Point-by-point response to the comments from the Proportionate Review Sub-Committee of the NRES Committee (Yorkshire & The Humber- Leeds East)

Backpack – Person Centred Health, Care and Wellbeing

Sponsor: **Glasgow School of Art**
Funding: **Digital Health Institute**
Principal Investigator: **Dr Nicolas Van Labeke**
Date: **17/08/2015**
REC Reference: **15/YH/0358**
IRAS Reference: **184209**

Dear all,

First, on behalf of the project team, I would like to thank the members of the panel for their prompt and thorough review of the study we submitted.

In the section below, I will address, point by point, the panel's comments, indicating changes made to respond to the issues raised.

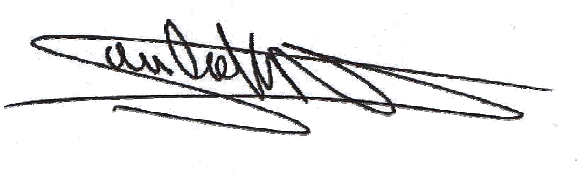
Several documents have been modified or added to the application:

- Backpack - Protocol **v2** **updated**
- Backpack - Participant Consent Form **v3** **updated**
- Backpack - Participant Information Sheet (Lab 1) - **v2** **updated**
- Backpack - Participant Information Sheet (Lab 2) - **v2** **updated**
- Backpack - Participant Information Sheet (minilab) - **v2** **new**
- DHI Approval Panel Letter - Backpack – 031215 **new**

With these clarifications and amendments, I am confident that the concerns raised by the panel will now be addressed and that you will be looking favourably at our application.

On behalf of the project team,

Dr Nicolas Van Labeke



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.*

    - A provisional timeline for the whole study has been added to the Protocol (section 4.1)
    - The phase 1 interviews (mini-lab) will be scheduled as follow:
        - 1 or 2 participants from the local MS Support Group
        - All interviews organised with the same period (week 5)
        - Organised at convenient time and location for interviewee (GSA office in Forres, to be changed if required)
        - 2-3 hour allocated for each interview, in a single slot; breaks will be offered to ensure wellbeing of interviewee

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.*

    - **As discussed with REC manager, the Principal Investigator confirms that Experience Labs 1 & 2 scripts will be submitted for review as substantial amendments to the protocol (weeks 8-9), once outcomes of the first mini-lab have been analysed.**
    - From the updated project timeline (added to Protocol):
        - Mini-lab reviewed by research team (weeks 6-7)
        - Experience Lab 1 & 2 scripted by research team (weeks 7)
        - Submission to REC (week 8-9)
        - Schedule of Experience Labs 1 & 2 will be amended according to approval timeline

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.*

    - The Principal Investigator confirms the use of video for both interviews and Experience Labs.
    - The Protocol document have been modified accordingly

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.*

    - Currently, there is no digital, personally-held copy of the relevant, central NHS information record pertinent to an individual with MS, which is controlled by the individual, in our case MS citizens.
    - There is a data schema, and the individual can collaborate to improve outcomes when they have a more active role in sharing information.
    - In order to define this personally-held copy data schema and its potential uses, MS citizens recruited in the Backpack project are invited, among other things, to consider the control and choice over sharing relevant data with services, giving consent and permission.

- In doing this, data exchange flows between participants all along the patient journey.
- This is a model for citizen-centric and trusted data exchange.
- As a result, interactions with relevant services and sharing by the individual are more accurate, transferred more efficiently. As a whole, the individual is indeed more empowered.
- When individuals have personal agency and identity, plus an active role in the self-management of their own data, control and choice means they are more likely to trust the system and to engage in prevention, earlier intervention and save the system time and cost.
- The study, with its two groups of participants (respectively MS citizens and Professionals) working on a similar design-led approach, will informing how such person-centred data management would impact on both side of the interactions between citizens and Government and other organisations for the citizen.

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.*

- Invitation to participate and a copy of the Participants Information Sheet will be mass-circulated through internal communication channels, accompanied with contact details for the researchers.
- Selection of appropriate communication channels will be devised jointly by our local coordinator for the Moray Council (one of our project partners) and the research team, informed by the inclusion/exclusion criteria.
- Communication channels such as internal council intranet and other professional networks (Moray Council and partner organisations such as Third Sector Interface) will be preferred. More targeted invitations might be send through specialised communication networks for specific public and professional participants with an existing – or potential – interest in the subject matter (e.g. social workers, digital transformation, etc.)
- When contacted by prospective participants, a member of the research team will organise a preliminary meeting, either face-to-face or by phone
- The project will be presented to the participant and opportunity to answer any question will be given.
- The Consent Form will be circulated and discussed for understanding.
- Invitation for the Experience Lab will then be sent to the participant

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.*

- The “blanket” circulation (through internal and general mode of communication) of an invitation for participation in a research project, as described above, will reduce pressure on individuals to take part, in particular by circulating outside of the existing line management and “chain of command”.
- The local coordinator is removed from the selection process, also contributing to reduce the risk of coercion.

