Project ASSENT Final Report:

Addendum

Project ASSENT:

Development of an assent-based process for the inclusion of adults with impairments of capacity and/or communication in ethically-sound research

Development of an assent-based process for the inclusion of adults with impairments of capacity and/or communication in ethically-sound research

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with Alex Tiseo

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Advisory Group

Most members of the Advisory Group on Project Assent continued during the extension period. Two members of the Working Group also joined the Advisory Group. The Advisory Group met twice during the one-year extension period of project ASSENT. In each meeting, the research team provided updates on project progress for review by the members. The agenda and the minutes for each meeting were produced in a range of formats (standard text, Easy Read and Easy Text).

We would like to thank every member for their time, suggestions and contributions during the extended project time. Their support has been invaluable in keeping the project relevant and accessible to all our stakeholder groups. The membership comprised:

- Professor Tom Shakespeare, OBE: London School of Hygiene & Tropical Medicine; expertise in disability research and ethics.
- 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.
- Linda Watson: Norfolk Conversation Partners (people with acquired language disorder after stroke); expertise through lived experience.
- Mandy Roper/Jennifer Knowle: Office of the Public Guardian.
- Joan Goulbourne: Senior Policy Advisor; from Ministry of Justice
- Ann Tunley: Head of Research Ethics Service (England) [representing Juliet Tizzard, Director of Policy at HRA]
- Colin Bell: Norfolk Conversation Partners (people with acquired language disorder after stroke); person with lived experience and member of the previous Project ASSENT Working Group.
- Joyce Bell: Supporter of person with lived experience (people with acquired language disorder after stroke) and member of the previous Project ASSENT Working Group
- Catherine Dennison, Programme Lead, Nuffield Foundation.

Administrative Support

Thanks to Sharon Vout who provided administrative support throughout the project.

Construction of Reusable Learning Object

We acknowledge the work of Marshall E-learning Consultancy in constructing an interactive Re-usable Learning Object based on the outcomes from Project ASSENT and its extension.

Our Participants

We express our thanks to all our participants who shared their thoughts and ideas with us during the project.

Original Artwork

The artwork in this report was done by the members of the Broadland Clinic art group.

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ASSENT web-based guidance

A major output from Project ASSENT was the development of a reusable learning object (RLO). This is web-based information and guidance in a digital format. The aim of the guidance is to promote inclusion in ethically-sound research, specifically concerning those individuals who may lack capacity and have communication difficulties and in relation to the Mental Capacity Act (2005). The RLO is relevant to our key stakeholder groups: the Health Research Authority Research (HRA); Research Ethics Committees (RECs); researchers; professional groups – pre- and post-registration practitioners (medicine; clinical psychology; speech & language therapy; occupational therapy; physiotherapy); voluntary sector and user-focused organisations representing people with capacity-affecting conditions (e.g. Mencap; Stroke Association; National Autistic Society; Mind; Headway).

The Assent guidance can be accessed here: Assent Guidance

Project Team

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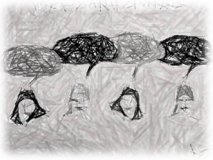


Executive Summary

This is the Executive Summary report of a 12-month extended period (2021-22) to Project ASSENT (2018-21). Project ASSENT was set up as a multi-disciplinary project about the inclusion of adults who may lack capacity and may have communication difficulties in ethically-sound research in England and Wales.

Overview of Project

The aim for the project extension period was to enhance the relevance and usability of the ASSENT web-based guidance (also referred to as a re-usable learning object: RLO) – a major output from the original ASSENT project.

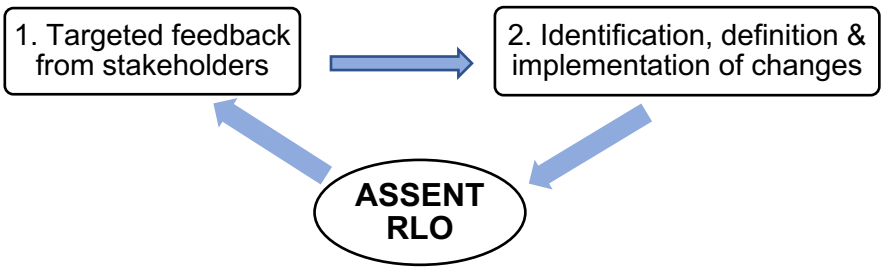
Methods, Approaches & Activities

Following initial feedback from 31 respondents using an e-questionnaire, we carried out a more comprehensive review of the RLO using focus group discussions and interviews as appropriate to the stakeholder groups. This was then followed by the identification, definition and implementation of recommended changes

Objective 1. Targeted feedback from stakeholders

The first objective was to refine and improve the ASSENT RLO through targeted feedback from stakeholders. To do this, we carried out focus group discussions with researchers, practitioners and research ethics committee (REC) members. In addition, we conducted interviews with adults living with capacity-affecting conditions and/or communication difficulties, either on their own or paired with their supporters/carers. Figure 1. Illustrates this process.

Figure 1. Process of evaluation of RLO and change



1.1 Focus Group Discussions

Using the content of the RLO as a stimulus for review, debate and feedback, we carried out two structured focus group discussions with each of three stakeholder groups: a. REC members; b. Researchers; c. Practitioners (included speech and language therapists, social workers, clinical psychologists). Participants in b. Researchers and c. Practitioners had recognised experience with adults who may lack capacity and/or have communication difficulties, including those with: learning disabilities; autism; acquired language disorder after stroke; acquired brain injury; dementia and mental health disorders. Each stakeholder group provided feedback on specific domains of the RLO as shown in Table 1 below.

1.2 Interviews – single or supported

To ensure the relevance and appropriateness of the RLO to the user group, we carried out structured interviews with adults living with capacity-affecting conditions and/or communication difficulties (adults with CCDs). There was the option to be interviewed with their chosen supporter (partner, spouse or carer). These interviews focused on the domain 'Adaptations & Accommodations'.

1.3 Sample

Researchers and REC members provided feedback on the domains: 'Law & Ethics' and 'Capacity & Decision-making'. Practitioners and reviewed 'Adaptations & Accommodations'. The sample included adults with: learning disabilities; autism; acquired language disorder after stroke; and acquired brain injury. We were unable to recruit adults with dementia and mental health disorder.

Table 1. Summary of RLO domains reviewed by targeted stakeholder groups (number of participants indicated)

<table>
<tr><th>Domain</th><th colspan="3">Focus Group (FG)</th><th>Single/Supported Interview</th></tr>
<tr><td>Law & Ethics
Capacity & Decision-making</td><td>Researchers (FG1: n = 8; FG2: n = 5)</td><td>REC members (FG1: n = 4; FG2: n = 4)</td><td></td><td></td></tr>
<tr><td>Adaptations & Accommodations</td><td></td><td></td><td>Practitioners (FG1: n = 3; FG2: n = 3)</td><td>Adults with CCDs (Single: n = 4; Paired: n = 4)</td></tr>
</table>

Objective 2. Identification, definition & implementation of changes

The second objective of the project was to identify, define and implement changes to the ASSENT RLO based on the feedback from Objective 1 activities.

2.1 identification and definition of changes

To identify revision points for the RLO, we carried out template analysis which used themes generated from an initial screening of the feedback in a template. These are termed a priori themes. We then mapped our findings from the focus group discussions and interviews to each page of the RLO.

2.2 Implementation of changes

From our findings, we then defined the action points in relation to RLO which were conveyed to the digital company responsible for the RLO design.

Findings

As shown in table 2., six a priori themes were identified with relevance to the RLO. Each theme contained sub-themes, which were translated into action points for revising the RLO. These were then tabulated and reported to the digital company responsible for the RLO design. Prior to finalising the RLO, a final step involved a usability test conducted by some university-based researchers who had expressed an interest in reviewing the RLO.

