NHS
Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds East
Room 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
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Telephone: 0191 4283564

24 July 2015

Dr Nicolas Van Labeke
Research Fellow / Creative Technologist
The Glasgow School of Art
Horizon Scotland
Forres Enterprise Park
Forres
IV36 2AB

Dear Dr Van Labeke

Study title:	**Backpack – Person Centred Health, Care and Wellbeing**
REC reference:	**15/YH/0358**
IRAS project ID:	**184209**

The Proportionate Review Sub-Committee of the NRES Committee Yorkshire & The Humber - Leeds East reviewed the above application in correspondence.

Provisional opinion

The Sub-Committee would be content to give a favourable ethical opinion of the research, subject to clarification of the following issues and the following changes being made to the documentation for study participants:

1. As the study involved stage 1 Interviews with MS care givers or MS support group organisers the REC requested sight of the interview schedule for the first phase as part of this main application.
2. The Committee stated that all aspects of the phase 2 and phase 3 sections of this study were to be provided as substantial amendments. The Committee advised that the study team should seek advice from the REC Manager in the first instance before submitting the substantial amendments.
3. The Committee noted that the protocol only referred to audio recordings; conversely, the IRAS application form mentioned video recordings. The REC requested confirmation that video recordings would be used.
4. The Committee agreed that it was not clear that this research would offer anything new that the Multiple Sclerosis charities did not already offer. With this in mind, the Committee required a clearer link between the outcomes of the research and patient/service benefits.
5. The REC noted that the pathway for contacting professionals had not been provided. The REC queried the method by which this would be carried out and requested sight of any documentation used to this effect.

6. The REC expressed its concern that professional participants may not feel able to say no. The Committee requested further information on how junior staff would be protected from pressure to take part.
7. The Committee queried if the patient participants had agreed in principle to being contacted by someone they did not know.
8. The REC noted that researchers wished to recruit newly diagnosed MS sufferers from the support group. In light of this, the Committee queried what would happen if the patient had not joined a support group.
9. The Committee commented that the process of contacting newly diagnosed MS patients within a month of diagnosis did not seem feasible, adding that sufferers of MS would not necessarily be severely affected by the condition at that point, dependent on the exact diagnosis of the type of Multiple Sclerosis and may still be working. With this in mind, the Committee suggested considering patients that had had the condition for a longer length and were in need of support services, or were considering changes that they needed to make to their lives to facilitate their condition.
10. The REC queried why participants had to be identifiable in the recordings, adding that group recordings sometimes experienced problems, for example, if one person wished to withdraw their data, the whole group session would have to be rerun.
11. The Committee asked what emotional support would be provided for participants that may experience depression as a result of their diagnosis.
12. With regards to the Participant Information Documentation:
    a. The Committee requested that a Participant Information Sheet for first interviews in the Mini-Lab stage be provided as part of the main application.
    b. The Participant Information Sheet should provide more information with regards to the procedures being undertaken by participants, as some participants may not be aware of what the procedures will involve.
    c. With regards to the Participant Information Sheet for MS Citizens in the second stage of the study, participants must be told that videos, audio and photographs would be used in presentations and that they could be potentially identified from this media. The Committee suggested using only transcriptions for the purpose of discussions.
    d. The Participant Information Sheet needed a section detailing the benefits and risks of participation, a complaints process and information on harm and compensation.
    e. In the Participant Information Sheet for Professionals, the Committee stated that the section about 'Our Medical Information' was not appropriate.
13. With regards to the consent form:
    a. The Committee queried how participants could withdraw their data if it was a video of group.
    b. The REC agreed that item five and item six of the consent form were very similar.
    c. The Committee agreed that item seven was too wide, and suggested that it be deleted or the criteria tightened so that it related to use for projects in specified areas such as 'backpack.
    d. The Committee requested that, as item seven referred to points 4 and 5, the list be numbered to make it easier for participants to refer to different paragraphs.
    e. The Committee noted that item eight contradicted items four and five.
    f. The Committee stated that item nine had the potential to cause major problems to the conduct of the trial.
    g. The Committee noted that the consent form needed a section to record the signature details of the researchers in line with the participant's details.
    h. The Committee recommended that, rather than a tick list, that initials be used if they are requesting permission to use video clips.
14. The Committee queried who on the study team was experienced or qualified to carry out interviews or running focus groups.
15. The Committee asked who on the study team was experienced in thematic analysis of interviews and focus groups.
16. The REC requested a copy of any independent review of the study.

17. The Committee noted that the web address www.dhiscotland.com in section A50 of the IRAS form was not correct, and that this lead to a site about hair loss. The Committee requested confirmation that www.dhi-scotland.com was the correct web address.

When submitting a response to the Sub-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.

Authority to consider your response and to confirm the final opinion on behalf of the Committee has been delegated to Dr Rhona Bratt.

Please contact Miss Christie Ord, REC Manager, if you need any further clarification or would find it helpful to discuss the changes required with the lead reviewer.

The Committee will confirm the final ethical opinion within 7 days of receiving a full response. A response should be submitted by no later than 23 August 2015.

Documents reviewed

The documents reviewed were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		16 September 2014
Participant consent form [Permission to Contact form]	v1	26 June 2015
Participant consent form [Consent form]	v1	26 June 2015
Participant information sheet (PIS) [PIS [Lab 1[]	v1	26 June 2015
Participant information sheet (PIS) [PIS [Lab 2]]	v1	26 June 2015
REC Application Form [REC_Form_15072015]		15 July 2015
Research protocol or project proposal [Research Protocol]	v1	26 June 2015
Summary CV for Chief Investigator (CI)		02 June 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/0358	Please quote this number on all correspondence

Yours sincerely

pp.
Dr Rhona Bratt
Chair

Email: nrescommittee.yorkandhumber-leedseast@nhs.net

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

Copy to: *Dr Alison Hay, Glasgow School of Arts*

NRES Committee Yorkshire & The Humber - Leeds East

Attendance at PRS Sub-Committee of the REC meeting in Correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rhona Bratt (Chair)	Retired Multimedia Project Manager	Yes	
Dr Stuart Jamieson	Consultant Neurologist	Yes	
Mrs Ann Kay	Retired Special Needs Coordinator	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	REC Manager
Ms Kirstie Penman	Application Coordination Assistant