- It will ensure that participation has been the result of an informed choice on the basis of information given (and self-organised contact with local coordinator, the researcher team or the independent advisor)

7. *The Committee queried if the patient participants had agreed in principle to being contacted by someone they did not know.*

    - MS citizens participants are covered by the "Permission to contact" consent form (see A30-1 and "Backpack - Permission to Contact v1" document). The form will be distributed and collected by the local coordinator (MS Support Group officer in this instance), seeking confirmation of their permission to be contacted by a member of the research team.

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.*

    - I would like to start by clarifying a general aspect of the study: the relation between MS citizens as participants, early MS diagnosis and the GSA Experience Labs.
    - In the documents, we might have inadvertently introduced an ambiguity regarding the early diagnosis of MS (e.g. "map out a typical journey for the first month(s) after diagnosis"). This was intended to relate to stereotypical persona ("Alison") of the scenarios used to support the two Experience Labs (phase 2 and 3) and not the diagnosis of the participants.
    - As far as the first Experience Lab is concerned, our inclusion criteria did not request prospective participants to be newly diagnosed. Since we will recruit participants solely on the basis of their membership of the MS Support group (see item 9), we will accept participants from any type and course of MS (see A17-1).
    - During the Experience Lab itself, when participants will be presented with the scenario, they will then be guided to draw on their personal experience to contribute to the workshops.
    - Our intention throughout the study is to look at the role and potential of personal data store at the early stage of a life-changing diagnosis, not at preparing participants for the life-changing effect of a diagnosis such as MS. This will be the long-term outcomes of the whole project.

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.*

    - As clarified above, all participants for the Experience Lab 1 will be recruited through the MS Support Group, regardless of when their own diagnosis was obtained.
    - However, considering participants that had had the conditions for a longer period of time might not only be more formative for the project (longer

reflective period from participants) but also more supportive for the participants (more time to come to term with the condition) and less risky for the researchers (see item 11 below).

- We will take the panel's suggestion into account when we report on the interviews with the MS support group to inform the design of the next two Experience Labs. **We will propose an amendment to the inclusion criteria (section A17-1 of REC form) for a minimum period since diagnosis.**

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.*

- Video (and audio-only as backup) will be used to record all Experience Labs and interviews.
- Audio tracks will be transcribed and anonymised (e.g. pseudonyms) for analysis, guarantying the consent of participant.
- Visual materials (video and picture) will be used by the research team for further analysis (e.g. visual analysis methods such as group interactions, personal spatial behaviour). Analysis will be anonymised (e.g. pseudonyms), guarantying the consent of participant.
- Visual materials might be used for dissemination purpose (e.g. illustration, case-study) and, as such, participant might be identifiable.
- In case of a participant withdrawing or not giving consent, measures will be taken on both anonymised and non-anonymised data. Participant will be warned that, in some instance (especially with video), it might not be feasible to remove them. Segments will therefore not being used or faces (and other identifiable signs) will be blurred out.
- See item 13 below and new version (v2) of Consent Form

11. *The Committee asked what emotional support would be provided for participants that may experience depression as a result of their diagnosis.*

- We are working on the assumption that participation to the study will be perceived as a positive experience, giving participants an opportunity to share and be listen to, and therefore limiting the risks of distress.
- Part of the interviews with the MS Support Group (mini-lab) will be to define operational guidelines for the research team to run Experience Lab 1 (with MS participants).
- A risk assessment will be issued following the interviews and checked again once participants have consented to the study.
- Preliminary discussion with the MS Support group will also investigate the possibility for a caseworker of the group to be present during the workshops, as observer. Such presence, and the established relationship that they would have through membership of the support group, will endure professional supports if required.
- Research team will also be briefed on conduct and support prior to the workshops.

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.*

        - A PIS for interviews has been added to the project documents (Backpack - Participant Information Sheet (minilab) - v2.pdf, 12/08/2014)

    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.*

        - Participant Information Sheet for both Experience Labs have been improved, giving more information about the procedure (section What will the research involve?).
        - In line with the fact that the exact script of the Experience Labs will be finalised after the phase 1 mini-labs, details have been kept as generic as possible.

