

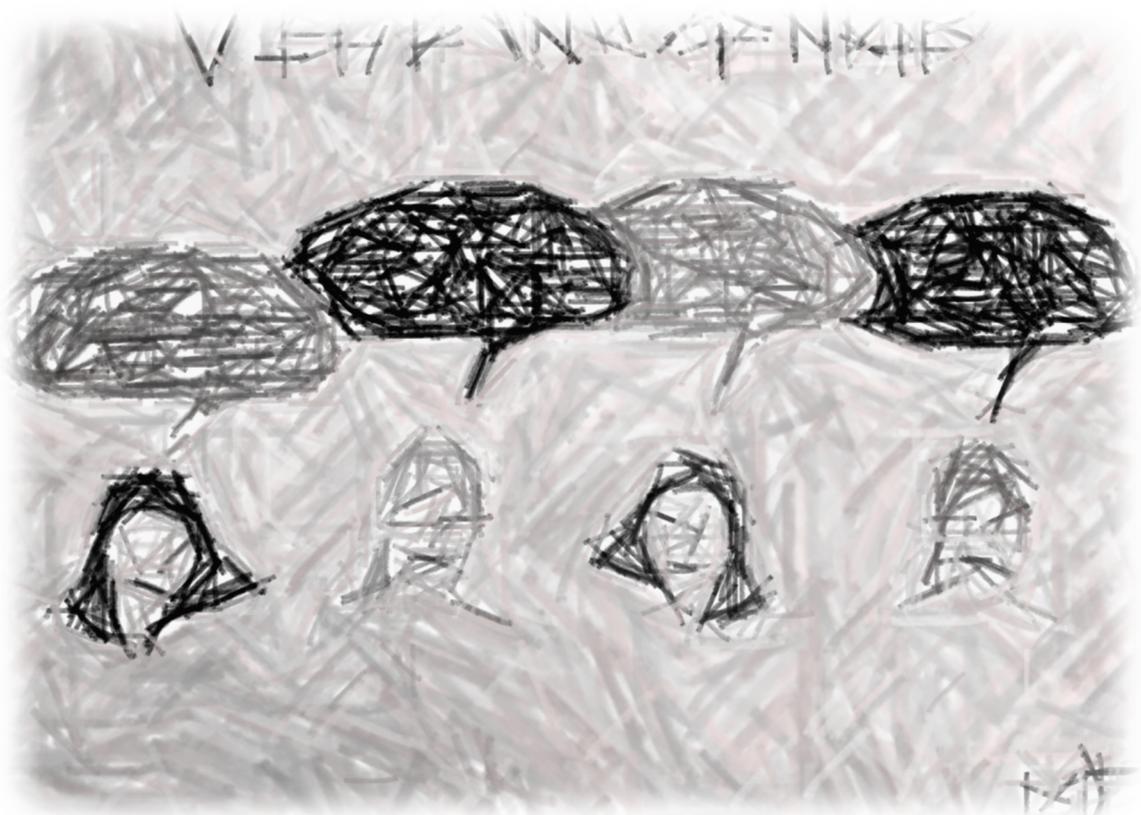


Easy Text

Project ASSENT 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

Karen Bunning, Oluseyi F. Jimoh, Rob Heywood, Anne Killeth, Ciara Shiggins and Peter E. Langdon

with Alex Tiseo



Acknowledgements

The Nuffield Foundation

The authors wish to acknowledge the support of the Nuffield Foundation in funding the extended period of project ASSENT. We would like to express our particular gratitude to Catherine Dennison for her invaluable support and encouragement.

The Nuffield Foundation is an independent charitable trust with a mission to advance social well-being. It funds research that informs social policy, primarily in Education, Welfare, and Justice. It also funds student programmes that provide opportunities for young people to develop skills in quantitative and scientific methods. The Nuffield Foundation is the founder and co-funder of the Nuffield Council on Bioethics, and the Ada Lovelace Institute, and sole funder of the Nuffield Family Justice Observatory. The Foundation has funded this project, but the views expressed are those of the authors and not necessarily the Foundation. Visit www.nuffieldfoundation.org.



This **project** was **funded by** 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.

We would like to **thank every member** for **their time, suggestions,** and **contributions** during the project. Your **support helped us** to make the **research suitable** and **easy** for everyone **to understand**.

Advisory group members are:

- Professor Tom Shakespeare: London School of Hygiene & Tropical Medicine/Nuffield Bioethics committee; **expert** in **disability research** and **ethics**.
- Liz Lund: Asperger's East Anglia/Research Ethics Committee (REC) member; **expert** in working with people who have **autistic spectrum conditions** and **Research Ethics Committee member**.
- Linda Watson: **Norfolk Conversation Partners** (people with acquired language disorder after stroke); **expert** through **lived experience**.
- Mandy Roper/Jennifer Knowle: **Office of the Public Guardian**.
- Joan Goulbourne: Senior Policy Advisor; **Ministry of Justice** Policy Advisor Mental Capacity Act
- 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

Thanks to **Marshall E-learning Consultancy** for helping to **make the e-guidance** based on what we found out from **Project ASSENT** and its **extension**.

