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Executive Summary

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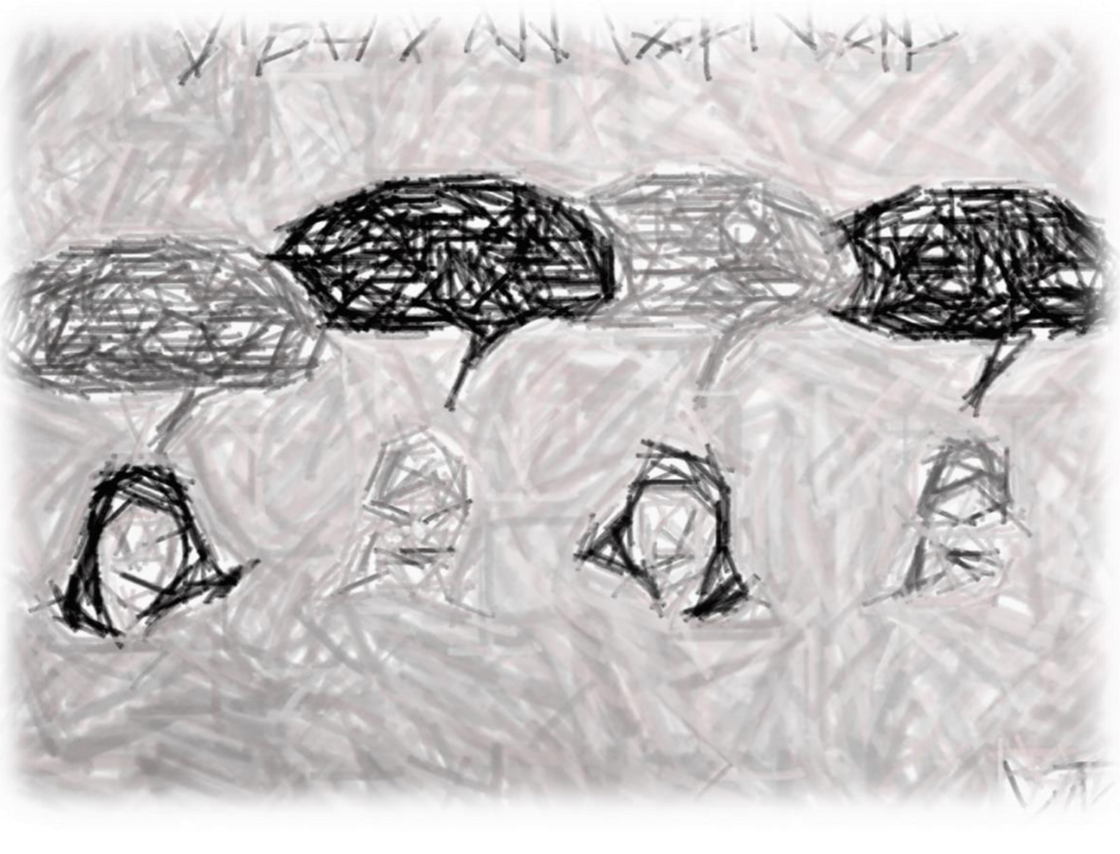

Including adults with capacity and communication difficulties in ethically-sound research

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- Professor Tom Shakespeare, OBE: London School of Hygiene & Tropical Medicine/Nuffield Bioethics committee; expertise in disability research and ethics.
- Craig Spary: Asperger's East Anglia; expertise through lived experience.
- Liz Lund: Asperger's East Anglia/Research Ethics Committee (REC) member; expertise in working with people who have autistic spectrum conditions and as current REC member.
- Dan Kipper: Norwich Age UK; expertise in older people and dementia.
- Linda Watson: Norfolk Conversation Partners (people with acquired language disorder after stroke); expertise through lived experience.
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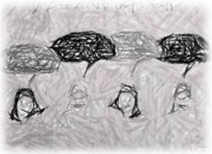
The full report is available to download from our project website: https://www.uea.ac.uk/groups-and-centres/assent



Executive Summary

This is the Executive Summary report of a three-year, multi-disciplinary project about the inclusion of adults with capacity and communication difficulties in ethically-sound research in England and Wales (2018-2021). It provides an overview of the project in terms of the background and aims; the methods, approaches and activities; the findings; the conclusions and recommendations.

