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Dementia Research Ethics Resources

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Developed by DemComm fellows at the Winter Residential School

NIHR | National Institute for Health and Care Research

Alzheimer's Society United Against Dementia

Development of this resource

This resource was developed following a DemComm Winter Residential School session in November 2023, titled ‘Navigating the Ethical Maze’, which built on a webinar delivered in August 2023 on ‘Ethics and dementia research’.

DemComm is a 2-year programme funded by the National Institute of Health and Care Research and the Alzheimer's Society. There are over 50 research fellows in the programme.

At the Winter School, DemComm fellows commented on a list of challenges, compiled during the webinar, and discussed potential solutions to these both in small groups and during an open discussion. The challenges and the solutions were mapped across the research cycle:

- Idea generation and proposal
- Recruitment (including consent and capacity assessment)
- Data collection/data access
- Data analysis
- Dissemination and engagement
- Patient and public involvement

This is a 'living document' and we are happy to receive ideas on what to add or change in the current version. As it is a short document, the list of resources is not exhaustive.

Glossary

CfAB – Centre for Ageing Better
DemComm – Dementia researcher community of practice
HRA – Health Research Authority
NHS – National Health Service
P*PIS* – Participant information sheet
PLwD – People Living with Dementia
PPIE – Patient and public involvement and engagement
REC – Research ethics committee

Idea generation and proposal

Problem	Solution
Protecting participants and managing risks (versus risk aversion)	› Do not avoid methods/designs just because they will require extra ethical scrutiny. Instead, argue your case as to why this is the best method/design and how you will manage risk. › Ensure confidentiality/anonymity are clearly covered in consent forms and reiterate this when talking to participants. › Proactively consider potential challenges around protection (capacity to consent, type of research site) together with others such as a PPIE group and a data protection officer. › Document a procedure to mitigate and reduce risk.
Identifying and addressing needs of the researcher in the proposal	› Ensure suitable supervision and debriefing opportunities. › Provide team/peer support (if possible); build in a buddy system. › Consider potential repercussions of research on sensitive topics and how to manage 'worst case' scenarios. › Consider the processes of signposting to support. › Factor in training for the researchers and lived experience co-researchers (e.g. dementia awareness for researchers, methods training for lived-experience co-researchers).
Impact of time taken for full REC consideration	› Try to complete additional parts of project that don't require review (e.g., literature review) while applying for ethics. › Go for university ethics approval (if this is faster) for those aspects that do not need NHS REC/HRA approval. › Be realistic when building REC approval into your timeline – the NHS REC process often takes 6 months. › Seek advice from your institution and beyond (including REC panel members where possible).
Participation burden of the participant (e.g. time taken, sensitivity of topic)	› Pilot potential approaches with PPIE groups. › Consider in advance how to manage potential repercussions of participation. › Develop a list of sources of support to signpost.
Research crossing country boundaries (divergent REC processes and rules)	› Legislative processes (e.g. Mental Capacity Act 2005) are different per country. Familiarise yourself with such processes in the countries you collaborate with. They might come up with ethical issues that need to be addressed. › Consider how appropriate and feasible it is to standardise the protocol across all sites/countries