Our Participants

Finally, thanks to all **our participants** who **shared their thoughts and ideas** with us during the **project**.

How to cite this report:

Bunning, K., Heywood, R., Killeth, A., Shiggins, C. & Langdon, P.E. (2022). Project Assent-Extension: Final Report. Including adults with capacity and communication difficulties in ethically-sound research. University of East Anglia, UK.

The **date** of this **report** is **17th February 2023**.

Project Team

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Research Associates:

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Administrator:

- Sharon Vout

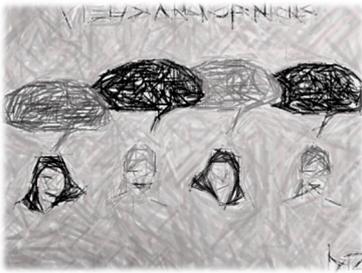


There are **words** in this document that **may be difficult** for you. **We have put these words in green.** These **words** are **explained** in the **glossary** below:

Glossary

Capacity	Able to make own decision in a particular context
Lack capacity	Not able to make own decision in a particular context
Research ethics committee	Team of people who read research proposals and say whether it is safe and sound or not.
Communication difficulties	Difficulty in understanding what people say and saying what you think.
Capacity difficulties	Difficulty in thinking what something means to you, remembering it, and making an informed decision.
Capacity and Decision-making	Being able to understand information and then deciding what to do.
Adaptations and accommodations	Extra supports in place to help people understand information and express their views.
Law and ethics	The law and safe research.
Focus group	A group of people that discuss a particular topic together.

Researcher	People who carry out research activities.
Stakeholder	A person with interest in something.
Practitioner	A person who practices something specific, such as a medical doctor or psychologist
Expert	Having great knowledge and experience in a particular area.
Ethics	Moral principles that tells us how to research should be carried out.



Project Summary

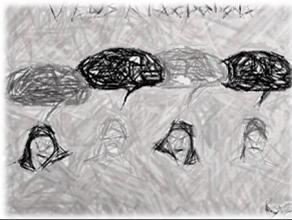
This is the **summary report** of a **12-month extension** of **Project ASSENT**. The project lasted **four years**. The original Project ASSENT began in **2018**. It was **meant to end** in **2021** but was **extended** until **2022**. The project is about **including adults who may lack capacity and have communication difficulties** safely in **research** carried out in **England and Wales**.

In this **summary report** you will **read about**:

- Why we extended Project ASSENT
- What we did
- How it was done
- What we found out
- What the findings mean
- What we have done with the findings.

The **full report** is available at:

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



Overview of Project

An **online guidance** was developed during original Project ASSENT. The project was extended to **make the online guidance better**.

Methods, Approaches & Activities

Firstly, we received **completed questionnaires** from **31 people** about ASSENT online guidance. We then carried out a more thorough look at the online guidance through **focus group discussions** and **interviews**.



Objective 1. Feedback from stakeholders

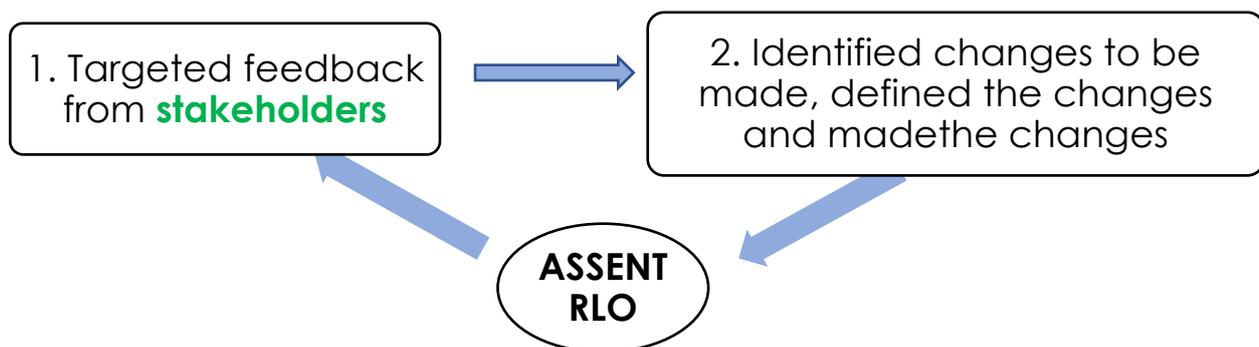
The **first objective** of the project was to **make the online guidance better**. We **asked the views** of **people with interest** in **adults** who **may lack capacity** and who **may have communication difficulties**. To do this, we carried out **focus group discussions** with:

- **researchers**
- **practitioners**
- **research ethics committee members**

We also **interviewed adults who may have difficulties with capacity** and who **may have communication difficulties**. This was either **on their own** or **with their supporter or carer**. We then **identified the changes** to be made.

We **described the changes** and told the company helping us to develop the online guidance.

