Scotland A REC 2nd Floor Waverley Gate 2 - 4 Waterloo Place

Edinburgh EH 1 3EG

Telephone: 0131-465-5680

02 April 2015

Prof Simon Thomas

Professor of Clinical Pharmacology and Therapeutics

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: | 151SS/0047 |
| IRAS project ID: | 172425 |

The Research Ethics Committee reviewed the above application at the meeting held on 26 March 2015. Thank you for attending to discuss the application.

# Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

1. Review wording in protocol regarding sampling, to make it clear, that only leftover samples, obtained during clinical interventions would be used for research purposes and only once consent had been obtained.
2. Make required changes to relative's PIS sheet, asking them to consider what they think the patients would want, in regards to consent.
3. Correct all grammatical errors in both patient PIS and relative's PIS and ensure pronouns are correct. Reference to travel arrangements could be omitted if not relevant.
4. If there are any unchanged and tracked change copies of both; the consent form for patient's who regain capacity and the information sheets, could you please submit them, as they must all be seen by the Committee.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Alex Bailey on 0131-465-5679 or by e-mail at alex.bailey@nhslothian.scot.nhs.uk

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link:

http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submittina-response-provisionalopinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 02 May 2015.

Summary of the discussion at the meeting

# Ethical issues raised, noted and resolved in preliminary discussion

* Independent review

Reviewed by NIHR who are the funders of the study and also by an English REC.

* Suitability of the Applicant and Supporting Staff

The Committee felt that a suitable team were conducting the research.

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

The Committee felt that this was well planned research and that the social and scientific value of this research was high, as at present there is no UK system linking substances to toxicity. They also noted that it had been discussed with local drug users who appeared to be supportive of it.

The main purpose of the research; is to identify NPS that may be involved in toxicity cases, being presented by patients in an acute hospital setting. The secondary objective; is to monitor trends and epidemiology, develop screening and analysis methods and link substances to toxic effects. The research consists of four linked studies, with only the fourth arm of the study involving collection and analysis of samples from patients directly.

* Suitability of supporting information

The Committee felt that it was acceptable for GPs to not be informed of participation in the study.

* Recruitment arrangements and access to health information, and fair participant selection

The participants would be recreational drug users, which could include children (only in first two annonymised studies) and also prisoners and young offenders in every study, which the committee felt were reasonable.

* Other general comments

The Committee noted that the W6/NR PIS does not ask about what the patient would want to do when obtaining consent from next of kin. It instead asks the next of kin, 'if you think you might be interested in your relative taking part.' The English REC asked for this to be rectified to ensure that the relative is asked to consider what the patient would want. This has been done for the approved English document. The Committee feels this change must be made to the Scottish document as well. The Committee also noted that both the Patient and Relative PIS have grammatical errors that need to be corrected.

* Suitability of the summary of the research

No issues arose.

Ethical issues raised by the Committee in private discussion, together with responses given by the investigator when attending the meeting

* Favourable risk benefit ratio: Anticipated benefits/risks for research participants (present and future)

The Committee identified the 4 digit postcode and theoretical identification of participants as a potential risk - see researcher's response below in Care and protection of research participants.

The Committee felt that it could be illegal to take samples before consent for research had been obtained - see below in Informed consent process.

* Care and protection of research participants; Respect for potential and enrolled participants welfare and dignity

The researchers claim that the first three arms of the study are consistent with the MRC Guidance and Human Tissue Act on exception for the need to consent. Aggregated data from positive samples of blood, urine or saliva from participating toxicology laboratories and the National Poisons Information Service are to be used in the first three studies. In the protocol it is suggested that although data is provided in an anonymised format to researchers for the first two studies, it is actually linked anonymised, thereby making it pseudonymous. In the protocol there is also a mention of a theoretical risk, of individuals being inadvertently identified should clinical data be triangulated with media reports. The Committee were concerned about patients being identifiable.

The researcher assured the Committee that use of the four digit post code identification was normal process in Scotland and that the team collecting and analysing the samples are all suitably qualified clinical professionals.

* Informed consent process and the adequacy and completeness of participant information

The Committee's main concern was that of not obtaining consent in AWI participants before samples were taken, even though nothing would be done to the sample, before consent was obtained.

The researcher informed the Committee that blood is taken for clinical purposes as part of the patient's care. Laboratories keep the blood once they have reported clinical findings. The researcher stated that they wish only to use left over blood for research and only after consent has been obtained, either from the patient or the next of kin, would samples be used in any research.

The Committee asked what percent of patient's the researcher thought might be able to give consent.

The researcher felt that it would be about 90% of patients. It would probably be obtained the morning after admission. There was, however, a 12 hour time limit to taking bloods for it to be of use in the research, which is why they would like samples to be taken during clinical treatment on admission.