Table 2. Summary of a priori themes and data-generated themes used in template analysis

A priori themes	Data-generated themes	Action Points
1. Presentation	1.1 Organisational devices	• Increased use of bullet points; headings and sub-headings; • Use of larger font size and avoidance of capitalised words
	1.2 Abbreviations	• Replace abbreviations with full text
2. Media	2.1 Text to audio	• Add audio to text (make it optional)
	2.2 Graphics	• Remove background pictures or reduce size • Check the relevance of pictures Consider use of original artwork by user group
	2.3 Animations	• Remove problematic animations as identified • Replace with revised infographics

3. Navigation	3.1 User control	• Introduce map for tracking user progress • Make sliders more visible • Clarify instructions to user as required
	3.2 Organisation	• Insert numbers for different slides
4. Scenarios	4.1 Content	• Revise to relate to the four principles of capacity (understand, retain, weigh up and communicate) • Simplify case content
	4.2 Placement	• Locate case scenarios in separate section
5. Language	5.1 Content	• Condense textual content. • Remove all specific references to sections of the Code of Practice • Relace 'guidelines' with 'Guidance'
	5.2 Plain English	• Simplify language for improved accessible.
	5.3 Usability	• Usability testing when revisions are complete
6. Resources	6.1 Bespoke forms	• Provide a researcher checklist on adjustments and supports • Provide consultee declaration forms (personal & nominated)
	6.2 Links to relevant resources	• Provide a list of useful resources with web-links as appropriate

Conclusions and Recommendations

The perspectives of our stakeholder groups revealed similar issues that related to the following aspects of the RLO: presentation; media; navigation; scenarios; language; and resources. The majority of the recommendations arising from the evaluation data were addressed. Usability testing revealed that the RLO in its current version is easier to use and understand. It is considered a useful tool to guide people working in the context of the research provisions of the Mental Capacity Act (2005).

Chapter 1. Introduction

Background

Project ASSENT, a three-year project (2018-2021), with a year extension (2021-2022), was conducted with the aim of defining a way through the complexities of including adults who live with capacity and communication difficulties (CCDs)in ethically-sound research, as they are often excluded (Bunning et al., 2022; Hamilton et al., 2017; V. Shepherd, 2020).

The final stage of the original Project ASSENT (2018-2021) focused on developing guidance based on evidence established in the previous two stages (stage 1. Ethico-legal landscape; stage 2. Current Practice). The purpose of the guidance was to provide enhancements to the Mental Capacity Act (2005) Code of Practice within the context of existing legislation. The web-based guidance took the form of a Re-usable Learning Object (RLO) that covered:

- The Law and Ethics (setting out the ethico-legal landscape for research involving people with CCDs);
- Capacity and Decision-making (exploring decision-making as a continuum from those who have capacity for informed consent, through those who require adaptations and accommodations to support their decision-making, to those who rely on another person to inform on their likely wishes and feelings, but can be supported to express their assent or dissent and
- Adaptations and Accommodations (exploring the range of practical supports available to people with CCDs

Mental Capacity Act (MCA, 2005)

Variability in the understanding and application of the MCA provisions by practitioners who have received statutory training has been reported (Hinsliff-Smith et al., 2017). In particular, the assessment of capacity and the decision-making process present some challenges (Alonzi et al., 2009) with a lack of confidence affecting around two thirds of practitioners (Manthorpe & Samsi, 2012). Suggestions for improvement include: more opportunities to engage, learn and implement provisions and the promotion of legal literacy regarding research involving adults who lack capacity to consent (Scott et al., 2020; Shepherd et al., 2018). Scott and colleagues (Scott et al., 2020) also highlighted the need for regular training opportunities for health and social care professionals, with a focus on supporting the link between theory and practice, as well as review of case studies. Similarly, Jayes et al (Jayes et al., 2020), revealed knowledge and practice gaps amongst health and social care professionals regarding mental capacity. They

reported that professionals who had received training still found capacity assessment challenging and would benefit from additional training, especially one that involved the discussions of clinical scenarios and practical aspects of assessments. Fletcher and colleagues argued for greater clarity regarding the MCA's research provisions, suggesting that this be achieved through detailed guidance regarding the various challenges that could occur with implementation and publishing of researchers' experiences of working with the MCA (Fletcher et al., 2019). The need for guidance on the Mental Capacity Act (2005) was asserted in NICE guidelines 108 (2018) where it stated that "practitioners did not always understand the requirements of the Act and that their practice did not always comply with these". The NICE guideline further highlights the importance of training and support for practitioners to improve their practice regarding support for decision-making and the conduct of capacity assessments (NICE, 2018).

Web-based learning

The use of web-based resources to enhance the quality of education, training and professional development is expanding across the different sectors (Fontaine et al., 2019; Lawn et al., 2017; Regmi & Jones, 2020),including academia (Hefter, 2021) healthcare professionals and patients (Huang et al., 2018; Lawn et al., 2017; Tezak et al., 2022) researchers (Health Research Authority, 2021) and the public more broadly (Ballew et al., 2013). Web-based training offers flexibility and accessibility and promotes user control of the learning process (e.g. timing and duration) (Hefter, 2021). It promotes user-centred learning by supporting different learning styles, with the potential to deliver learning at scale (Rawashdeh et al., 2021).

Factors of computer literacy, technology and learner discipline are also relevant here. Whilst the effectiveness of web-based resources over traditional face-to-face methods of learning has not been established emphatically, some slight improvement in learner's knowledge has been attributed to user satisfaction with web-based resources (Du et al., 2013; Lahti et al., 2014). Involvement of end users in the development process may be a factor here (Latif et al., 2017; Sabater-Hernández et al., 2018). A participatory design at all stages of development may enhance the content, and improve usability and satisfaction (Ferguson et al., 2018; Latif et al., 2017). Furthermore, perceived usefulness and perceived ease of use are the most influential factors in meta-analysis literature (Bai & Jiang, 2022).

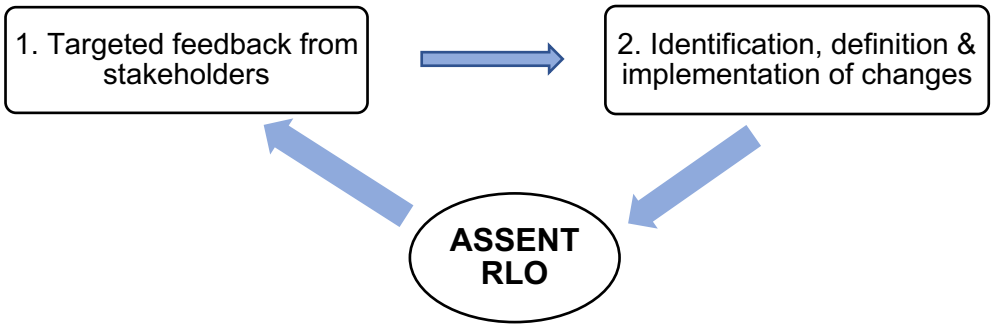
Re-usable Learning Objects (RLO) are web-based, self-contained and repeat-use resources with a clear educational purpose (Onofrei & Ferry, 2020). They promote accessibility and deliver bite-sized units of learning (Khan et al., 2019), which can include real-life scenarios (Cowdery et al., 2019). The content, context and learning activities can be modified to meet specific learning outcomes (Ferguson et al., 2018). There is a growing body of evidence on the use of RLOs in a variety of contexts (Hardie et al., 2021; Khan et al., 2019). For example, the RLO was used to support international healthcare students to learn about the UK National Health Service (NHS) and UK health professional roles (Evans, 2012). Similarly, researchers effectively used an RLO to raise awareness about dyslexia and to provide guidance on coping with dyslexia in the workplace (Wharrad et

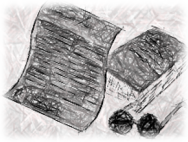
al., 2012), Moreover, the translation of research findings into RLOs has been reported as an effective way of achieving knowledge transfer (Wharrad et al., 2012) and improving understanding (Bath-Hextall et al., 2011).

Project Aim

The aim for the project extension was to further enhance the relevance and usability of the main output: the ASSENT web-based guidance in the form of a RLO. Devised in stage 3 of the original project ASSENT, the purpose of the RLO was to provide a resource for individuals involved in the development and review of research proposals (e.g. researchers, healthcare practitioners, members of research ethics committees) that promoted the inclusion of adults with CCDs in ethically-sound research under the research provisions of the MCA (2005). The current project extension built on the small-scale pilot of the ASSENT RLO carried out in stage 3. where thirty-one participants reviewed the RLO and completed an e-questionnaire. The questionnaire focused on the content, language, readability, functionality of graphics and navigation of the RLO. While there was overall satisfaction by its users there were also suggestions for amendments. Figure 1 shows the process of evaluation undertaken in the extended period of the project.