Overview of Project

Gaining consent is a fundamental prerequisite for involving human participants in ethical research. Founded on the principle of respect for autonomy, it formally recognises people's interest in making decisions, acting voluntarily, and understanding and processing information relating to these decisions. However, our society also includes people who lack mental capacity and people with communication difficulties, either as separate impairments or in combination. This includes adults with: learning disabilities, autism, language disorder after stroke, acquired brain injury, mental health disorder, and dementia.

As people live longer, so the number of people who have dementia or who have had strokes rises. Improved neonatal care means that premature babies are also surviving in greater numbers, with an associated risk of developmental disability. Thus, the proportion of people who require some kind of support in decision-making is increasing. There are ethical questions about whether it is appropriate to include such people in research. Researchers and ethics committees may find it easier to err on the side of caution and exclude people who seem unable to give informed consent. This results in the under-representation of these groups in research, which negatively impacts the development of medical, educational and social interventions.

This project was conducted with the aim of defining a way through the complexities of including adults with capacity and communication difficulties in ethically-sound research.

Methods, Approaches & Activities

We adopted a mixed methodology that was defined variously across three stages.

Stage 1. Ethico-legal Landscape

We investigated the legal, ethical and regulatory frameworks governing capacity and consent under the Mental Capacity Act (MCA, 2005) and its accompanying Code of Practice (CoP, 2007). This was completed across three sources of data:

1.1 The Law

We reviewed a number of primary and secondary legal sources in order to construct an in-depth critical legal analysis of the research provisions of the Mental Capacity Act 2005 (MCA). In terms of primary sources, we analysed the legislative provisions of the MCA and also reviewed some relevant legal cases. In respect of secondary sources, we analysed the Hansard Reports in the build-up to the implementation of the MCA and also reviewed accompanying policy documents, such as the MCA Code of Practice (MCA COP, 2007).

1.2 Policy Guidance

We surveyed the content of the research-focused Chapter 11 of the MCA COP (2007) and advisory documents that were publicly available on the Health Research Authority (HRA) website. We looked at the vocabulary used as an initial indication of the subject matter being addressed, before carrying out a summative content analysis.

1.3 Research Application

We carried out a systematic review of the literature (with narrative synthesis), focusing on research involving adults with capacity and communication difficulties published since the implementation of the MCA (2005).

Stage 2. Current Practice

We explored research practice around the inclusion of adults with capacity and communication difficulties in ethically-sound research in England and Wales. This was completed across four sources of data:

2.1 Review processes

Firstly, we carried out a retrospective survey of studies carried out in England and Wales, featuring the provisions of the MCA (2005). The targeted period was from 2007 (the year of implementation). Data were collected using the publicly available HRA database (http://www.hra.nhs.uk/news/researchsummaries/). Secondly, we conducted a prospective survey of research applications to MCA-flagged Research Ethics Committees (REC) in England and Wales over a 12-month period.

2.2 Adapted resources for participant recruitment

We analysed the design features and linguistic content of a sample of participant information sheets devised and used by researchers for people with communication difficulties and/or capacity-affecting conditions.

2.3 Researcher reasoning

We were particularly interested in researcher decision-making in relation to the inclusion/exclusion of people with capacity and communication difficulties. We surveyed researchers using a questionnaire devised for the purpose.

2.4 Stakeholder views and opinions

We carried out structured interviews with four stakeholder groups: a. REC members; b. researchers; c. practitioners, supporters and carers; d. adults with communication and/or capacity difficulties. The last group included adults with: learning disabilities; autism; acquired language disorder after stroke; acquired brain injury; dementia; and mental health disorder.

Stage 3. Strategic Guidance

Within the context of existing legislation, and drawing on the evidence from our investigations, we developed and piloted structured guidance to promote inclusion in research.

3.1 Synthesis of data from stages 1 and 2.

We mapped our findings on the ethico-legal landscape to those arising from our review of current practice, identifying points of convergence and divergence across the data sets.

3.2 Development of evidence-based guidance.

We organised the key messages from the data into practical information and guidance within a navigable learning object.

3.3 Evaluation of guidance.

We piloted the guidance by inviting researchers, REC members and commissioners of research to try out the digital learning object and to complete an evaluation questionnaire.

