Ethical Considerations for Participatory Action Research Involving Groups with Potential Cognitive Impairment

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Case Study: COM-IC Project

2020 - Grant Application MRFF Dementia Futures Fund (2 year research project)
1 Jun 2021 - Grant Successful, Commencement date for research
1 Apr 2022 - Extension/Delayed start
11 Jul 2022 - Ethics Application for Stakeholder Reference Group submitted
18 Aug 2022 - First administrative review
15 Sep 2022 - First submission to HREC panel
28 Sep 2022 - Request for additional information
20 Oct 2022 - Review submitted
21 Nov 2022 -Approval from UQ - ratification needed from industry partners
29 Nov 2022 - Ethics applications and documentation submitted to industry HREC
1 Dec 2022 - First industry approval received
10 Jan 2023 - First amendment submitted
25 Jan 2023 - Second industry HREC not processed - new form submission required
30 Jan 2023 - New paperwork submitted to second industry HREC
31 Jan 2023 - Second industry approval received
16 Feb 2023 - Outstanding approvals on HREC
16 May 2023 - Second amendment submitted
17 May 2023 - Revision of second amendment (HREA portal form not printing)
24 May 2023 - Second amendment approved

Aim: To improve measurement of quality of life and quality of care by identifying key outcomes of programs for people living with dementia. The aim is realised through bringing together people living with dementia, caregivers, industry and funding bodies to understand how to measure outcomes of care that matter to everyone.
Setting: Australian aged care (community-based and residential aged care)
Methods: Mixed-methods, AHR framework applied to dementia care, incorporating co-design and participatory action research methods AT EACH STAGE OF THE DESIGN PROCESS
Ethics experience:
The ethics application for this program of study, despite peer review in competitive grant processes, has been frustrating, uncertain, inconsistent, complicated and time-consuming, threatening project time-lines and potential success. Each component of the project requires separate ethics applications, so that stakeholders can be involved in designing, implementing, evaluating and distributing research. For a two year fully funded project, ethics approval for STAGE 1, has taken 9 months and design for this component was undertaken by researchers with lived experience, not 'participants'.

Grant Application → Grant Approval → Ethics App 1 → Ethics App 2

WHAT COMES FIRST?

The keynotes from our HREA experience for a research program that does not follow traditional pathways serve to define an important discussion and debate for health research that truly includes people with lived experience at each stage of the research process. It is important that those most affected by a policy or program should have a voice in its development. It is equally important that research conducted, irrespective of preposition (with, on, for, about), is ethical. Fundamentally, this is protecting human rights and mitigating risk of harm. Secondary considerations are reported, such as resourcing, tensions over differences of perspective pertaining to scientific rigor, feasibility of design elements such as outcomes and whether these are validated, and a risk that involvement may be perceived or treated as tokenistic, achieving the opposite intention of co-design.

INFORM → CONSULT → INVOLVE → COLLABORATE → EMPOWER

Participants or co-researchers?

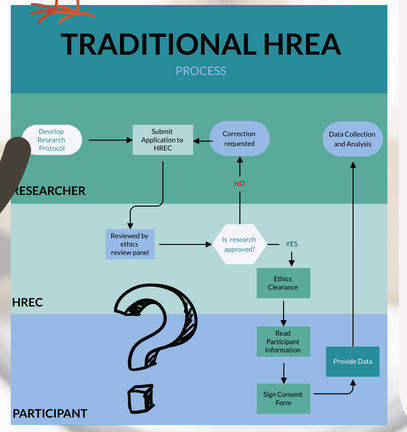
Co-design involves including those most affected by outcomes in the research process, from design to completion (8). Participatory action research methodologies position power with those most affected by the outcomes of the program (3). While there are a number of papers and frameworks proposing participant involvement and engagement in research, there is limited advice on how this applies to the research design phase (prior to informed consent) or how to balance the benefits of extended stakeholder engagement with protecting vulnerable groups (2,5,6,9). One possibility is to redefine the relationship between stakeholders with the research team, defining them as co-researchers rather than participants. How do we then ensure vulnerable people are protected when there are currently no risk assessments on potential harm to researchers by researchers?

FIGURE 1: PARTICIPATORY ACTION RESEARCH

How can researchers protect vulnerable groups in research co-design?

The nature of participatory research and co-design is to be iterative and regenerative, with input from 'participants' informing the research activities as they progress (Figure 1). There needs to be provision within ethics review to operate alongside the research activities. Presently, this function is satisfied with submission of 'amendments', when new research materials are generated, they are submitted to HREC and 'added' to the existing ethics application. However, this process is implemented after the design phase, when materials have already been subjected to ethics review and risks have been assessed. For 'participants' to be included in the design phases, activities are completed prior to formal ethics review. What can be done to involve stakeholders in the design phase and still ensure they're protected from harm?

FIGURE 2: BUSINESS FLOW DIAGRAM OF TRADITIONAL HUMAN RESOURCES ETHICS APPLICATION (HREA)



How can HREC support co-design?

The purpose of the Human Research Ethics processes is to safeguard the well-being of research participants, including the protection of dignity, rights, and welfare of people involved in research (1). Traditionally, researchers submit an extensive protocol for approval that details each stage of the research, a risk-based approach is adopted to ensure research activities meet relevant legislative requirements, policies and procedures, and ethics approval is received before participants joint the project (Figure 2). As research evolves and more research is conducted 'with' participants instead of 'on' them, participant involvement occurs prior to protocol development, regardless of the perceived vulnerability of involved groups (3-5). Participatory research challenges traditional ethics review processes, because it necessarily creates uncertainty around the detailed research design and therefore what risks it poses to 'participants' at each stage of the research process (6).

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