Figure 1. Process of evaluation of RLO and change





Chapter 2. Methods

Project outline

Our specific aims for the extended project period were to: (a) expand the scale of evaluative feedback; (b) respond to the feedback gathered from the initial evaluation in stage 3, together with the additional feedback completed in the extension period by making revisions to the RLO; (c) support the embedding of the RLO in research practice across the health and social sciences.

We extended our evaluation of the ASSENT RLO by soliciting and using targeted feedback from our key stakeholder groups on its three key domains: the law & ethics; capacity & decision-making; adaptation & accommodations. This was so that the content of the RLO could be refined for optimal relevance and usability.

Methods

Sample

We aimed to recruit a purposive, stratified sample of participants from our stakeholder groups of: Research Ethics Committee (REC) members; researchers; practitioners; and people with CCDs (those living with: intellectual disabilities, autism, acquired brain injury, aphasia after stroke, mental health conditions and dementia).

Project information sheets and consent forms were sent out to potential participants detailing the domains that they were being asked to review (see table 1). Participants were recruited in the following ways:

- REC members were recruited through the Health Research Authority across the different regions in England and Wales.
- Researchers and practitioners with experience of working with adults living with CCDs were recruited from health and social sciences department across the UK and from our existing network.
- People with CCDs with optional supporter presence were recruited through the project's existing networks

Once consent forms were returned, we contacted individuals to arrange mutually convenient times and venues for data collection.

Table 1. Summary of sample by targeted stakeholder group (FG = number of participants)

Domain	Focus Group (FG)			Single/supported Interview
Law & Ethics Capacity & Decision-making	Researchers (FG1.1: n = 8; FG1.2: n = 5)	REC members (FG2.1: n = 4; FG2.2: n = 4)		
Adaptations & Accommodations			Practitioners (FG3.1: n = 3; FG3.2: n = 3)	Adults with CCDs (Single: n = 4; Supported: n = 5)

As shown in table 1., the sample comprised researchers, REC members, practitioners and adults with CCDs. There were thirteen researchers in two focus groups who were clinical academics, researchers in universities, or researchers in charitable organisations. There were eight REC members in two focus groups, representing different regions of the UK. Three were REC chairs, three were lay-plus members, with one expert and one lay member. There were six practitioners in two focus groups, including speech & language therapists, occupational therapists, clinical psychologists and social workers. The practitioners were experienced professionals who had worked with one or more of: adults living with learning disabilities, autism, dementia, mental health difficulties, acquired brain injury, aphasia, progressive neurological and other long-term conditions. Adults with CCDs included people with autism (n = 2); learning disabilities (n = 3); aphasia after stroke (n = 2) and acquired brain injury (n = 2). Three carers were involved in supported interviews. We were unable to recruit participants from our two remaining stakeholder groups – adults with mental health conditions and adults with dementia. Table 2., provides a summary of participant characteristics.

Table 2. Characteristics of stakeholder groups and participants

Characteristics	Researchers (n=13)	REC members[1, 2] (n=8)	Practitioners (n=4)	Adults with CCDs[3] (n= 9)	Supporters	Sum (%)
Age						
23-34	3	0	1	4	1	8 (21.6)
35-44	0	1	1	1	1	4[4] (10.8)
45-54	5	2	1	1	0	9 (24.3)
Over 54	5	5	1	3	2	16 (43.2)
Gender						
Male	2	2	0	5	1	10 (27)
Female	11	6	4	4	2	27 (73)
Ethnicity						
White British	11	7	3	8	0	29 (78.4)
Black British	2	1	1	1	3	8 (21.6)

Notes

[1] REC experience: >15 yrs = 2; 11-15 yrs = 1; 5 -10 yrs =2; >2 yrs = 1; <1 yr = 1.

[2] Regional representation: London = 2; London/Brighton = 2; East of England = 1; Yorkshire & Humberside Leeds = 1; Hampshire = 1; Camden & King Cross = 1.

[3] Adults living with: Autism = 2; Acquired brain injury = 2; Aphasia = 2; Intellectual disabilities = 3.

[4] Some data missing.

Data collection

Two topic guides with questioning routes were developed based on the earlier pilot feedback (see Appendix i).

Topic Guide 1. This was for the Researchers and REC members focus groups addressing the RLO domains of: Law and Ethics; and Capacity and Decision-making. Participants reviewed each slide and made observations on: the general appearance; language content and any missing information; navigational properties; accessibility factors; information needs.

Topic Guide 2. This was for the focus group of practitioners and the single/supported interviews by people with CCDs addressing the RLO domain of 'Adaptations and Accommodations'. Participants made observations on each slide by consideration of: the general appearance and layout; the identified accommodations and communication supports; important communication supports that need to be included.

Focus Groups: Focus group discussions were held online using the Microsoft Teams platform, which also provided automatic transcription. The discussion lasted for a maximum of one and a half hours. The number of participants in a group ranged from 3 to 8 as shown in table 1. Group discussion was moderated by a senior member of the research team. Each group focused on the relevant section of the RLO assigned to them.

For example, practitioners discussed “Adaptations & Accommodations’, while researchers and research ethics committee members looked at ‘Law and Ethics’ and ‘Adaptations and Accommodations’.

Each focus group followed the same format:

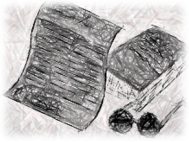
- The participants introduced themselves;
- The researcher provided a brief overview of the structure and content of the RLO;
- The targeted domain was shown to participants slide by slide, with the researcher asking for comments and observations after each slides;
- Prompts were provided by the researcher as required. These took the form of probes into particular constituents of the slides, e.g. the layout, the language used, presentational features, etc.

Single/supported interviews: Interviews lasted approximately one hour and were held in the place preferred by the participant(s). This ranged from interview rooms at the university, participant’s homes and meetings rooms of affiliated organisations. With the exception of one participant who preferred to use Microsoft Teams, all interviews were face-to-face. Participants with CCDs chose whether to be interviewed individually or with support. Understanding of project information and participant consent was checked/confirmed immediately before each interview.

The interview consisted of structured open-ended questions with follow up probes focusing on each page of the relevant section of the RLO. Face-to-face interviews were recorded using a digital recorder supplemented by researcher notes. The one interview carried out on Microsoft Teams was automatically transcribed.

Data analysis

The transcripts were analysed using template analysis (Brooks et al., 2015; King, 2004). An Excel spreadsheet was configured using the six main categories, derived from the earlier pilot evaluation of the RLO, as initial a priori themes (e.g., editorial, content, language, presentation, navigation and case scenarios) (Bunning et al., 2021). Three members of the research team met to discuss, define and agree the themes. The data were inspected against the template of a priori themes. A first level of data-generated themes was identified and located within the themes (Brooks et al., 2015). The template was then applied to the entire data set. The flexible nature of template analysis allowed for development of the framework (Cassell, 2011) through the addition of data-generated themes. A reflective process was used to ensure that coding was rooted in the data, instead of being influenced by individual biases and assumptions. The final stage involved populating a summary table with selected excerpts from the data transcripts.



Chapter 3. Results

Table 3 provides a summary of the different focus groups and participants that are referenced in the results.

Table 3. Summary of focus groups and participants as referenced in results

Stakeholder Group	Focus Group	Participant	Participant-Supporter
Practitioners	FG1.1; FG1.2		
REC members	FG2.1; FG2.2		
Researchers	FG3.1; FG3.2		
Adults with CCDs		P1- P9	P2/S; P4/S

The results of the RLO evaluation are organised according to each a priori theme and the relevant data-generated themes. These are summarised below in Table 4.

