

Response to second Provisional Opinion letter (20/08/15, 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**

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1. The Committee noted that the study timeline provided, although helpful, was not the specific information required. A list of potential interview questions or prompts would need to be submitted for review to inform the Committee of the general line of questioning, although it was acknowledged that this interview schedule would vary based on responses given in individual interviews.

The purpose of the mini-lab (interviews) is to have semi-formal discussions with experts (i.e. MS Support Group team leader and senior care workers) on topics surrounding MS and MS citizens, in order to: 1) educate the research team on the background and relevant topics; 2) inform the design of the subsequent workshops (Experience Labs 1 & 2); and 3) explore the ground for support and collaboration with the MS support group, within and without the current study.

The interviews will therefore take the shape of a dialogue between the interviewees and the researcher(s), hence a focus on *semi-structured* interviews. The objective will be to gather insights on topics the research team is not familiar with; the discussion will therefore be highly reactive to the topics, assertions and prompts received from interviewees.

Interviews will be preceded by a short introduction of the project's objectives and of the study's aims and structure (supported by the Participant Information Sheet circulated beforehand).

Semi-structured interview will be organised to gather insights, *from the support group* perspective, on the following topics:

1. Multiple Sclerosis (MS): cause, pathology, diagnosis, course and management.
2. MS citizens: individual's perception and reaction to condition (self and others'), coping with life-changing event, lifestyle (re)organisation, lifelong support.
3. "Newly diagnosed" citizens: diagnosis and preparation, role of immediate support (family, care worker, support group, etc.), short-term adjustments, change of behaviour (expected or observed), mid-term planning, role of digital/virtual support.

4. MS citizens' experiences and two-way interaction with relevant public/private/third sector (public services, government, health and social care, employment, etc.): administrative tasks, information access, support seeking, help on personal & professional adjustments.
5. Typical burdens and obstacles in MS citizen "journeys" throughout their life-long conditions
6. Recent and future developments in easing citizen's life with MS: support, digital health and care, community groups.

Topic-based interview will be followed by discussion on project-related issues:

7. Perception of Personal Data Store: awareness and familiarity with concepts and solutions, personal and professional views on impact for MS (e.g. individuals, carers, organisations), concerns and issues with person-centric control and data exchange, usage and distribution guidelines for MS citizens.
8. Participation of MS citizen to Experience Labs: inclusion criteria for recruitment, expectation from research team, preparation, risks and remediation strategies.
9. Invitation to observe the Experience Labs: silent observer, "chaperone", support for MS citizens (especially during Experience Lab 1).

16. *The Committee acknowledged receipt of the acceptance letter from DHI review panel; clarification was sought as to whether a written review with feedback was provided along with the acceptance letter. If feedback was provided, please submit this for consideration.*

No further review or comments was ever circulated with the acceptance letter.

Recommendation: *The Committee also suggested that, for best practice, the consent form is revised to include the following standard regulatory authorities' paragraph:*

"I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records."

This item has been added in the new version of the consent form (Backpack - Participant Consent Form v4, 20/08/15) added to the submission.

On behalf of the project team,

Dr Nicolas Van Labeke