Recruitment pathways

Problem	Solution
Capacity assessments	› Be open-minded – assume people can participate unless proven otherwise. › Communicate the value of research and inform about the consent process to maximise inclusivity and accessibility. › Involve the clinical team in designing recruitment pathways and (if appropriate) carrying out recruitment. › Nominate supporters/professionals who know the PLwD to help inform you about your participants' capacity. › Ensure consultees, researchers and clinical team understand that a judgement is needed on what the PLwD would have wanted had they the capacity to choose themselves (not 'what is in their best interests', but a substitute judgement) (Shepard et al. 2018). › Train with or shadow capacity assessment processes; use a checklist for capacity assessment (e.g. SCIE).
Developing suitable materials for PLwD that also meet REC requirements	› Design accessible summary sheets of PIS. Talking through the summary may be enough. › Use multiple forms of communication – oral, images, text, Talking Mats etc. – respond to each person's needs (consider communication tools used by speech and language therapists and similar). › Use PPIE to ensure recruitment materials are suitable and emphasise PPIE co-design with the REC. › Use accepted terminology (e.g. DEEP Guide). › Consider social stimulation and meaningful activity in your recruitment strategies for more inclusion.
Approaches to assent/dissent after consent has been given	› Take time to build rapport with the participant, so they have confidence to dissent, and you can better-interpret assent/dissent; where possible ensure the same researcher sees a participant at each contact (Oh et al, 2024). › Use a method for process consent (Alzheimer's Society, 2024; Dewing, 2008). › Reflect on your own biases and cultural sensitivity regarding interpreting assent/dissent cues. › Ensure participants understand when/how they can withdraw, respect their decisions.
Exclusion or overrepresentation of specific sub-groups	› Engage people from diverse communities in the research planning stage. › Add deliberate enrichment/targeting under-represented/under-served groups in the protocol (factor in extra time for this). › Reach out to community groups. › Consider which incentives are most appropriate for different participants and allow diversity, e.g. BACS payments vs vouchers.
Minimising harm and distress	› Recognise the value of inclusion (social stimulation, meaningful activity). › Take steer from the person with dementia and their supporters.
Changes in capacity over the course of a study	› Seek prospective consent if participation is longitudinal: "If you do lose capacity…" but continue to be watchful for any signs of dissent in the event capacity is lost. › Consider safeguards in the protocol and engage with appointed attorney from recruitment stage. › Reflect on your own biases – seek a 'critical friend' to discuss cases with.

Data collection and data access

Problem	Solution
Use of creative methods to overcome difficulties using standard methods	› Provide a strong, evidence-based rationale for the methods – show PPIE input on choice of methods. › Consider other approaches and clearly explain why this is the most relevant. › Emphasize that this will increase equity of participation (with evidence if available).
Time needed to build and maintain rapport	› Consider if a single timepoint of data collection is appropriate, or if you may need to do it over multiple occasions (e.g. two interviews instead of one). › Manage expectations of the ethics panel, funders and the participants about how long data collection can take. › Emphasise the value of taking time to build rapport to potential funders, ethics panels and prospective participants.
Potential for participants to access research materials and collected data	› Consider formal co-researcher roles for PLwD/supporters, with care to minimize institutional/administrative burdens (speak to your institution about accessible contracting and payments processes). › Prepare a clear data sharing agreement.
Data collection with presence of a family/friend supporter	› This will need to be included in REC application as supporter will also need to consent to their participation. › Discuss process and purpose of study with PLwD and supporter before data collection to ensure they understand their role (e.g. supporter can be present but not as participant or both can participate).
Distress during data collection	› Develop a distress protocol/strategies (including signposting and debriefing), ideally with PPIE and clinical/social care input. Check that signposted sources of support remain open throughout the study – if not, update the protocol with alternatives.
Data collection in public spaces (e.g. care homes, hospital wards)	› Where possible, seek quiet area within the public space or consider other means to provide relative privacy and make participant comfortable (e.g., using a screen, moving chairs to face away from others). › Ensure you have considered all potential ways to obtain prior consent and have a strong rationale for why these would not be feasible/acceptable › Seek Confidentiality Advisory Group approval (England/Wales) if necessary.
Managing 'unexpected' disclosures (e.g. of harm, suicidal thoughts)	› Include a safeguarding strategy in the protocol – develop this with PPIE, clinical and social care input, as appropriate. › Inform participants on what your duty of care covers.
Access to data when PLwD has passed away	› To help participants/consultees consider whether or not to allow access to their data after they have died, provide information on the pros and cons of each different option. This should be phrased in a neutral tone.
Consultation fatigue	› Carefully consider how much data and how many data collection events (e.g. follow-up surveys) are appropriate; consult your PPIE about this. › Make participants aware of the benefits and drawbacks of repeat data collection.
Data sharing after the project (e.g., in repositories) especially with qualitative data, video recordings.	› Consider whether it is appropriate to seek consent for using data in future. › Set clear boundaries of withdrawal of consent (i.e. give participants two weeks to change their minds). › Anonymise data in pairs within the research team – one member conducts initial anonymisation, another checks. › Provide an option to opt out of data sharing. › Consider what you will do with data that cannot be anonymised.