Table 4. Summary of a priori themes and data-generated themes

A priori themes	Data-generated themes
1. Presentation	1.1 Organisational devices
	1.2 Abbreviations
2. Media	2.1 Text to audio
	2.2 Graphics
	2.3 Animations
3. Navigation	3.1 User control
	3.2 Organisation
4. Scenarios	4.1 Content
	4.2 Placement
5. Language	5.1 Content
	5.2 Plain English
	5.3 Usability
6. Resources	6.1 Bespoke forms
	6.2 Links to relevant resources

1. Presentation

This theme was about the visual features of each slide (as shown in table 5), which subdivided into:

1.1 Organisational devices, which focused on the internal structure and organisation of content; font style and font point size used in written text; and general accessibility to the user.

1.2 Abbreviations, which asserted the importance of avoiding acronyms and jargon within the RLO in order to maximise user understanding.

Table 5. Summary of 'presentation' [data source provided]

1. Presentation		
Data-generated themes	**Items**	**Excerpts from data**
1.1 Organisational devices	• Bullet points	*'Putting things in clear bullet points…. could have basically a title that were like summarise, what is being said in that bullet point …'* [FG1.2] *'no bullet points 'too crunched' 'crunches your brain up'* [P7]
	• Headings and sub-headings	*'…one thought or key concept per sentence…….clear headings?'* [FG3.2] *'heading and sub-headings - yeah'* [P4].
	• Title case	*'…words in capitals makes it more difficult to read.'* [P3]
	• Clear font (point size, colour, style and bold)	*'Increasing the font size just for accessibility'* [FG3.1] *'… key words on the lefthand side, maybe next to a bold start. You think about the colour of what your text is, the colour of your background'* [FG1.2] *'I have a problem with red 'cause … signifying …. telling me off.'* [P3] *'…bold makes things 'stand out' …. as that is what this is about, so that you can understand the point of the message* [P1]
	• Background colour	*'…. pastel coloured background to aid those of us with visual stress'* [FG3.2] *'black on coloured background is easier to read'* [P3]

		'coloured background or coloured overlay' could prove useful when reading text [P5]
1.2 Abbreviations	• Acronyms	*'If something is DP and that that could be a that direct payments or understand it could be uh. And that data protection.'* [P3] *'...as a rule of thumb as much as possible to try to steer away from abbreviations'* [FG2.1]

1.1 Organisational devices

Organisational devices were valued by the participants because they draw the user's attention to key 'information carrying words' within the text. This included use of a bold font, text underlining and bullet points.

The practitioners advised greater use of bullet points to add structure to the text, particularly where text is dense. The researchers felt it conveyed writing in a 'punchier way' which 'helps a bit more with reading clearly' [FG3.1]. One adult with CCD described the use of 'bullet points' as 'spot on', something which helps to break information up [P7]. They also advocated for an increased font size 'for accessibility' while avoiding writing in 'italics' as 'they are quite hard to read' ['FG3.1].

The practitioners recommended underlining or making words bold, particularly for people with aphasia 'to minimise cognitive load of understanding'[FG1.2]. Text and background colours were considered relevant to text readability. As one REC member suggested 'blue on white is not the easiest of colours to read as such' [FG2.1]. This also resonated with a REC member who identified as dyslexic and found the use of bright pink 'incredibly difficult … to see', choosing rather to 'flip through them' because they were 'just too difficult to actually see [FG2.2]'. In contrast, a researcher who identified as disabled noted that 'some of the text is black on white background' and asked if this 'can always be on a pastel-coloured background to aid those … with visual stress', identifying pale grey as a good choice.

It was also recommended that text be presented on plain background while avoiding its overlap with images. Adults with CCD provided some elucidation of these factors during their interviews. The use of contrasting colours as text and background helps with focus as it allows key words to 'stand out' [P1]. White background can 'cause a glare' for some people but a coloured background is easier to look at [P3] and read [P3]. Three adults with CCDs in separate interviews hinted that the use of red colour to highlight words may not be the best as it is linked with negative events, such as 'stay away or danger colour'[P5], 'someone shaking 'or 'telling off' [P3] or 'rude', the latter being associated with getting red marks back at school [P7], with a suggestion to use blue instead [P5]. In addition, an adult with CCD explained that words in capital are 'more difficult to read' [P3] as 'it's easier to grab the shape in title case than it is in capital letters [P3].

1.2 Abbreviations

REC members suggested 'as a rule of thumb as much as possible try to steer away from abbreviations'[FG2.1]. An adult with CCDs said abbreviation could be misleading, confusing or misinterpreted. The example given was 'DP' which could mean 'direct payments' or 'data protection' [P3].

2. Media

As shown in table 5., this theme was about different media used to enhance usability of the RLO. It subdivided into:

3.1 Text to audio, which focused on improving accessibility to the user.
3.2 Graphics, which covered background and separate images, their relevance and meaning.
3.3 Animations, which focused on the usefulness of particular animations to clear understanding and usability.

Table 5. Summary of findings on a priori theme: 'media' and data generated themes [data source provided]

2. Media		
Data-generated themes	**Items**	**Excerpts from data**
2.1 Text to audio	• Add audio to text	*'I looked for a button to make it play. I assumed the amount of text would be supported by a narrative'* [FG1.2] *'The videos do not have the option to have subtitles - which excludes those with hearing loss'* [FG3.1] *'I find reading very tiring. I'll have an audio rather than a written book'* [P1].
2.2 Graphics	• Size of pictures in relation to text	*'I think a lot of the pictures can be reduced in size …. don't let the text overlap the images - must have a plain background against the text* [FG3.1]
	• Relevance	*'I did wonder who this funny person sitting in her hand was supposed to be and what that had to do with being a consultee….'* [FG3.1] *'I love pictures and definitely visual sticks in my mind more than text'*[P1]
	• Diversity	*'…. basically there are three white women behind each with a picture….there is diversity. I can just see it here, but the third*

		one we looked in …it's all white women again [FG1.2].
2.3 Animations	• Relevance and meaning enhancement	*'…visually the sparks that are coming out of the COGS are…. quite distracting and I'm not really sure what the purpose of them is'* [FG2.1] *'I think on both of those videos the bits that keep popping up on them. I'm not sure that they're really adding anything...'* [FG2.1]

Recognition and support for the use of multi-media within the RLO resonated throughout the data set. Suggestions centred around text to audio, the use of relevant graphics of the right size and the use of animations. The participants recommended the addition, removal or modification of various media to complement the text within the RLO.

2.1 Text to audio

Audio was seen as complimentary to written text, especially where there are lots of texts, audio can be listened to over and over again [P1]. Researchers suggested the addition of 'subtitles on video as an option' to support the inclusion of 'those with hearing loss' [FG3.1]. Similarly, it was suggested that text could be supported by a spoken narrative [FG1.2]. Adults with CCDs also supported the use of subtitles on video as it makes easier to process information [P8], [P1] and was less tiring [P1].

2.2 Graphics

The review of pictures and images within the RLO triggered comments of relevance to meaning and representation of ethnic diversity. Pictures were said to 'stick more than written words' [P1], as 'it is more options especially with memory' [P1]. Other feedback was about reducing the picture size or removing altogether to create space for larger fonts or bullet points, thereby improving readability [FG2.1; FG3.1]. Pictures were seen to 'explain information for people who cannot focus for long' [P6]. An adult with CCDs further suggested that borders around picture can help support 'visual discrimination' [P3]

Some participants also suggested the use of pictures from diverse population (e.g. age, gender and ethnicity) to show inclusion. A REC member made a note of the greater representation of younger people in the RLO 'there is a lot of young people in your pictures' and advocated for inclusion of older adults, saying 'quite a lot of people in mental capacity research are not spring chickens' [FG2.2]. Participants also suggested the removal of graphics that could be easily misunderstood. In an instance, the use of a 'seesaw picture' with research value and protection on one side and autonomy on the other side did not convey the message of balance. One researcher said: '*the way it tilted is suggesting the research value and protection way more heavily than autonomy. And actually I'm not sure that that's really the message that you're trying to portray*' [FG2.1].

2.3 Animations

This includes animations and videos embedded in the RLO. One particular animation drew the attention of both REC members and practitioners. Its purpose was questioned regarding its meaning in relation to the narrative. It was seen as 'visually distracting' and serving no purpose [FG2.1] and only '…vaguely to do with what was being said' [FG3.1].