Data Summary

Table 1. Summary of data across all project stages

Stage	*Activity*	*Sample*	
1. Ethico-legal landscape	1.1 Review of MCA (2005)	Primary sources Secondary sources	31 54
	1.2 Review of COP (2007) & policy guidance	Policy guidance documents COP	14 1
	1.3 Systematic review of the literature	Full text review Final sample	134 29
2. Current Practice	2.1 Survey of REC review of research applications	Retrospective survey Prospective survey	1617 83
	2.2 Adapted resources for participant recruitment	Participant Information Sheets	25
	2.3 Survey of researcher reasoning	Questionnaires	128
	2.4 Values and opinions of stakeholder groups	Interviews	60
3. Strategic Development	3.1 Data synthesis	N/A	
	3.2 Development of guidance	N/A	
	3.3 Evaluation	E-questionnaire	31

Findings

Stage 1. Ethico-legal Landscape

The Law

We identified some problems that stem from the fact that the MCA is mainly focused on treatment, welfare and financial decisions as opposed to research. Insufficient time seems to have been devoted to identifying clear aims and objectives to the research provisions of the MCA and to creating an effective legislative regime that would adequately meet them. Establishing a separate set of substantive tests that must be met in order to gain approval for research involving incapacitated participants does not, in reality, achieve a fair balance between protection and empowerment. The additional measures introduced that require the appointment of a consultee and the final approval from an approved Mental Capacity Act Research Ethics Committee (MCA REC) are also of questionable effectiveness. The idea that a third-party consultee can act as an effective advocate and thus empower an incapacitated participant by ensuring that her voice is heard is frustrated by its impracticalities. A system that promotes cooperation between a researcher and a participant, with a renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making. Similarly, very little is known about how an approved MCA REC actually forms its opinion and about what is at the forefront of the minds of its members when making a decision on a given project. Significant variation in interpretation of the requirements for approval could lead to a pattern of inconsistency between MCA RECs, which has the potential to undermine the perceived value of the system. What is clear, however, is that the manner in which the research requirements have been drafted creates the impression that the researcher, the consultee and the MCA REC are subject to differing obligations which all potentially overlap, but which may not necessarily be viewed in that way. This sense of confusion may cause researchers to become disillusioned with the system of approval and therefore reluctant to consider incapacitated participants in the future.

Policy Guidance

Capacity and communication difficulties were referred to in both the HRA documents and the COP (e.g. aphasia; learning disability; autism; dementia). The semantic category inclusion in research was largely determined in terms of ‘risk’, ‘benefit’ and ‘protection’. In contrast, terms associated with ‘empowerment’ and ‘autonomy’ were far less frequent. Vocabulary associated with media to facilitate participant understanding of research was present only in the HRA documents.

The content of the surveyed documents (14 multi-authored guidance documents and the COP) was attributed to three organising themes: Ethics; Capacity & Decision-making; and Accommodations. Ethics and Capacity & Decision-making appeared to be connected, with Ethics focusing on the moral principles governing actions and decisions in relation to research, and Capacity & Decision-making describing the procedures used to include people in research. Accommodations focused on considerations for people with capacity and communication difficulties participating in research.

Whilst Capacity & Decision-making was dominant in the research guidance, Ethics occupied the greater content of the COP (2007). Both of these themes corresponded to governance procedures under the MCA (2005). They included references to ‘protection’ and ‘risks & benefits’ in both the research guidance and the COP (2007), with the latter promoting the importance of ‘research value’. In the policy guidance documents, Accommodations included references to ‘context’; ‘language’; and 'media'. Typically, they were presented as isolated position statements with no obvious connection to the other two domains. The COP (2007) contained just one generic statement on the need for support.

Applications in Research

We reviewed primary research studies carried out in England and/or Wales from 2007, which included participants aged 16 years and above, with capacity and communication difficulties (e.g. autism; stroke; mental health, dementia, acquired brain injury and learning disabilities). Reports of clinical trials were excluded. Twenty-eight studies met the inclusion criteria.

Table 2. Summary of studies included

Conditions	n	%
Learning disability	12	42.9
Dementia	9	32.1
Autism	3	10.7
Mental health disorder	2	7.1
Aphasia after stroke	2	7.1
Acquired brain injury	0	0

Participants deemed to lack capacity were included in 15 studies (54%) based on consultee advice and excluded from 7 studies (25%). Of the remaining 6 studies, one study made provision for consultee advice but in fact all the participants were able to give informed consent. The participants in the remaining studies (n=5) were able to give informed consent

Despite report of a range of adapted materials and information sharing procedures to support the recruitment of potential participants, relatively few studies included adults with communication and/or capacity-affecting conditions. Existing regulations appear to be interpreted variably. Sporadic use of consultees and the exclusion of individuals on the basis of incapacity indicated that this group continue to be under-represented in research.