Data analysis

Problem	Solution
Privacy and confidentiality	› Use anonymous health data if possible. › Expect and respect that participants may feel happy to have anonymous quantitative data publicly available, but may not feel the same about qualitative data. › Explain possibility of identification from quotes and how you will minimize this – consider developing a template explanation, with PPIE input, that can be used across studies within your organisation.
Deciding whose priorities should be represented in analysis	› Provide a robust justification of research purpose/limitations. › Set well-defined data parameters. › Consult PPIE on analytical approaches (where possible) and cite their advice.
Safe data handling and storage	› Consult your institution's data protection officer in planning stages of research to develop a robust data management plan. › Discuss feasible and safe alternatives with co-researchers – if working with PlwD co-researchers, discuss their understanding, needs and abilities with regards to data handling and storage.
Ensuring accuracy and transparency of analysis (incl accounting for communication difficulties)	› To make sure analysis is accurate perform data validity checks, take analytical interpretations back to participants or PPIE groups. › Consider whether returning transcripts to participants would be helpful. › Ensure that you feed back your analysis/findings to participants in a form that they can understand and comment on for transparency. If possible, involve PPIE in developing accessible explanations of how the data was analysed.
Involving co-researchers with dementia in data analysis	› If involving PLwD co-researchers in the analysis process, consider what kind of data is the most accessible to them (e.g., audio of interviews vs reading transcripts). Factor this into the proposal along with implications for anonymisation, participant identification and data security breaches. › If on-site access with a researcher is the only REC-approved option for involving PLwD co-researchers in data analysis, consider the increased burden on the co-researcher and reflect this in timescales.

Dissemination and engagement

Problem	Solution
Ensuring dissemination materials are understandable to people in various stages of dementia	› Develop different versions of dissemination materials. › Pilot test/ask PLwD to review or co-design.
Sharing potentially distressing content (e.g. institutional abuse)	› Work with PPIE group to develop acceptable language/ways to share distressing content. › Provide warnings to audience that some of the content may be distressing. › Have a distress protocol in place for dissemination and signpost audience to appropriate, accessible support.
Dissemination leading to harm to PLwD /family disruptions	› Researchers to fully consider the risk and likelihood of risk from participant identification when preparing dissemination materials. › Make participants aware of safeguarding procedure at recruitment stage (e.g., in PIS). › Follow up with participants after dissemination.
Research timelines meaning dissemination can occur quite long after project end, esp. given progressive nature of dementia	› Make participants/PPIE members aware of predicted timeline from outset. › Ensure funding for PPIE/dissemination is ringfenced and can be used after formal 'end of project'. › Provide 'interim' findings after initial analysis but before formal write-up/main dissemination. › Maintain relationship with participants/PPIE group throughout project, to give progress updates if not results.
Managing the balance of power when engaging with PLwD in dissemination	› Provide training and refreshers on dissemination. › Listen to participant's needs and be flexible; gather feedback on how engagement has gone.
Depicting challenges of living with dementia vs perpetuating stigma	› Engage with a wide range of people from dementia community to check appropriateness of dissemination materials. › Avoid use of images of PlwD that perpetuate stereotypes (e.g. in distress or ostracised). Consider using CfAB image library. › Balance coverage of challenges with potential solutions if possible.
Translating research into impact that benefits PlwD	› Develop impact plan with PPIE group and with audiences during dissemination. › Remember it is important to disseminate null results and explain why these are still important.

Patient & public involvement & engagement

Problem	Solution

Representation and diversity	› Spend time with different communities to build a relationship first, to help them get to know more about research and you to get to know more about their needs and values.
	› See resources list for UK standards for PPIE.
	› Consult FOR EQUITY website.
	› Consult NIHR INVOLVE framework.
	› For Ethnicity and cultural diversity consult:
	  › NIHR race equality framework
	  › INCLUDE ethnicity framework
	  › Centre for Social Justice and Community Action toolkits.