3. Navigation

As shown in table 6., this theme was about the user interface with the RLO. It subdivided into:

3.1 User control, which focused on mapping progress through the RLO and use of devices to reveal text.
3.2 Organisation, which identified the importance of numbered slides.

Table 6. Summary of findings on a priori theme: 'navigation' and data generated themes [data source provided]

3. Navigation		
Data-generated themes	**Items**	**Excerpts from data**
3.1 User control	• Tracking progress	*'…and if you've got discussions, you definitely want to know where you were last looking at"* [FG2.1] *'… helpful to have some way of marking that a section has been read ……. I did repeatedly access sections I had already read'*[FG3.2].
	• Use of scroll bars	*'the one thing that has struck me when I was going through it was much easier when I didn't have to scroll down'* [FG3.1]. *'it might be a good thing to so that people are aware that slide is there and we can scroll up and down…. tie the colour in if possible with the MCA and the you know the green and then it bit more vivid and it catches your eyes'* [FG2.1] *'if you have to scroll down, you either forget to do it and miss half of it, or you then have to work out where you have to go….'* [FG3.1]
	• Instructions to user	*'I didn't realise I have to click on the cloud'* [FG3.1].

		"I've got the slides and I have bigger screen so I can see it and I didn't realise I have to click on the cloud" [FG3.1].
3.2 Organisation	• Number slides	*'… know where you are in the slide deck. So not sure whether there's going to be a numbering system, more colour coded system just so you can pause it at a particular time point and then get on…'* [FG3.1]

Participants were sent the link to access the current version of the RLO before the group meeting. This was to give them the chance to look through the section that is relevant to their group, if they wanted to. However, it required their use of the navigation system. Different stakeholder groups (practitioners, REC members and researchers) spoke about the need to improve the navigation system of the RLO.

3.1 User control

Participants spoke of how they 'couldn't get back' to where they wanted to go in the RLO, 'getting lost' or repeatedly accessing sections already read. This was partly because there were no back buttons or for some, there were too many navigation buttons (side menu, top menu as well as navigation buttons on each of the slides) that it became confusing. The addition of a back button 'would be very helpful' [FG3.1]. There were conflicting views about the menu. While a participant found the menu on the side good for navigation and preferred same to the navigation button on the pages of the slides [FG2.2], another asked 'if there is any way to ensure the navigation buttons remain at the top of the page' [FG3.1]. It was suggested that finding a way to mark the section that has been read either with 'a tick mark' or darker colour to the background' will prevent repeatedly accessing section already read [FG3.1].

Participants found it easier to move through the RLO when they did not have to scroll down for information [FG3.1]. It was suggested that a reduction in information on a slide would remove the need to scroll down. Others spoke of missing out on information when the scroll bar was not obviously visible There were lots of useful suggestions such as the use of 'bold' sliders, or 'colour' such as green for sliders thereby creating a contrast to make the navigation system stand out or become better 'identifiable', whichever style is chosen, a participant suggested that it should be 'consistent'.

Instructions to "Click" on an object to reveal further information were viewed as useful. A need to be consistent throughout the RLO was also expressed.

3.2 Organisation

Participants suggested numbering the pages of the RLO slides "just so you can pause it at a particular time point and then get OK. "I can start now at 9 slide #50 or whatever" [FG3.1]. Organisation will make it easier for users to find the content they are looking for, thereby enhancing user's experience.

4. Language

As shown in table 7., this theme was about the language content of the RLO. It subdivided into:

5.1 Content, which focused on volume and clarity of information.
5.2 Plain English, which considered readability and access to information in the RLO.
5.3 Usability, which highlighted the importance of usability testing post-revision of the RLO.

Table 7. Summary of findings on a priori theme: 'Language ' and data generated themes [data source provided]

4. Language		
Data-generated themes	**Items**	**Excerpts from data**
4.1 Content	• Reduce verbage	*'It's too much for me to process…... ' [FG3.1]* *'…..just a bit too busy. It could be simplified, it's too wordy and I think it needs to make very, very clear…'* [FG2.1] *'Avoid long sentences as words can begin to jump if it's too long'* [P6] *'Concise, straightforward'* [P4/S]
4.2 Plain English	• Simplification	*'….could it be just written in a more simplified manner? …..'* [FG3.1]
	• Accessibility	*'The community of researchers isn't just academics… my colleagues with learning disabilities who are conducting research …..need to be able to access the information as well, and sometimes people outside of academia……..'* [FG3.2] *'Also English - not a first language' 'have them easy for people'* [P8]
	• Concreteness and familiarity	*'…try to make it as kind of concrete as you … otherwise it can all just feel a bit murky and abstract'* [FG1.1] *'language people can understand'* [P9]
	• One key concept at a time	*'… one thought or key concept per sentence'* [FG3.2] *"If each sentence is a new line, it is far easier to read"* [FG3.1]

4.3 Usability	• Testing	*'…more about the usability and the layout of it. And will you be doing any usability testing with it before it's kind of launched?'* [FG3.1] *'The web site needs to be checked whether it is accessible for screen readers'*[FG3.2]

4.1 Content

Participants described some pages of the RLO as 'too wordy' [FG2.1] or having ''too much to process' [FG3.1] which might make them 'skip over it' [FG3.1]. One participant suggested that 'sometimes less is more' and 'woolly stuff' takes up headspace which is no longer available [P1]. According to adults with CCD, reading 'lots of text can be tiring' [P1] and words can begin to jump' if it is too long [P6]. This was echoed by a supporter who advised that information should be 'concise and straightforward' incorporating 'short sentences' [P4/S]. There were suggestions that content might be reduced by presenting it in bullet format and removing information which appears to be repeated in some ways [FG2.1]. One researcher suggested that slides with lots of information 'would be better if split into more slides' [FG3.1].

4.2 Plain English

There was support for simplifying the language content. Participants suggested the use of 'layman's terms' for the benefit of all users. The need for accessible materials was supported by a researcher who observed that 'the community of researchers isn't just academics' and there are researchers 'with learning disabilities who are conducting research [FG1.2]. If the language is not plain, 'we make readers try to work out what something means' [P3], which undermines the purpose of the guidance. Avoidance of complex, unfamiliar and abstract, [P6], [FG1.1] or technical words [P4/S] was recommended with deliberate adoption of relatable, familiar, concrete and straight forward words, whilst avoiding use of slang or jargon [P9; P7; P6] [FG1.1; FG1.2], as it does not support understanding [P7]. In addition, autistic people do not 'get implied meaning' it is therefore important that 'language is explicit' [P5]. Participants also said it was far easier to read when 'one thought or key concept per sentence' [FG3.2] with each sentence starting 'as a new line' [FG3.1].

4.3 Usability

The need to run a usability test of the RLO before its final launch was articulated [FG3.1, FG3.2 to assess the effectiveness and efficiency of the guidance while providing opportunities to improve the overall user experience and overcome potential issues with use. There was particular mention of ensuring that it is 'accessible for screen readers', possibly using website's usability testing software, such as 'Silktide' [FG3.2].

5. Scenarios

The RLO contained case scenarios at the end of each domain [Law & Ethics, Capacity & Decision-making; Adaptations & Accommodations]. Each scenario was a narrated presentation designed to trigger problem solving regarding informed consent and the assessment of capacity.

As shown in table 8., this theme was about the case 'scenarios' within the RLO. It subdivided into:

5.1 Content, which focused on the description and complexity of the problem situation.
5.2 Placement, which considered the location of the scenarios within the RLO.

Table 8. Summary of findings on a priori theme: 'scenarios' and data generated themes [data source provided]

5. Scenarios		
Data-generated themes	**Items**	**Excerpts from data**
5.1 Content	• Relevance	*'….refining the questions so it's a bit more focused on what actually you want from that scenario'* [FG3.1] *'….The consultee is absolutely useless at this point because you never mentioned it before'* [FG3.1]
	• Simplification	*'I've forgotten what those first two questions were. So having them on this page and having the sub questions and then maybe having another page with the answers…* [FG1.1]
5.2 Placement	• Separate section at end of RLO	*'… in the wrong order….* [FG3.1] *'….quite a big jump from what we've just been looking at……I mean, you're now expecting people to unravel some quite complex, subtle ideas.[*FG2.1]

5.1 Content

Content referred to the relevance of the cases to the animations of the informed decision-making processes [FG3.1]. Participants also expressed the need to simplify the cases as it was difficult remembering the content sufficiently to then answer the questions that followed [FG3.1]. Participants even suggested the addition of 'another page with the answers' as they struggled to know what these would be.

