaluation of heterosubtypic immune responses in older people before and after seasonal and pandemic influenza vaccination, an open label study (UHL10548).' ('UHL 10548'); **Admitted and Found Proved**
3. You were the co-investigator in the study, A phase II, randomised, partially observe-blind, single-centre study to evaluate safety and immunogenicity of MF59-adjuvanted or non adjuvanted H5N1 booster influenza vaccines in adults primed with MF59-adjuvanted influenza A/Vietnam/1194 (H5N1) vaccine (UHL 10492). ('The Prime Boost Study'); **Admitted and Found Proved**
4. On the vaccine log for Study UHL 10548 you forged the signature of Dr Tristan Clarke. Those forgeries appear against the following dates
 - a. 21 October 2009, **Admitted and Found Proved**
 - b. 22 October 2009, **Admitted and Found Proved**
 - c. 23 October 2009, **Admitted and Found Proved**
 - d. 31 March 2010, **Admitted and Found Proved**
 - e. 8 April 2010, **Admitted and Found Proved**
 - f. 5 May 2010; **Admitted and Found Proved**
5. In the study file for UHL 10548 you forged the signature on the Curriculum Vitae of
 - a. **Deleted**

- b. Professor Karl Nicholson, **Admitted and Found Proved**
 - c. Dr Tristan Clarke; **Admitted and Found Proved**
6. On the vaccine log for study UHL 10548 you recorded that volunteers had been administered with the vaccine designated for UHL 10548 when they had not; **Admitted and Found Proved**
7. On 12 May 2010 you asked Nurse Phayre Parkinson to countersign the vaccine log to confirm that two volunteers had been administered the UHL 10548 vaccine, when it had not been administered; **Admitted and Found Proved**
8. You destroyed the UHL 10548 Vaccine Log Sheet in relation to subjects 52 to 56; **Admitted and Found Proved**
9. You replaced the destroyed Vaccine Log Sheet with two new Vaccine Log Sheets of your own creation; **Admitted and Found Proved**
10. You consented volunteers to participate simultaneously in UHL 10548 and the Prime Boost Study; **Admitted and Found Proved**
11. You took part in UHL 10548 as a volunteer; **Admitted and Found Proved**
12. To disguise your involvement in UHL 10548 you changed the spelling of your name in trial records; **Admitted and Found Proved**
13. On the 4 June 2010 you asked Dr Tristan Clarke to backdate his signature on documents where you had forged his signature;
14. Your actions in relation to paragraph 10 and 11 were inappropriate; **Admitted and Found Proved**
15. Your actions in relation to paragraphs 4, 5, 6, 7, 8, 9, 12 and 13 were
- a. dishonest,
Admitted and Found Proved in relation to paragraphs 4, 5, 6, 7, 8 and 12
 - b. inappropriate.
Admitted and Found Proved in relation to paragraphs 4, 5, 6, 7, 8, 9 and 12

And that by reason of the matters set out above your fitness to practise is impaired because of your misconduct.”

This information reflects the allegation as it stands at the point when this document was updated. The allegation may be amended as the hearing progresses and when

the findings of fact are made by the Panel. If you require up to date information regarding the allegation throughout the course of the hearing please contact the GMC's press office.

The Panel will be chaired by Mr David Kyle BA (Hons) Cantab CBE