Power asymmetries	› See INVOLVE framework; ensure all non-PPIE members of team are also aware of this framework . Take time to build rapport with PPIE members to help them feel valued.
Clarity of role and potential impact	› Discuss likely timelines and desired impact from research with PPIE at outset, manage expectations – revisit expectations throughout the project. › If the same deliverable do not meet expectations of each audience, consider setting out a range of deliverables (or different formats of the same deliverable); factor all in budget and timeline.
Capacity building vs professionalisation	› It is important to ensure that PPIE contributors feel confident and able to take part – discuss their potential training needs at outset of project. › There are NIHR training resources for PPI members. › Try reverse mentoring schemes, adopting accessible aids. › Consider the appropriateness of engaging with the same people on multiple/subsequent projects – will vary from project to project.
Conflicting interests and research integrity	› Consult Embassy of Good Science resources on COI.
Inadequate funding/ sustainability	› Seek central university/ARC funding to develop a long-running PPIE network (but be aware of potential for professionalisation). › Continue to request funds for PPIE for grant development.

Top Tips

ALLOW TIME

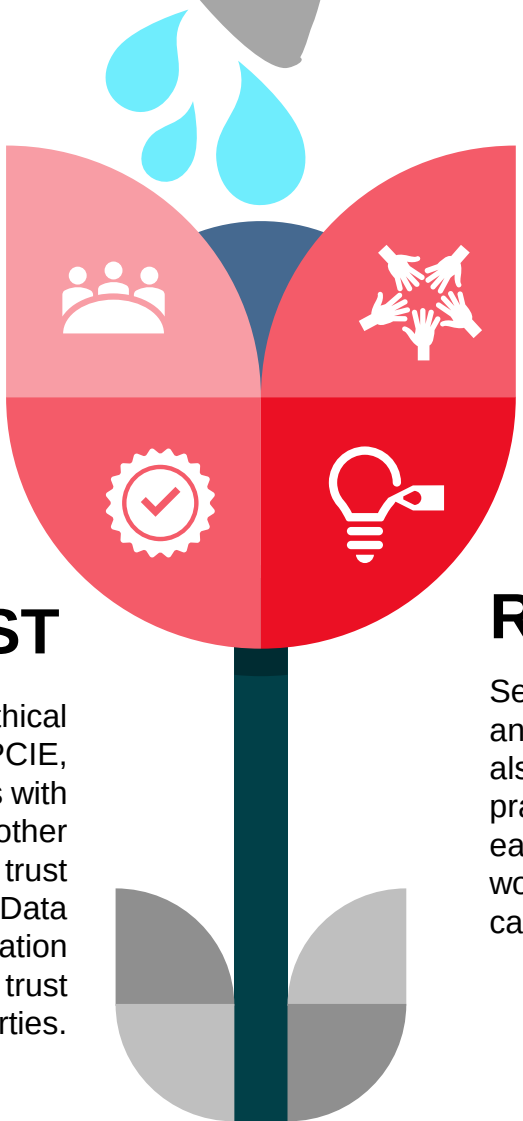
Excellent dementia research takes time! Don't be afraid to factor this into funding applications and protocols.

ADAPT

Be prepared to be flexible – dementia (and research in general!) can be unpredictable.

CONSULT

Consult people with lived experience at every stage of your study. Use this advice to justify study choices to ethics commitees.



INCLUDE

Consider Equality, Diversity and Inclusivity throughout your project. PCIE and recruitment in particular should involve underserved and marginalised groups.

BUILD TRUST

Trust is key to good and ethical research. Whether it is PCIE, participants, co-researchers with lived experience or any other group, focusing on mutual trust and openness will pay off. Data collection and joint dissemination in particular require trust between all parties.

REFLECT

Set up a contingency plan and manage expectations, but also keep reflecting on your practice and how these fit with each research site/person you work at/with. If needed, you can apply for an amendment.

If you come across resistance when asking for more time – push back!
Explain the reasons behind time/other measures being necessary and encourage other (dementia) researchers to do the same!