5.2 Placement

The participants felt that the scenarios were not in the best place within the RLO or in the wrong order' [FG3.1], as the questions asked after the animation were sometimes about a concept that was yet to be covered in the RLO [FG3.1]. This was also flagged by a group of REC members: 'quite a big jump from what we've just been looking at' [FG2.1]. The cases were considered to be 'quite complex'. It was suggested that the questions need to be refined a bit more, focusing on the purpose of the scenario [FG3.1].

6. Resources

As shown in table 9., this theme was about the language content of the RLO. It subdivided into:

5.3 Bespoke forms, which included practical resources for use
5.4 Other resources, which identified the inclusion of references and hyperlinks to useful resources.

Table 9. Summary of findings on a priori theme: 'Resources' and data generated themes [data source provided]

6. Resources		
Data-generated themes	**Items**	**Excerpts from data**
4.1 Content	• Researcher checklist	*' … a literal checklist before they meet somebody of visual needs … hearing needs. I don't know if that's something that's elsewhere in the guide...* [FG1.1] *'If somebody needs support with their communication, this is what you should be providing. If somebody needs support to make a sound decision, this is what you provide....'* [FG3.2]
4.2 Other resources	• Hyperlinks	*'hyperlink from personal consultee to the part of the Act or the Code of Practice that talks about.'* [FG3.2]
	• Other	*'And further information to explain the terms or whether you have a glossary'* [FG3.2]

6.1 Bespoke forms

Participants were asked "What do you think is missing?" Both researchers and practitioners expressed the need to include bespoke forms, especially 'a checklist' that researchers could refer to as they prepare applications for ethical approval or engage in research with

adults living with capacity and communication difficulties [FG2.2; FG1.2; FG3.2]. Practitioners and REC members spoke of the need for samples of different versions of participant information sheet [FG1.2; FG2.2] as well as consultee declaration form. The need for 'further information to explain terms' was flagged by both researchers and adults living with CCDs. However, researchers suggested that glossary at the end of the RLO whilst adults with CCDs suggested that difficult words should be explained in context [P3].

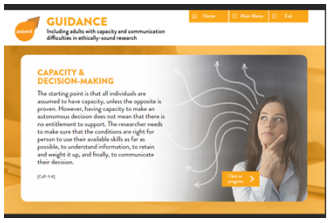
6.2 Other resources

Exploration of the data also showed the mention of a printable version of the RLO, such that 'you can print off the appropriate section and give it to people' [FG1.1]. There was also suggestion of a hyperlink to the relevant parts of the Mental Capacity Act Code of Practice [FG3.2].

Chapter 4. Revisions to ASSENT guidance

From findings to revisions

The findings from the focus group discussions and individual/supported interviews were translated into action points in relation to each slide of the RLO. Each action point was then summarised in terms of instructions and revisions to the textual content. These were then conveyed to the developer and an iterative process of revision, review and feedback with the developer followed. Examples of the template used to capture the revisions for the developer are provided below.

Slide reference	Instruction / Revised text
	Use bullet points; remove picture or reduce size.
	Deciding whether to act as consultee or not

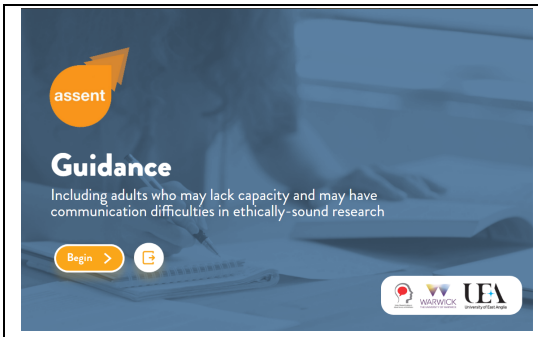
1. **Presentation:** Strategic use of bullet points, headings and subtitles, title case instead of all capitals, clear font and pale coloured background in contrast to text were introduced as appropriate.
2. **Media:** Text to audio has been introduced. Pictures deemed to be irrelevant have been removed and others have been resized as appropriate. Images produced by the project's art group have been added in. Animations that were not helpful or consistent with narrative have been removed.
3. **Navigation**: A hierarchical flowchart was generated to capture the internal structure of the RLO domains to check navigational options within the RLO. Numbering of slides was considered to support the user's navigation but rejected as too complicated due

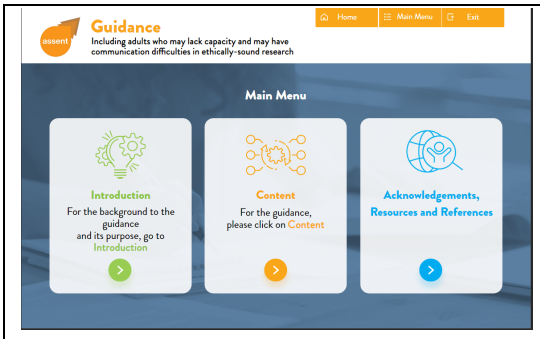
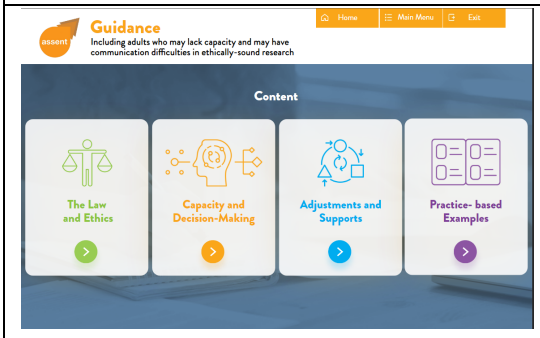
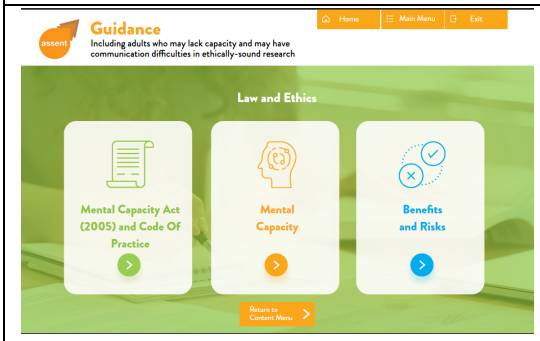
to the number of embedded menus. Slide content was condensed and scroll bars rendered as more visible.

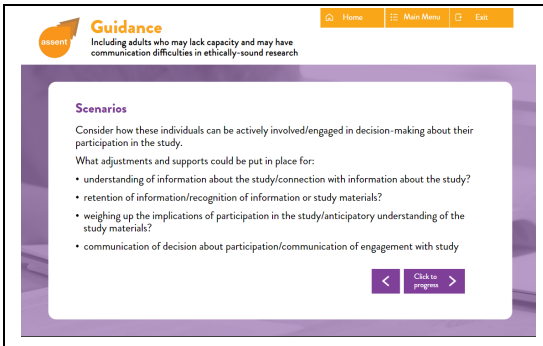
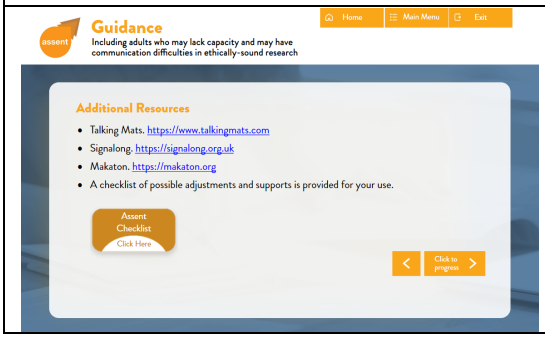
4. **Language**: The language content was reduced, with information expressed more concisely through use of shorter sentences and expanded use of bullet points. Based on feedback received, the strapline of the project was changed to: 'Including adults who may lack capacity and may have communication difficulties in ethically-sound research'. Technical words were removed and abbreviations or acronyms written in full.
5. **Scenarios:** The original scenarios were extracted from individual domains and relocated to a separate domain entitled 'Practice-based Examples'. The scenarios were introduced as cases for consideration and discussion. Some further scenarios were generated that presented particular challenges for the informed consent process and offered possible solutions around the four principles of: understanding information; retaining in formation; weighing up the implications; and communicating the decision. These were piloted on REC development days successfully and scrutinised by a group of experts representing practitioners and persons with lived experience to ensure authenticity of content.
6. **Resources:** In addition to existing practical resources, a checklist for researchers was devised to help the preparation of recruitment strategies. The aim is to help researchers to consider approaches to reasonable adjustment in the development of study materials. The areas for consideration reflect those addressed under the Supports and Adjustments domain.