Stage 2. Current Practice

Representation & Accommodations

Review Processes

We conducted a retrospective survey of research recorded on the public database of the Health Research Authority (HRA) between 2012-2017. We retrieved 1617 records featuring people with communication difficulties and/or capacity-affecting conditions. The majority of research applications focused on people with mental health conditions (n=521; 32.2%) and dementia (n=514; 31.7%), followed by people with acquired brain injury (n=248; 15.3%) and people with aphasia after stroke (n=229; 14.2%), then people with learning disabilities (n=136; 8.4%) and autism (n=107; 6.6%). We classified the research using the International Classification of Functioning framework (World Health Organisation, 2001). The majority of studies were focused on 'activities & participation' either as a single focus (n=389) or connected to some form of intervention (assigned to the category of 'environment') (n=622). A focus on 'body function & structure' either singly (n=152) or in combination with some form of intervention ('environment': n=177) or 'activities & participation' (n=120) was less frequent. Reported opinions by Research Ethics Committees were similar across all groups with capacity and communication difficulties with 7% receiving an unfavourable opinion and less than 1% after further information; 30% receiving a favourable opinion and 63% after further information.

We carried out a prospective survey of research applications made to MCA-flagged Research Ethics Committees in England and Wales over a 12-month period. Data were collected by the Health Research Authority and focused on the following sections of Integrated Research Application Systems (IRAS):

- IRAS A 17.1 Population-types targeted for recruitment
- IRAS A 17.2 Exclusion criteria relating to communication and/or cognitive difficulties affecting capacity
- IRAS A 33.1 Information sheets –used as source of information to identify key provisions made to communicate project information with prospective participants.

As shown in table 3., just over half the applications focused on adults with dementia.

Table 3. Summary of applications by associated condition

Adults with:	n (%)
Dementia	42 (50.6%)
Acquired brain injury	21 (25.3%)
Learning disabilities	6 (7.2%)
Aphasia after stroke	5 (6%)
Mental health disorders	5 (6%)
Autism	4 (4.8%)

Around 50% did not identify any exclusion criteria in relation to communication and/or capacity. Of the cited exclusion criteria cited in applications, 18 related to a lack of capacity; 5 to communication difficulties; 11 to lack of a consultee; 17 to limited English language skills.

Accommodations for recruiting participants were various, and featured adaptations to the format and content of the Participant Information Sheet (PIS) (n=46; 55%), e.g. using pictures/images; large print typography. Twenty-one applications highlighted the mode of delivery for project information, e.g. interacting with potential participants offering verbal explanations, using a slow rate of speech, simple phrases, repetition was identified in 21 applications (25%). Extra support from the family, carers and others was considered in 25 applications (30%). Use of a consultee was only reported in 5 applications, although procedures to check the assent or dissent of incapacitous participants featured in 15 applications (18%).

Adapted Resources for Participant Recruitment

Of the 30 Participant Information Sheets (PIS) we received, 5 were excluded because the content was not aimed specifically at adults with communication difficulties and/or capacity affecting conditions population. Of the 25 PIS included in the sample, just less than half were prepared for people with dementia (n=12); 8 were for people with aphasia after stroke; 2 for adults with learning disabilities; and 2 for people with mental health disorders. No PIS were received for people with autism and acquired brain injury. The majority were prepared as Microsoft word documents with just 2 using a PowerPoint format. The number of pages of the PIS ranged 1-24 (*Median*=4; *Mean*=5).

Use of pictures featured in 56% of the sample. The location of pictures in relation to text varied across the sample with 50% placing the pictures on the right and the left of the text, or immediately below. A font point size greater than12 was use by 60% of the sample. Sub-headings were used in all but 1 PIS and other space organising devices were used less frequently, e.g. bullet points (28%); numbered lists (20%). The content of the PIS varied broadly across the sample in terms of quantity of words and sentences. Vocabulary used in the PIS looked at the indices of: familiarity *(how familiar a word seems to an adult, which relates to ease of processing)*; its concreteness (*how concrete or non-abstract a word is, which relates to the sense the word evokes)* and imageability (*how easy it is to construct a mental image of the word)*. The vocabulary in use achieved a level of reasonable familiarity generally, although values for concreteness and imageability were lower. The median reading ease score for information sheets was 67.7 on a scale of 0-100 – difficult to easy) although this varied across the sample.

