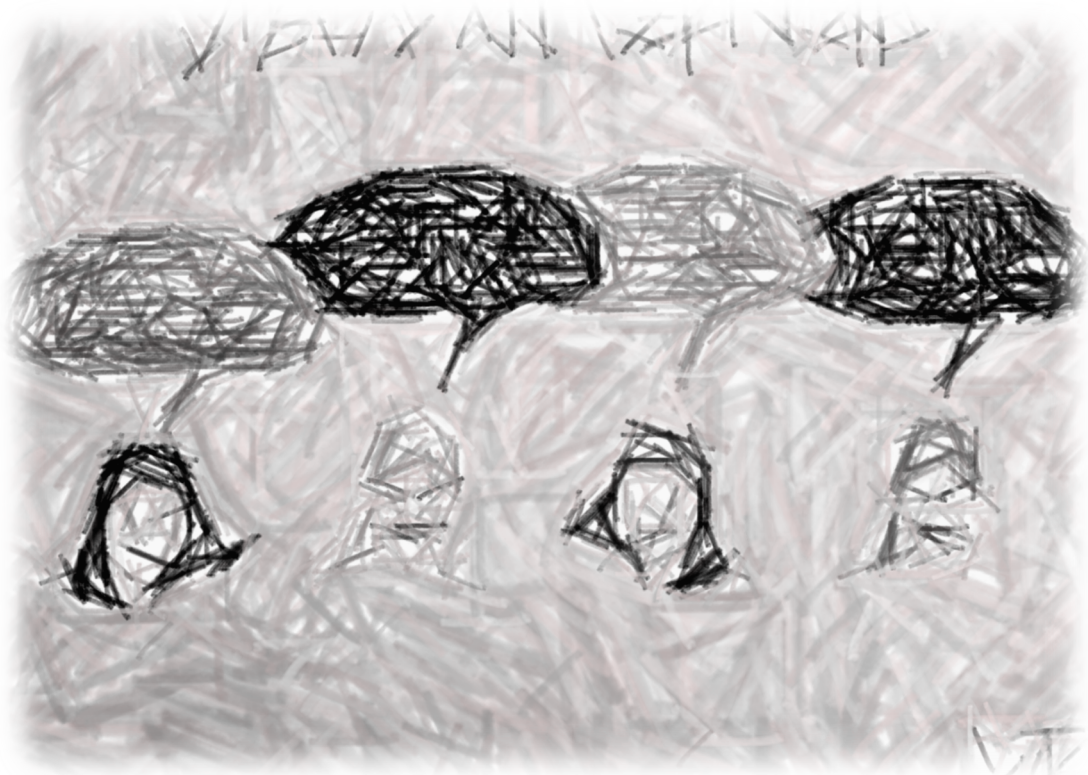# Project ASSENT
Executive Summary:
Addendum

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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WARWICK
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University of East Anglia

assent

Acknowledgements

The Nuffield Foundation

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/Nuffield Bioethics committee; 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.

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The full report is available at:

https://www.uea.ac.uk/web/groups-and-centres/assent/documents

Project Team

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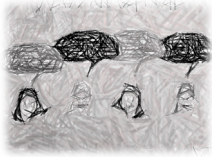
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Oluseyi F. Jimoh

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Administrator:

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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
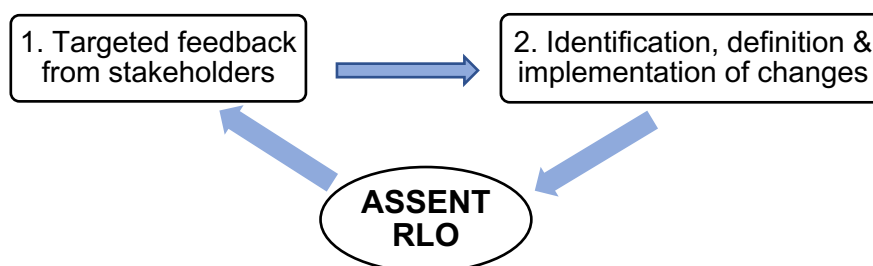
1.1 Focus Group Discussions

Using the content of the RLO as a stimulus for review, debate and feedback, we carried out two structured focus group discussions (FGD) 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)

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

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

We carried out template analysis to identify revision points for the RLO. Using a priori themes generated from an initial screening of the feedback, we analysed the data. 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 was conveyed to the digital company responsible for the RLO design.

Findings

As shown in table 2., six a priori themes were identified as relevant 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 a group of researcher volunteers.

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 within the context of the research provisions of the Mental Capacity Act (2005).