Summary of Revised RLO

The ASSENT RLO reported here is prototype 2. A summary of RLO content is provided here.

	The user accesses the RLO and sees the cover slide, which leads to author details and affiliations. On the left-hand side of the screen are the titles of all the slides in the RLO. As the user progresses through each slide a tick indicates their journey.

	The user progresses to the Main Menu and selects the Introduction which describes the purpose of the guidance.
	The user progresses to the Content Menu. Content is divided into four key domains: The Law and Ethics; Capacity and Decision-making; Adjustments and Supports; Practice-based Examples. The user decides which domain they wish to enter.
	The Law and Ethics menu presents three content areas to explore: Mental Capacity Act (2005) and Code of Practice; Mental Capacity; Benefits and Risks.
	The Capacity and Decision-making menu presents four content areas to explore: Capacity and Communication; Decision-making; Consultee; Continuum of Engagement.
	The Adjustments and Supports menu presents four content areas to explore: Language; Media; Context; Relevance.

	Practice-Based examples are presented in two ways: 1. Scenarios that present an individual's capacity and communication difficulties in relation to a study and also offer options for providing adjustments and supports. 2. Scenarios with talking heads in relation to the three content domains of the Law and Ethics; Capacity and Decision-making; and Adjustments and Supports. These are for mutual problem-solving and discussion by the user and their colleagues.
	Additional Resources have been provided with web links as appropriate. There is also a link to a checklist for users to access and use in their research and for the inclusion of people who may lack capacity and may have communication difficulties.

Usability

We carried out usability testing to ensure that the new version of the guidance reflected the changes suggested.

Researchers, practitioners and Research Ethics Committee members, who had taken part in focus group discussions were provided with a summary of the changes and a link to the updated version of the guidance. They had a week to provide feedback via a Microsoft Forms survey.

Twelve participants completed the survey. They were mostly female (83.3%), over 54 years (41.7%), predominantly white (91.7%) and worked as researchers (50%). Their research interests overlapped and included aphasia (n=4), learning disabilities (n=7), autism (n=5), dementia (n=4), mental health conditions (n=6) and acquired brain injury (n=3).

Responses overall were positive. Almost all participants (91.6%) found the animations useful, and all reported that the side bar was useful for tracking their progress through the guidance. The removal of abbreviations supported presentation for all participants while the use of bullet points and headings and sub-headings supported presentation for over 90% of participants. Almost all participants (91.7%) found the language used appropriate for a lay audience while most (83.4%) considered the volume of text on each page to be about the right amount. Structuring the case scenarios around the principles

of capacity was regarded as helpful by almost all participants (91.7%). Similarly, most participants found researchers' checklist (83.3%) and links to other resources (91.7%) useful.

Further feedback with free text showed that that online guidance is considered an 'excellent' and 'a really useful tool' which 'should be used by ethics committees as well as researchers and participants'. Participants were happy to 'see the implementation of the recommended changes … developed in a very positive way', which they believe 'will support researchers in their future applications'. We could not number the slides usefully because the content was organised around domains containing embedded menus. The text to audio as an option was not completed due to time and financial constraints.

Chapter 5. Conclusions, Recommendations and Next Steps

Summary

The development of the ASSENT RLO was a complex process defined by an iterative process that involved review, feedback and revision through prototypes 1 and 2. Initial development of the RLO (prototype 1) was based on evidence derived from investigations into: the **ethico-legal landscape** for research under the provisions of the MCA (2005) in England and Wales; **current practice** concerning the implementation of the provisions. Protype 1 was subjected to two types of review involving our key stakeholder groups (researchers; REC members; practitioners and supporters; people with CCDs):

1. Trial usage and feedback by participants on their user experience via a bespoke e-questionnaire;
2. Facilitated review of specific domain content through focus group discussions or interviews as appropriate to the stakeholder group and individual preferences.

Feedback was organised according to six a priori themes:

Presentation	**Media**	**Navigation**
Scenarios	**Language**	**Resources**

Each theme converted into action items that informed changes to the RLO. However, there were exceptions where a moderated action or no action was applied to feedback.

The first two exceptions were: introduction of a text to audio option; and numbering of slides. Both items were discussed with the developer.

- A text to audio option was identified as a possible enhancement to the RLO. The volume of RLO content meant that this would have constituted a major amendment with related time and financial costs. Therefore it was decided to apply audio options to selected areas of the RLO instead.
- Numbering of slides was feedback as one way to help user navigation of the RLO. However, the structure of the RLO and its use of embedded menus was considered inappropriate for sequential numbering. Instead, the navigational content displayed in a left-hand list was improved with ticks applied to enable the use to track progress.

The third exception was the aim to include video footage of decision-making processes with people with CCDs. We originally set out to capture real-life interactions involving individuals with CCDs and the person who knows them best. This was to showcase the different ways people with CCDs may express their feelings and opinions with appropriate support. Although not about research participation, but we still needed to establish the informed consent of the individual and their supporter according to the best interests of the person with CCDs. Post application via the Integrated Research Application System (IRAS), we were informed that this fell outside normal research and did not require this form of ethical approval. We then submitted an application to the online ethics monitor at the University but were informed that this fell outside their jurisdiction. We were concerned that our planned activity needed some form of ethical scrutiny, but none seemed to be available. A further complication was the time and resources that would be needed to develop a video resource of this nature. We, therefore, following a recommendation from the Advisory Group, approached Dipex, a charitable organisation with a large video library of people living with various health conditions. We explored potential video clips for the e-guidance, but none was fitting. Following this review, the issue of using video footage to exemplify decision-making for the e-guidance was discussed in detail at a team meeting. We collectively decided that we would not pursue the creation of videos further, because of the complexity of capturing interactions that were representative of the various decision-making processes. Instead we developed some new case scenarios that were structured around the four principles of capacity (understanding; retention; weighing up; communication). These were trialled in a series of REC development days in England and with representatives from our stakeholder groups of people with lived experience.

Conclusions and Recommendations

Development of guidance in the form of a RLO is a complicated business! Our participatory design enabled a range of user perspectives to inform the structure and content properties of the RLO. The different methods of soliciting feedback from our different stakeholder groups were useful. The e-questionnaire supported a timely pilot with a convenience sample of participants. The focus groups and review of selected content domains yielded feedback from a more representative sample and facilitated discussion amongst the participants. The individual and supported interviews enabled people with CCDs to review RLO content with relevant communication supports in place.

Central to the development and refinement of the RLO was a positive working relationship with the developer. Our relationship was characterised by clear and regular two-way communications; structured presentation of action items for address by the developer that gave slide refences and clear instructions regarding any changes or additions; timely review of all new and revised content; repeated usage of the RLO.

The revised ASSENT RLO supports the three recommendations arising from the main study. It upholds:

- **Promotion of researcher-participant cooperation** by unpacking the research provisions of the MCA (2005) with deliberate consideration of the needs of people who may lack capacity and may have communication difficulties.
- **Support for participant autonomy** by exploring the ways people who may lack capacity and may have communication difficulties can actively participate in decision-making about their participation in research.
- **Use of a full range of adaptations and accommodations** by examining a range of methods and alternative processes for understanding, retaining and weighing up information so that an informed decision can be communicated.

