NRES Committee North East - Newcastle & North Tyneside 2
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Telephone: 0191 4283563

28 January 2015

Professor Simon Thomas
Professor of Clinical Pharmacology and Therapeutics
Newcastle Hospitals NHS Foundation Trust
Medical Toxicology Centre
Newcastle University
Newcastle upon Tyne
NE2 4HH

Dear Professor 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.**
REC reference:	**15/NE/0023**
IRAS project ID:	**168706**

The Research Ethics Committee reviewed the above application at the meeting held on 21 January 2015. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Helen Wilson, nrescommittee.northeast-newcastleandnorthtyneside2@nhs.ne t. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Mental Capacity Act 2005

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005. The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1 A brief cover sheet to be written to accompany the Participant Information Sheet which consultees are shown to include the statement that,

"Please read this Information Sheet that all participants read before deciding whether or not they would like to take part in this study. We will then ask you whether or not you think the person we are asking you about would have chosen to take part in the study, *if* they been able to read this Information Sheet and make that decision for themselves."

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

You joined the meeting for discussion.

Social or scientific value; scientific design and conduct of the study

Members enquired the rationale for the samples not being retained indefinitely to allow for Secondary Analysis in the event, for example, that new laboratory testing becomes available in the future. Members enquired whether there would be the possibility of the samples being retained.

You stated that during the analysis mass spectrometry was undertaken and the spectral output was retained and as such there was no need to retain the actual sample itself as the results of the analysis would be available.

Members queried the procedure if some of the substance taken remained and was given to the researcher and turned out to be a controlee substance; in particular how would it be disposed of and what position did that place the researchers in with respect to possession?

You stated that you only receive samples in good faith from participants and the Police are not interested in these samples and they do not use biological samples in police cases. You confirmed that the senders of the samples are anonymous and the results of the taken samples are not returned.

The Chair clarified that the concern related to the possibility that you may inadvertently find yourself to be in the possession of an illegal substance and the disposal of that substance was queried.

You confirmed that the laboratory already has a licence for holding such samples so this was not an issue.

Informed consent process and the adequacy and completeness of participant information

The Committee reviewed the information to be provided to consultees about the proposed research and their role and responsibilities as a consultee. The Committee considered that the information was not adequate and requested that a cover sheet be written to accompany the participant information sheet for consultees to include a statement that they were not being asked to consent on behalf of the person but to give their considered opinion as to whether the person concerned would have consented to the study had they been able to.

You accepted this point.

You left the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		09 January 2015
IRAS Checklist XML [Checklist_09012015]		09 January 2015
Letter from funder		13 December 2013
Other [Consent form (person with relevant powers, Scotland)]	1.3	05 January 2015
Other [Consultee declaration form (England and Wales)]	1.3	05 January 2015
Other [Consent form (person previously inc when they did not have capacity)]	1.3	05 January 2015
Other [Research Contract]		
Participant consent form	1.3	05 January 2015
Participant information sheet (PIS)	1.3	05 January 2015
REC Application Form [REC_Form_09012015]		09 January 2015
Research protocol or project proposal	1.3	05 January 2015
Summary CV for Chief Investigator (CI)		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/NE/0023	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Alasdair MacSween
Chair

E-mail: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Mr Michael White, R&D Officer, Newcastle University & The Newcastle Upon Tyne Hospitals NHS Foundation Trust

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Attendance at Committee meeting on 21 January 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Chris Barron	ECMC & CTU Manager	Yes	
Mrs Nermine Basta	Research Assistant/Statistician	Yes	
Mrs Ann Boardman	Retired Educationalist	Yes	
Mr Andrew Brenikov	Historian	No	
Mrs Jane Curry	Head of Cardiac and Respiratory Services	No	
Dr Sumeet Gupta	Consultant Psychiatrist	Yes	
Dr Alasdair MacSween (Chair)	Principal Lecturer in Research Governance	Yes	
Mrs Gaynor Mitchell	Part-time Biology Lecturer (Retired)	Yes	
Mrs Susan P Phillips	Clinical Lead Pharmacist	Yes	
Dr Meiyi Pu	Consultant	Yes	
Ms Vicky Ryan	Statistician	No	
Miss Hannah Stevenson	Data Manager, Clinical Research	Yes	
Dr Jared Thornton	Clinical Trials Co-ordinator	No	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kerry Dunbar	REC Assistant
Mrs Helen Wilson	REC Manager