NHS
Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds West
Room 001, Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283548

20 April 2015

Ms Gemma Donovan
Academic Practitioner
University of Sunderland
Dale 113, Sciences Complex
Wharncliffe Street
Sunderland
SR1 3SD

Dear Ms Donovan

Study Title:	**Exploring Multidisciplinary Use of unLicenSed medicines In primary and secONdary care (EMULSION)**
REC reference:	**15/YH/0191**
Protocol number:	**2046**
IRAS project ID:	**162518**

The Research Ethics Committee reviewed the above application at the meeting held on 10 April 2015. Thank you for attending to discuss the application.

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to Alternate Vice Chair, together with Mr. V. Sharma.

Further information or clarification required

1. Confirmation that audio recordings would be deleted once transcribed.
2. Rewrite of the participant invitation letter to use more suitable language.
3. Confirmation that consent would not be assumed if a patient did not contact the research team after invitation, as stated at A31 in the IRAS application form.
4. Within the Participant Information Sheet, the following revisions should be made:
    a) Definition of unlicensed medication in lay language
    b) The information sheet for Patient Participants should be rewritten in more appropriate language

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 Miss Christie Ord, REC Manager.

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-submitting-response-provisional-opinion/

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 20 May 2015.

Summary of the discussion at the meeting

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

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

The Committee noted that this study was looking into off-licence use of medication. Members queried why the applicant was not looking into off label use or prescription of drugs that had been in clinical trials but not yet approved.

You explained that it would be difficult to identify when off label medication was being used unless there were specific notes on the prescription, so this was not being looked at due to the logistical issue. You explained that there was a greater risk with using unlicensed medication and that this was only a small study so you had chosen to narrow the focus.

You stated that you were not looking into the use of medication prior to licensing, such as those that have been in a clinical trial, as you were more interested in routine use of off-licence medication and that drugs in clinical trials had different criteria as they aimed to obtain a license. You stated that you would be analysing interviews using grounded theory and that this approach meant that if any of these themes emerged you would follow them.

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

Members discussed the notion of GPs selecting potential participants from their surgery lists and questioned whether this may bias the research. It was agreed that the approach described was the most pragmatic given that patients would not know they were being given unlicensed medication and that their thoughts about this was the purpose of the research

The Committee requested a brief overview of the recruitment process.

You explained that in primary care the GP would be recruited through the NIHR portfolio. A practice level search would be run to identify patients based on the sampling criteria, and a letter

of invitation and information sheet would be sent to these patients. You explained that in secondary care prescribers in outpatient clinics would go through their clinic records routinely and the same process as in the primary care setting would be followed.

The Committee queried how many participants would be in each group.

You explained that you aimed to achieve 5 participants in each group. This would mean you would recruit 5 primary care prescribers, pharmacists and patients and the same within secondary care. You stated that if data saturation was reached in one stream there was some flexibility in the numbers for the other groups. You also stated that you may recruit more than 30 participants if this was required to get sufficient data for thematic analysis.

The Committee advised that a substantial amendment should be submitted if the applicant wished to increase her numbers.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The REC sought clarification as to the procedures in place if bad or negligent practice was disclosed at interview.

You explained that this would be assessed on a case by case basis and would either be referred to an individual or someone higher up to deal with.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee noted that all audio recordings should be deleted once transcribed.

Informed consent process and the adequacy and completeness of participant information

The Committee noted that at A31 on the IRAS form it stated that consent would be assumed. It was agreed that this was probably a typographical error and that this should be confirmed.

Members noted that unlicensed medication should be defined in lay language in the Participant Information Sheet.

The REC agreed that the Participant Information Sheet for patients should be rewritten in appropriate language, as with the other information sheets.

Suitability of the applicant and supporting staff

The Committee queried whether the applicant had done training in qualitative research.

You confirmed this.

Suitability of supporting information

The Committee noted that the invitation letter for patients should be rewritten in more appropriate language.

The Committee commended the applicant for her topic guides.

You thanked the Committee for this feedback.

Other general comments

You stated that patient participants would be notified that they were being prescribed an off license medication by her initial contact as part of the research. You queried whether this was acceptable to the Committee.

The Committee stated that the applicant had submitted a well written invitation letter and acknowledged that this was a good area of research. Members advised you that you had been sensitive with your approach and stated that they had no concerns regarding your first contact with participants.

The Committee noted that there may be further issues raised in correspondence.

You left the meeting.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [REC Covering Letter]	2	26 March 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Sunderland Insurance Certificate]	1	13 June 2014
GP/consultant information sheets or letters [Prescriber notification of patient participation]	2	05 March 2015
Interview schedules or topic guides for participants [Topic guide for interviews for pharmacists]	2	26 March 2015
Interview schedules or topic guides for participants [Topic guide for interviews for patients]	2	26 March 2015
Interview schedules or topic guides for participants [Topic guide for interviews for prescribers]	2	27 March 2015
Letter from funder [Pharmacy Research UK Letter]	1	24 March 2015
Letters of invitation to participant [Invitation letter for interviews for healthcare professionals]	1	05 March 2015
Letters of invitation to participant [Invitation letter for focus groups for healthcare professionals]	2	05 March 2015
Letters of invitation to participant [Invitation letter for interviews for patients]	4	05 March 2015
Letters of invitation to participant [Invitation letter for focus groups for patients]	2	05 March 2015
Other [Invitation letter to prescriber to recruit patient participants to the study]	1	26 March 2015
Other [Information for prescribers to recruit patient participants to the study]	1	26 March 2015
Participant consent form [Consent form for interviews for healthcare professional]	2	05 March 2015
Participant consent form [Consent form for focus groups for healthcare professionals]	1	05 March 2015
Participant consent form [Consent form for interviews for patients]	4	05 March 2015
Participant consent form [Consent form for focus groups for patients]	2	05 March 2015

Participant information sheet (PIS) [Participant information sheet for interviews for healthcare professionals]	4	05 March 2015
Participant information sheet (PIS) [Participant information sheet for focus groups for healthcare professionals]	2	05 March 2015
Participant information sheet (PIS) [Participant information sheet for interviews for patients]	5	26 March 2015
Participant information sheet (PIS) [Participant information sheet for focus groups for patients]	4	05 March 2015
REC Application Form [REC_Form_27032015]		27 March 2015
Referee's report or other scientific critique report [Funder Review Panel Comments]	1	14 July 2014
Research protocol or project proposal [EMULSION Project Summary]	1	05 March 2015
Summary CV for Chief Investigator (CI) [Gemma Donovan CV]	1	12 February 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.

15/YH/0191	**Please quote this number on all correspondence**

Yours sincerely

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Mr Anthony Warnock-Smith
Alternate Vice Chair

Email: nrescommittee.yorkandhumber-leedswest@nhs.net

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

Copy to: *Ms Charlotte Emmerson, University of Sunderland*

Catherine Adams, North of England Commissioning Support