Researcher Reasoning

Of the 127 researchers who responded to our online survey about their use of the Mental Capacity Act within their studies, just over 50% of the respondents reported having worked with people who have difficulties with communication and/or capacity for more than ten years. Just over 50% of the sample also reported having more than ten years of experience working in research, and just over 80% reported that they thought their knowledge of the Mental Capacity Act was good to excellent, with 78% agreeing that they felt confident when working with a consultee.

The majority of the researchers stated that they included people who have difficulties with communication and/or capacity within research because their project was specifically about this population. They also reported that inclusion was to improve the quality of research and to give this group a voice. A variety of communication aids and accommodations to meet the needs of participants were used by researchers, including using increased hand and body gestures, easier to read text, being flexible and offering breaks, and making sure to ask participants about their needs. Around 35% reported that they did not make use of any communication aids within their research projects.

Analysis of the answers given to free text boxes using content analysis revealed that some were knowledgeable about the Mental Capacity Act as used within a clinical context, and the analysis suggested a degree of confidence in the assessment of capacity within this specific context. Surprisingly, there was evidence to indicate that researchers appeared unclear about some aspects of the application of the Mental Capacity Act within research settings. This included some confusion about the role of a consultee, where some confused the role with that of an advocate, or with a best interest assessment within a clinical setting. Some researchers were unsure as to whether the assessment of capacity was their responsibility or the responsibility of those involved in the provision of care.

Stakeholder Views and Opinions

Adults with capacity-affecting conditions and communication difficulties:

Participants thought people with these difficulties should be included in research to improve understanding of the impact of various conditions, for research to be more comprehensive and to give a voice to these groups. Participants identified benefits to individuals from taking part in research, including feelings of altruism, a sense of achievement and feeling useful. Anger was expressed that people with capacity and communication difficulties would be excluded from research. This gave rise to a sense of being ‘disregarded’, ‘locked out’, of discrimination and that their issues would not be recognised, contributing to invisibility associated with some disabilities. Some participants were concerned about the MCA (2005) consultee process, but others thought it beneficial if it meant more people could be included. Participants said they would want to be involved as much as possible in the process and that the consultee should be someone who knew them well. Participants expressed the view that people who can’t communicate are thought not to understand and are not noticed.

Supporters and practitioners: Most participants thought it was wrong to have left groups of people out of research as then assumptions are made about their experiences which are not accurate. There should be more attempt to make research participation accessible. For example, research approaches could be more engaged and make more use of observation of people's everyday lives. One to one support helps people to take part. Some participants were not familiar with the MCA consultee process. Several supporters felt they wouldn't want to speak for someone else. There was a view that researchers were inclined to err on the side of caution. Not all 'gatekeepers' saw themselves as such but made judgements about research that is 'badly run' or 'using' participants and not passing on information to service users. Others were proactive in seeking research opportunities for their group. Researchers assessing capacity should have the communication skills to be able to adapt the information to the individual.

Researchers and ethics committee members: Respondents viewed it as morally good to involve adults with capacity and communication difficulties in research. Ethics committee members thought that research applicants understood the main principles of the MCA, although ethics committee respondents themselves had weaker understanding in some areas of the Act, including distinguishing between personal and nominated consultees. Some felt the HRA was overly focused on written information and signatures although respondents agreed that information sheets should be "easier to read". Less evident was a commitment to the full range of methods for supporting people to make autonomous decisions. Only a minority of respondents appeared to understand that under the MCA people should be actively supported to make autonomous decisions and that a person judged to lack capacity should still be involved in the decision-making process, even where a consultee is involved.

Conclusions from Stages 1 and 2

The ethico-legal landscape for research in England and Wales is informed by the MCA (2005) and its accompanying Code of Practice (2007). The MCA's concern for people who lack capacity is largely focused on treatment, welfare and financial decisions, with additional provisions for research. We found the research provisions to be poorly drafted and lacking an appropriate balance between protection and empowerment. The MCA COP (2007) provides some elucidation of the technical aspects of the MCA, including formal governance procedures related to protection and risk management. However, the ethical approval process appears to place contrasting obligations and expectations on different parties (e.g. MCA REC members, researchers, consultees), which may blur the allocated responsibilities and the formation of ethical opinions. Generally, there was a noted lack of strategic and practical guidance to support the execution of responsibilities. We found relatively few studies linked to the MCA and featuring adults with capacity and communication difficulties. Sporadic use of consultees and the stated exclusion of adults with communication and/or capacity difficulties indicates that this group continue to be under-represented in research. The complexities of balancing protection with empowerment may cause researchers to err on the side of caution and exclude incapacitous individuals.