    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.*

        - Participant Information Sheet for both Experience Labs have been modified accordingly, highlighting the risk of identification (section What will the research involve?).

    d. *The Participant Information Sheet needed a section detailing the benefits and risks of participation, a complaints process and information on harm and compensation.*

        - Section "What are the benefits and risks if I take part in the research?" and "What should I do if I want to complain?" added on all three versions of the Participant Information Sheet.

    e. *In the Participant Information Sheet for Professionals, the Committee stated that the section about 'Our Medical Information' was not appropriate.*

        - Modified to reflect difference between research (personal data store in the journey experienced by MS citizens) and their participation to this workshop (replay the journey of newly diagnosed MS citizens. raising their awareness)

13. *With regards to the consent form:*
    a. *The Committee queried how participants could withdraw their data if it was a video of group.*

        - Anonymity from a video is usually done fully by cutting off the segments where participants appear or partially by localised editing (e.g. blurring).
        - Withdrawal of from study altogether is a bit more difficult for reasons mentioned above and we are proposing, as described in the new item 5, to do it in a similar way (anonymity rather than withdrawal).

    b. *The REC agreed that item five and item six of the consent form were very similar.*

        - The intention with items 4 to 7 was to allow varying consent on the use and distribution of audio-visual materials, anonymised or not. Re-reading the questions put together (from two different forms initially), I can understand the confusion.

- Questions have been simplified and reorganised to make clearer level of consent/anonymity on audio-visual materials.

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.*

- Question has been removed

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.*

- Item numbered

e. *The Committee noted that item eight contradicted items four and five.*

- Questions reordered to clarify distinction between information collected and audio-visual materials.

f. *The Committee stated that item nine had the potential to cause major problems to the conduct of the trial.*

- Removed

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.*

- Details added

h. *The Committee recommended that, rather than a tick list, that initials be used if they are requesting permission to use video clips.*

- Initial boxes now replace tick list

14. *The Committee queried who on the study team was experienced or qualified to carry out interviews or running focus groups.*

- Dr Nicolas Van Labeke has a PhD in Computer Science, with 20 years of experience in research and participant-based studies, mostly in Technology-Enhanced Learning but using qualitative research methods coming from education, psychology, HCI and user-centred design.
- Running (and analysing) interviews and focus groups have been a significant part of the core skills developed over the years, notably in projects such as Calques 3D (participatory design with groups of geometry teachers, bi-monthly pedagogical knowledge elicitation and activity co-design), MyPlan (prototype evaluation with lifelong learners, A/B testing and feedback), NBRUH (auditory training with tinnitus patients, semi-structured interviews after game-based training sessions) and SAFeSEA (focus groups with university students, requirements analysis for essay writing feedback system). See for example:
  - Hoare, D. J., Van Labeke, N., McCormack, A., Sereda, M., Smith, S., Taher, H. A., et al. (2014). Gameplay as a Source of Intrinsic Motivation in a Randomized Controlled Trial of Auditory Training for Tinnitus. *PLoS ONE* 9(9), pp. e107430.
  - Alden, B., Van Labeke, N., Field, D., Pulman, S., Richardson, J. T. E., and Whitelock, D. (2013). Using student experience to inform the design of an

automated feedback system for essay answers. In *Proceedings of the 2013 International Computer Assisted Assessment Conference* (CAA'13 - Southampton, UK). pp. 1-10.

- Van Labeke, N., Magoulas, G. D., and Poulovassilis, A. (2009). Searching for 'People like me' in a Lifelong Learning System. In *Proceedings of the 4th European Conference on Technology Enhanced Learning* (EC-TEL 2009 - Nice, France). Springer, pp. 106-111.
- Van Labeke, N., Aiken, R., Morinet-Lambert, J., and Grandbastien, M. (1999). IF "What is the Core of AI & Education?" Is the Question THEN "Teaching Knowledge" is the Answer. In *Proceedings of the 9th International Conference on Artificial Intelligence in Education* (AIED'99 - Le Mans, France). IOS Press, pp. 241-250.

15. *The Committee asked who on the study team was experienced in thematic analysis of interviews and focus groups.*

    - As above. Dr Van Labeke also developed practical experience with software packages such as NVivo, QDA Miner and the CAT Toolkit.

16. *The REC requested a copy of any independent review of the study.*

    - The initial project proposal was reviewed and accepted by the DHI Approval Panel (DHI Approval Panel Letter - Backpack – 031215.pdf, 03/12/2014). A copy of the acceptance letter is added to the project documents.

17. *The Committee noted the that 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.*

    - The URL is indeed a typo. www.dhi-scotland.com is the correct link.