Idea generation and proposal	› Armstrong, M. J., Gamez, N., Alliance, S., Majid, T., Taylor, A., Kurasz, A. M., ... & Smith, G. (2020). Research priorities of caregivers and individuals with dementia with Lewy bodies: An interview study. PLoS One, 15(10), e0239279. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239279 › Kelly, S., Lafortune, L., Hart, N., Cowan, K., Fenton, M., & Brayne, C. (2015). Dementia priority setting partnership with the James Lind Alliance: using patient and public involvement and the evidence base to inform the research agenda. Age and Ageing, 44(6), 985-993. › The Dementia Enquirers Gold Standards for Ethical Research (2023) https://www.dementiavoices.org.uk/wp-content/uploads/2020/07/The-DEEP-Ethics-Gold-Standards-for-Dementia-Research.pdf
Recruitment pathways	› Alzheimer's Society (2024). Process method of consent. https://www.alzheimers.org.uk/dementia-professionals/dementia-experience-toolkit/how-recruit-people-dementia/consent-and-capacity. › Bartlett, R., Milne, R., & Croucher, R. (2019). Strategies to improve recruitment of people with dementia to research studies. Dementia, 18(7-8), 2494-2504. https://journals.sagepub.com/doi/full/10.1177/1471301217748503 › DEEP Guide – Dementia words matter: Guidelines on language about dementia. https://dementiavoices.org.uk/wp-content/uploads/2015/03/DEEP-Guide-Language.pdf › Dewing, J. (2008). Process consent and research with older persons living with dementia. https://journals.sagepub.com/doi/pdf/10.1177/174701610800400205 › Griffiths, S., Gude, A., Greene, L., Weston, L., Sutcliffe, C. L., Wheat, H., ... & Byng, R. (2022). 'Do I have the capacity to make capacity judgements?'Researcher reflections from a person-centred dementia support study. Dementia, https://journals.sagepub.com/doi/full/10.1177/14713012211067320 › Shepherd, V., Griffith, R., Sheehan, M., Wood, F., Hood, K. (2018). Healthcare professionals' understanding of the legislation governing research involving adults lacking mental capacity in England and Wales: a national survey. *Journal of Medical Ethics*, 44(9):632-637. https://doi.org/10.1136/medethics-2017-104722 › Social Care Institute for Excellence (SCIE). MCA: Assessing capacity. https://www.scie.org.uk/mca/practice/assessing-capacity/ › Oh, T. M., Batool, S., Musicha, C., Greene, L., Wheat, H., Smith, L., ... & Byng, R. (2024). In-person and remote recruitment of people with dementia into a primary care-based cluster randomised controlled trial: lessons from the Dementia PersonAlised Care Team (D-PACT) feasibility study.
Data collection & data access	› Bussu, Lalani, Pattison and Marshall (2020). Engaging with care: ethical issues in Participatory Research. *Qualitative Research,* **21**(5): 667-685. https://doi.org/10.1177/1468794120904883
Data analysis	› Smith, S.K., Mountain, G.A., and Hawkins, R.J. (2023). A Novel Approach to Support the Use of Visual Methods when Researching with People Living with Dementia. *International Journal of Qualitative Methods*. **22**: 1-11. https://doi.org/10.1177/16094069231184122 › Bussu, Lalani, Pattison and Marshall (2020). Engaging with care: ethical issues in Participatory Research. *Qualitative Research,* **21**(5): 667-685. https://doi.org/10.1177/1468794120904883
Dissemination and engagement	› Embassy of good science resources on COI: https://embassy.science/wiki/Theme:2f1668e3-c46b-44b0-bf6a-fc4698b671ca › Link to CfAB image library - https://ageing-better.org.uk/news/age-positive-image-library-launched
Public and Patient Involvement	› UK standards for PPI: https://sites.google.com/nihr.ac.uk/pi-standards/home?authuser=0 › FOR EQUITY website: https://forequity.uk/ › Values Principles Framework INVOLVE: https://www.invo.org.uk/wp-content/uploads/2017/08/Values-Principles-framework-Jan2016.pdf › NIHR race equality framework: https://www.nihr.ac.uk/documents/NIHR-race-equality-framework/30388 › INCLUDE ethnicity framework: https://www.trialforge.org/trial-forge-centre/include/ › Centre for Social Justice and Community Action toolkits: https://www.durham.ac.uk/research/institutes-and-centres/social-justice-community-action/toolkits/#d.en.436866 › NIHR training resources for PPI members: https://www.invo.org.uk/resource-centre/learning-and-development/ › Embassy of good science resources on COI: https://embassy.science/wiki/Theme:2f1668e3-c46b-44b0-bf6a-fc4698b671ca