Our review of current practice revealed that, intrusive research under the MCA appears to be most commonly focused on participant ‘activities and participation’ and/or interventions, with a lesser focus on ‘body functions and structure’. Although incapacitous individuals were included in research because of their presence in the target population, exclusions continue to be made on the basis of a lack of capacity. Where participants with capacity and communication difficulties are included, researchers use a range of materials, resources and procedures to support their understanding of the planned research. However, the majority of recruitment procedures seem to involve the use of some form of documentation to convey project information. Furthermore, the accessibility value of such resources in terms of the language content and presentational features to augment meaning is inconsistent. The use of consultees is variable across our populations of interest, i.e. adults with learning disabilities, autism, dementia, acquire brain injury, aphasia after stroke and mental health disorders, and a source of some confusion to researchers regarding the responsibilities and obligations of the role. Where a consultee is involved in giving advice on the individual’s likely wishes and feelings about participation, there appears to be minimal recognition and report of the active involvement of incapacitous participants in decision-making as far as their abilities allow.

Recommendations from Stages 1 and 2

1. Promotion of researcher-participant cooperation

The system for developing, reviewing and conducting ethically-sound research that includes adults with capacity and communication difficulties would benefit from redefining. This requires promotion of cooperation between a researcher and a participant such that empowerment is recognised within a system that protects. A renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making.

2. Support for participant autonomy

There is a strong and enduring need for guidance that focuses on the researcher's efforts to promote the autonomy of the participant as far as possible, regardless of their assessed capacity, and even where a consultee is involved, with specific attention to strategic adaptations and accommodations that enable people with capacity and communication difficulties to have a voice in research.

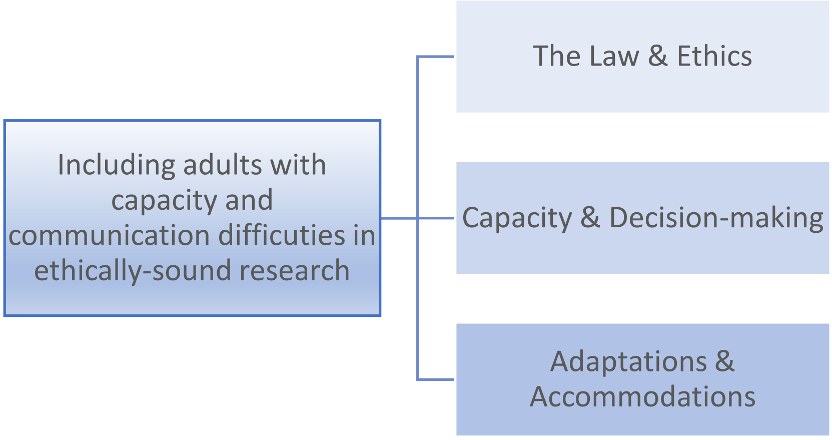
3. Use of a full range of adaptations & accommodations

Researchers and ethics committee members need to be better informed about the full range of methods to support people to make autonomous decisions so they can advise applicants seeking ethical approval for their research. The researcher needs to make sure that the conditions are right for a person to use their available skills as far as possible, to understand information, to retain and weight it up, and finally, to communicate their decision. Traditional ways of obtaining informed consent are not appropriate for all, and there is a need to consider alternative processes.

Stage 3. Strategic Development

The final stage of the project focused on the strategic development of guidance to address the recommendations emerging from stages 1 and 2 of the project: promotion of researcher-participant cooperation; researcher-participant cooperation; support for participant autonomy; and use of a full range of adaptations and accommodations. Accordingly, the content was defined in correspondence to the findings and organised in three key domains as shown in Figure 1.

