

Scotland A REC
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 2 - 4 Waterloo Place
 Edinburgh
 EH1 3EG
 Tel: 0131 465 5678

03 March 2017

Prof Simon Thomas
 Newcastle Hospitals NHS Foundation Trust
 Medical Toxicology Centre
 Newcastle University
 Newcastle, NE2 4HH

Dear Prof Thomas,

Study title: Identification and characterization of the clinical toxicology of novel psychoactive substances (NPS) by laboratory analysis of biological samples from recreational drug users (Scotland).
REC reference: 15/SS/0047
EudraCT number: n/a
Amendment number: Amendment 2 (REC Ref 15/SS/0047/AM02)
Amendment date: 12 January 2017
IRAS project ID: 172425

The above amendment was reviewed on 27 February 2017 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee had no ethical concerns regarding this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)		12 January 2017
Other [IONA Data Collection Sheet tracked]	3.0	12 January 2017
Participant consent form [IONA-S Consent Form (Person previously included when they did not have capacity) tracked]	3.0	12 January 2017
Participant information sheet (PIS) [IONA-S PIS & Consent Form Nearest Relative AWI tracked]	3.0	12 January 2017

Participant information sheet (PIS) [IONA-S PIS and Consent Form tracked]	3.0	12 January 2017
Research protocol or project proposal [tracked]	3.0	12 January 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/SS/0047:	Please quote this number on all correspondence
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Yours sincerely,



Dr Colin Selby
Chair

E-mail: chloe.eves@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mr Andrew Johnston, Newcastle Joint Research Office
Mr Michael White, The Newcastle upon Tyne Hospitals NHS Foundation Trust*

Scotland A REC

Attendance at Sub-Committee of the REC meeting on 27 February 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Matthew Reed	Consultant in Emergency Medicine	Yes	
Dr Colin Selby	Consultant Physician	Yes	(In the Chair)
Mr Robert Wyllie	Policy Advisor	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Chloe Eves	Research Admin Officer