The Committee asked that given there was a 12 hour window would it not be possible to contact the next of kin via telephone within that time frame. The Committee also asked if it was possible to go ahead with the research without the inclusion of AWI.

The researcher said that they probably could contact the next of kin within the twelve hours but they were trying to avoid taking two samples of blood from the patient. They wanted to use the left over blood from samples taken for clinical care purposes. The researcher then went onto explain that if the research went ahead without AWI they would lose the data from those that were intoxicated to the greatest extent by the use of NPS'. '

The Committee accepted that the study would benefit from the inclusion of AWI. They felt that the issue of sampling had arisen as a result of how it was described in the protocol, as it appeared to be suggesting extra sampling. The Committee felt this should be reviewed and it made clear that they would only use leftover blood for research purposes, prior to consent.

The consent form for patients that regain capacity contains tracked changes and refers to an information sheet that has not been submitted (vsl .3.5.15). This, along with the unchanged form will have to be seen by Committee.

Documents reviewed

The documents reviewed at the meeting were:

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| Document | Version | Date |
| Covering letter on headed paper [Cover letter to REC] |  | 13 February 2015 |
| Letter from funder |  | 1 1 December 2013 |
| Other [Consent form (person with relevant powers, Scotland)] | 1.4 | 13 February 2015 |
| Other [Consent form (Person previously included when they did not have capacity)] | 1.4 | 13 February 2015 |
| Other [Research contract] |  |  |
| Other [Favourable ethical opinion (England and Wales)] |  | 28 January 2015 |
| Other [Acknowledgement of addiional document (E &amp; W)] |  | 20 January 2015 |
| Other [Consultee information sheet (England and Wales)] | 1.3 | 28 January 2015 |
| Participant information sheet (PIS) | 1.4 | 13 February 2015 |
| REC Application Form |  | 03 March 2015 |
| Research protocol or project proposal [Protocol] | 1.4 | 13 February 2015 |
| Summary CV for Chief Investigator (Cl) |  | 05 January 2015 |

Membership of the Committee

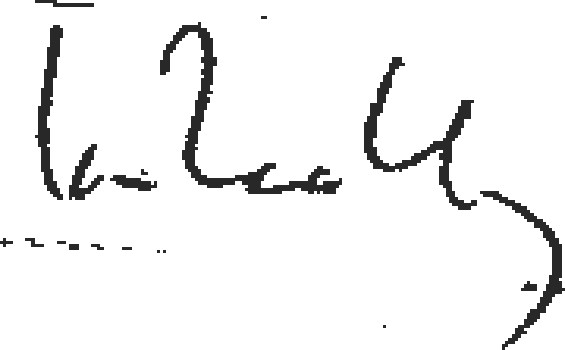
The members of the Committee who were present at the meeting are listed on the attached sheet

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.

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| --- | --- |
| 151SS/0047 | Please quote this number on all correspondence |

Yours sincerely



Dr Ian Zealley

# Chair

## Email: manx.neill@nhslothian.scot.nhs.uk

Manx Neill

Scottish A Research Ethics Committee Manager

2-4 Waverley Gate

Edinburgh

# EHI 3EG

Tel. No: 0131-465-5680

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| --- | --- |
| Enclosures: | List of names and professions of members who were present at the meeting and those who submitted written comments. |
| Copy to: | Sean Scott, The Newcastle upon Tyne Hospitals NHS Foundation Trust  Mr Michael White, The Newcastle upon Tyne Hospitals NHS Foundation Trust |

## Scotland A REC

Attendance at Committee meeting on 26 March 2015

Committee Members:

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| --- | --- | --- | --- |
| Name | Profession | Present | Notes |
| Dr Bridget Harris | Clinical Research Specialist | Yes |  |
| Dr Mary Macleod | Clinical  Pharmacologist/Consulta nt Physician | No |  |
| Mrs Katherine McGuigan | Nurse | Yes |  |
| Canon Matt McManus | Parish Priest | No |  |
| Dr Zoe Morrison | Senior Lecturer in  Management Studies | Yes |  |
| Mrs Wendy Nganasurian | Retired | No |  |
| Dr Anthony Pottage | retired Physician/Clinical  Pharmacologist | Yes |  |
| Dr Colin Selby | Consultant Physician | No |  |
| Dr Rachel Smith | MRC Programme  Manager (Training and Partnerships) | Yes |  |
| Mrs Mary Sweetland | Statistician | Yes |  |
| Mrs Margaret Thomson | Retired | No |  |
| Professor Nigel Webster | Chair of Anaesthesia & Intensive Care | No |  |
| Dr Ian Zealley | Consultant | Yes |  |

Also in attendance:

|  |  |
| --- | --- |
| Name | Position (or reason for attending) |
| Dr Alex Bailey | Scientific Officer |
| Ms Rosemary Beardon | Student Research Nurse |
| Mr Walter Hunter | Committee Coordinator |
| Ms Manx Neill | REC Manager |