Figure 1. The three domains for strategic development



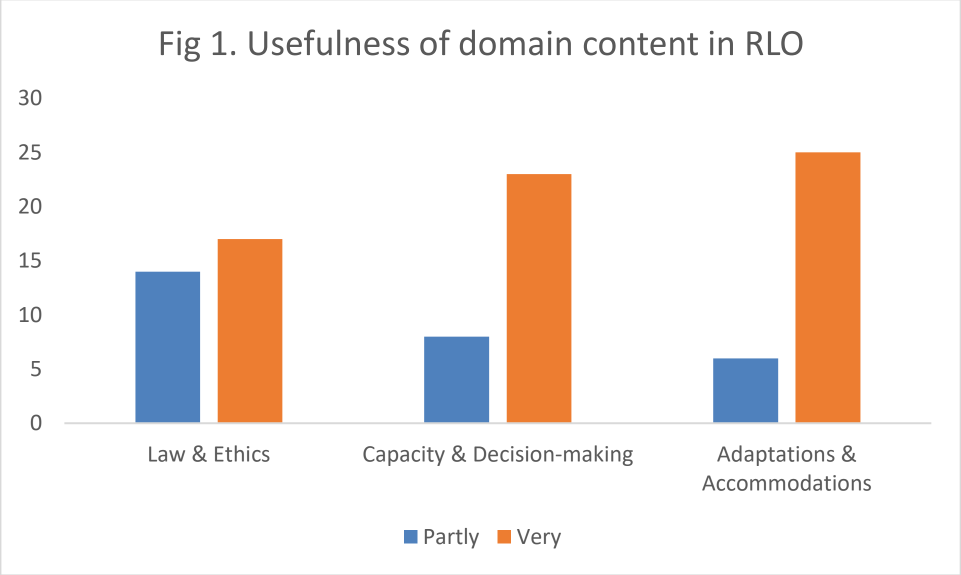
The aim was to develop a Reusable Learning Object (RLO) containing guidance that would be of interest to a wide range of users/stakeholders including: researchers, reviewers of research proposal serving on ethics committees, and service user-focused organisations as potential consumers of research. A first draft of the content was completed in PowerPoint format and was accompanied by a narrative describing the proposed navigation, visualisation and animation of the RLO. At this stage, the proposed content was shared with representatives of the Working Group who had the opportunity to make comments and suggestions, which in turn fed into the development process.

The PowerPoint and narrative information were used as the basis for constructing the digital entity. The work was carried out by an independent digital learning company. Work samples were sent out for review by the project team at regular intervals and feedback was given. An e-questionnaire was developed to solicit feedback from parties interested in field-testing the RLO.

Researchers and Research Ethics Committee (REC) members were invited to evaluate the e-guidance or Re-usable Learning Object (RLO), developed from the research outcomes of stages 1 and 2 of the project. Although not part of the target population, 4 adults with aphasia, who connected to the project also provided their feedback.

We received 31 completed evaluation questionnaires on the RLO (19 below our target of 50 questionnaire returns). Most participants were female (67.7%), over 54 years (48.4%), predominantly white (90.3%) and worked as researchers (64.5%). Others were stroke survivors with aphasia (n=4), a student (n=1) and a recently stepped down Lay Plus member of a REC (n=1).

Participants were asked to rate the usefulness of each domain within the RLO according to the following response options: very useful; partly useful; not useful. The domain 'Adaptations & Accommodations' was rated the highest (Partly=6; Very=25), followed by 'Capacity & Decision-making' (Partly=8; Very=22). The Law & Ethics domain showed a fairly even distribution between 'partly' and 'very' (Partly=14; Very=17).



Feedback and suggestions included:

- Worked case examples: greater diversity in the scenarios needed; more examples needed of how to involve participants, make language accessible and work with consultees; how to evidence participant responses; use of audio file/narrations could be supplemented with practical examples and definitions.
- Structure: A navigational route to be presented visually and for the user to track their journey through the RLO with a 'back' button; introduce more

sub-headings and sections; greater clarity from the start about the target audience would be helpful.

- Presentation: review language content for acceptability; review text superimposed on a pictorial background with a screen reader; indicate when a sound file is playing.

Recommendation from Stage 3

The numbering of recommendations from Stage 3 follows on from the those articulated for Stages 1 and 2.

4. Enhance the relevance and usability of the ASSENT RLO

In order that the content of the RLO may be refined for optimal relevance and usability, feedback needs to be solicited from a wider and more representative sample. Drawing on the feedback established thus far, case-based scenarios that capture real-life communication processes and exemplify expressions of assent and dissent would serve to enhance the continuum of decision-making that is featured in the ASSENT RLO.