Next Steps

Next steps focus on dissemination of our work and impact evaluation. We have established a productive working relationship with the Health Research Authority (HRA) for England and Wales and are working to facilitate public access to our major output: ASSENT web-based guidance in the form of a Reusable Learning Object (RLO). This can be accessed here: Assent Guidance

We plan to carry out a series of data generating activities/evidencing tasks to capture and evaluate the use and impact of the ASSENT RLO, including:

- Communications about the ASSENT web-based guidance using a variety of formats to our key stakeholder groups and engagement in a range of promotional activities to highlight the relevance of and access to the RLO;
- Evaluation of RLO usage through a bespoke user-focused questionnaire and invited testimonials from our stakeholder groups;
- A survey of MCA-flagged RECs to assess the impact of the RLO on research proposals submitted for ethical review (sample characteristics and evidence of inclusion; reasonable adjustments for people who may lack capacity and may have communication difficulties), the outcomes of REC reviews and recommendations made. Implementation will require further funds so development of the protocol is the first stage.

Ultimately, our aim is for our work to be embedded in broader policy development concerning research with adults who have capacity and/or communication difficulties, and in the research practice of both researchers and reviewers of research proposals on Research Ethics Committees.

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Impact

During the extended period of project ASSENT, we have continued to disseminate our key messages to a range of audiences via platform presentations and seminar papers to university-based, national and international events. The update list is summarised below.

Conferences

Details	Platform presentation
Annual Conference of the Royal College of Occupational Therapists **Date**: Thursday 1st July 2021 **Venue**: Online	**Title**: Including adults with communication and understanding difficulties in ethically sound research. **Presenter(s):** Anne Killett
End of Project ASSENT Conference 2021 LOST VOICES IN RESEARCH: The development of a continuum of decision making for adults with communication and/or capacity difficulties in ethically sound research. **Date**: Friday 25th June 2021 **Venue**: Online	<u>Presentations:</u> **Title**: Introduction to project ASSENT **Presenter**: Karen Bunning **Title**: Inclusive approach to project ASSENT (Working Group) **Presenter**: Ciara Shiggins **Title**: The Law (Mental Capacity Act, 2005) **Presenter**: Rob Heywood **Title** Application of MCA in research (Systematic review) **Presenter**: Florence Jimoh **Title**: Researchers' reasoning of inclusion/exclusion of adults with capacity and communication difficulties **Presenter**: Peter Langdon **Title:** Assent guidance **Presenter**: Karen Bunning **<u>Further details</u>**: Registered – 140 Attended – 60 Interested in evaluating the RLO – 23

International Aphasia Rehabilitation Conference; June 2020; University of British Columbia (accepted for poster presentation but cancelled due to COVID-19)	**Title:** Lost voices in research: supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research – the case of adults with aphasia (Project ASSENT). **Presenter(s**): Shiggins, C., Ryan, H., Killet, A., Langdon, P., Heywood, R. & Bunning, K
International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) Conference; August 2019; Glasgow	**Title:** Supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research: the current situation for people with intellectual disabilities in England and Wales **Presenter(s):** Karen Bunning; Hayley Ryan; Yvonne Plenderleith; Rob Heywood; Anne Killett; Pete Langdon & Ciara Shiggins.
British Aphasiology Society Clinical Symposium; 10th September 2019; University of East Anglia	**Title:** Supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research: the current situation for people with aphasia in England and Wales. **Presenter(s)**: Shiggins, C., Ryan, H., Plenderleith, Y., Heywood, R., Killett, A., Langdon, P. & Bunning, K
Health Sciences Festival; Tuesday 4th June 2019; University of East Anglia	**Title:** The Mental Capacity Act 2005: Whose business is it anyway? **Presenter**: Hayley Ryan
3MT Project ASSENT; 2019; University of East Anglia wide research conference	**Title:** Lost voices in research: The current climate of evidence-biased practice **Presenter(s):** Yvonne Plenderleith and Hayley Ryan **Further details**: Best Presentation Award.

Seminars

Details	Platform presentation
Project ASSENT Seminar Series; Thursday 14th July 2022; University of East Anglia	**Title:** Lost voices: Including adults with capacity and communication difficulties in ethically-sound research. The focus was on Stakeholders views on the reasoning and underlying values about inclusion and exclusion of adults living with capacity and/or communication difficulties. **Presenter(s):** Killett, A.

Project ASSENT Seminar Series; Thursday 10th March 2022; University of East Anglia	**Title:** Lost voices: Including adults with capacity and communication difficulties in ethically-sound research. The focus of the seminar was on 'Researchers' decision about making inclusion or exclusion of adults living with capacity and communication difficulties; strategies, resources and accommodations used to support research involvement. **Presenter(s):** Langdon, P.
Project ASSENT Seminar Series; Wednesday 23rd February 2022; University of Essex University	**Title:** Lost voices: Including adults with capacity and communication difficulties in ethically-sound research. The focus of the seminar was on 'The Law and ethics' in research, application of the law in research and an introduction to Project ASSENT online guidance. **Presenter(s):** Bunning, K; Jimoh, O.F.
HSC Seminar Series; Wednesday 21st July 2021; University of East Anglia	**Title:** Lost voices in research: Including adults with capacity and communication difficulties in ethically-sound research **Presenter(s):** Bunning, K; Killett, A.
Qualitative Research Forum; Wednesday 26th June 2019; University of East Anglia	**Title:** Semi-structured interviews to explore stakeholder priorities & views on in/exclusion of adult with communication and/or capacity (AwICC) difficulties in ethically-sound research. **Presenter(s):** Ryan, H., Bunning, K.
Title: Qualitative research methods seminar talk **Date**: 17th January 2019 **Venue**: University of East Anglia	**Title:** Co-production in research: Facilitating a Working Group with 'Experts by Experience'. **Presenter(s):** Hayley Ryan & Yvonne Plenderleith

Health Research Authority REC Development Days

Date	Region
7th April 2022	London, Euston
25th May 2022	York
28th June 2022	Manchester
13th July 2022	London, Oxford Circus
8th September 2022	Birmingham
20th October 2022	Reading
24th November 2022	London South

Journal Papers

Published

Bunning, K., Jimoh, O.F., Heywood, R., Killett, A., Ryan, R., Shiggins, C. & Langdon, P.E. (2022). How are adults with capacity-affecting conditions and associated communication difficulties included in ethically sound research? A documentary-based survey of ethical review and recruitment processes under the research provisions of the Mental Capacity Act (2005) for England and Wales. *BMJ Open*;12:e059036. doi:10.1136/bmjopen-2021-059036

Jimoh, O.F., Ryan, H., Killett, A., Shiggins, C., Langdon, P.E., Heywood, R. & Bunning, K. (2021). A systematic review and narrative synthesis of the research provisions under the Mental Capacity Act (2005) in England and Wales: Recruitment of adults with capacity and communication difficulties. PLOS One. Sep 1;16(9):e0256697. doi: 10.1371/journal.pone.0256697. PMID: 34469482; PMCID: PMC8409627.

Ryan, H., Heywood, R., Jimoh, O., Killett, A., Langdon, P.E., Shiggins, C. & Bunning, K. (2021). Inclusion under the Mental Capacity Act (2005): A review of research policy guidance and governance structures in England and Wales. Health Expectations 24(1):152-164.

Heywood, R., Ryan, H., Killett, A., Langdon, P., Plenderleith, Y., Shiggins, C. & Bunning, K., (2019). Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005. *Medical Law International* 19(2-3): 81-112

Under review

Killett, A., Langdon, P.E., Heywood, R., Jimoh, O.F., Redley, M., Ryan., H., Shiggins, C., Bunning, K . Inclusion of adults with adults with capacity-affecting conditions and/or communication difficulties in research: triangulation from a mixed methods study of current practice and values across multiple stakeholders. *BMJ Open*

Professional Papers/Opinion Pieces

Bunning, K., (2022). Having a voice in research: including people who may lack capacity or need support to consent. HRA blog by Dr Karen Bunning, Project ASSENT. https://www.hra.nhs.uk/about-us/news-updates/having-voice-research-including-people-who-may-lack-capacity-or-need-support-consent-blog-dr-karen-bunning-project-assent/

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Bunning, K., (2021). Lost voices. Adults with capacity and communication difficulties are underrepresented in research. Research Fortnight. https://online.fliphtml5.com/qetge/vkfw/#p=14