Figure 1. below shows the process:



1.1 Focus Group Discussions

We used the **content** of the **online guidance** as the **starting point** for **discussions**. We carried out **two focus group discussions** for each of:

- a. **Research Ethics Committee** members;
- b. **Researchers**;
- c. **Practitioners** who have **experiences** of **working** with adults who may lack **capacity** and who may have **communication difficulties**. This group included:

- speech and language therapists,
- social workers
- and clinical psychologists.

They worked with adults living with:

- learning disabilities;
- autism;
- acquired language disorder after stroke;
- acquired brain injury;
- dementia
- and mental health disorders.

Focus groups were on the sections called:

- **'Law and Ethics'**
- **'Capacity and Decision Making'**

1.2 Interviews – single or supported

We also **interviewed adults who may lack capacity** and who **may have communication difficulties**. This was to **make** the online **guidance suitable** and **easy** for everyone **to understand**.

We interviewed adults either **on their own** or **with** their **supporter** or **carer**. The interviews were on the section called '**Adaptations** and **Accommodations**'.

Each group shared their thoughts on different parts of the online guidance. **Table 1 shows** you **more**.

Table 1. Number of people involved in looking at the guidance

Section of the online guidance	Focus Group Discussion		Single or Supported Interview
<p>The Law</p> <hr/> <p>Capacity & Decision-making</p>	<p>Researchers</p> <p>Focus group 1: 8 people</p> <p>Focus group 2: 5 people</p>	<p>Research ethics committee members</p> <p>Focus group 1: 4 people</p> <p>Focus group 2: 4 people</p>	
<p>Adaptations & Accommodations</p>			<p>Practitioners</p> <p>Focus group 1: 3 people</p> <p>Focus group 2: 3 people</p> <p>Adults with difficulties</p> <p>On their own: 4 people</p> <p>With support: 5 people</p>

1.3 Sample

As shown in table 1., different groups looked at different parts of the online guidance.

Researchers and **research ethics committee members** looked at:

- **Law and ethics**
- **Capacity and Decision-making.**

Practitioners and **adults who may lack capacity** and those who **may have communication difficulties** looked at:

- **Adaptations** and **Accommodations.**

These are **adults living with:**

- **learning disabilities;**
- **autism;**
- **acquired language disorder after stroke;**
- **and acquired brain injury.**

We were **unable to find** and interview **adults living with:**

- **dementia**
- **and mental health disorder.**



Objective 2. Identification, definition & implementation of changes

The **second objective** of the project was:

- to **identify** the **changes needed to the guidance**
- **define** those **changes clearly**
- **make** the **changes suggested** by our participants.

2.1 identification and definition of changes

We used a **structure** to **look at the results** of the **focus groups and interviews**. We **grouped similar thoughts** and views and **applied** these to **each page** of the **online guidance**.

2.2 Implementation of changes

We drew up a list of **action points** for the **digital company** with the job of **making changes** to the **guidance**.

Findings

Six categories of **changes** were **relevant** to the **online guidance**. These are shown below in tables 1-3.

Table 1. Changes in relation to 'Presentation' and 'Media'.

Category	Content	Action Points
1. Presentation	1.1 Organisational devices	<ul style="list-style-type: none"> Increased use of: bullet points; headings and sub-headings; Use of: larger font size and avoid capitalised words
	1.2 Abbreviations	<ul style="list-style-type: none"> Replace abbreviations with full text
2. Media	2.1 Text to audio	<ul style="list-style-type: none"> Add audio to text. Make it optional
	2.2 Graphics	<ul style="list-style-type: none"> Remove background pictures or reduce size Check relevance of pictures Use original artwork by user group
	2.3 Animations	<ul style="list-style-type: none"> Remove problematic animations Replace with simpler diagrams

Table 2. Changes in relation to 'Navigation' and 'Scenarios'.

Category	Content	Action Points
3. Navigation	3.1 User control	<ul style="list-style-type: none"> • Introduce map for tracking progress • Make scroll bars more visible • Clarify instructions to user
	3.2 Organisation	<ul style="list-style-type: none"> • Insert slide numbers
4. Scenarios	4.1 Content	<ul style="list-style-type: none"> • Structure around the four principles of capacity (understand, retain, weigh up and communicate) • Simplify content
	4.2 Placement	<ul style="list-style-type: none"> • Move case scenarios to separate section

Table 3. Changes in relation to 'Language' and 'Resources'.

Category	Content	Action Points
5. Language	5.1 Content	<ul style="list-style-type: none"> • Reduce text content • Remove references to Code of Practice • Relace 'guidelines' with 'Guidance'
	5.2 Plain English	<ul style="list-style-type: none"> • Simplify language for improved accessible.
	5.3 Usability	<ul style="list-style-type: none"> • Usability testing when revisions are complete
6. Resources	6.1 Bespoke forms	<ul style="list-style-type: none"> • Provide a researcher checklist • Provide consultee declaration forms
	6.2 Links to resources	<ul style="list-style-type: none"> • Provide list of useful resources

Conclusions and Recommendations

The **views** of people with interest in including adults who may lack capacity and who may have communication difficulties in research **were similar**. They all **suggested** that **changes be made** to the following aspects of the online guidance:

- **Presentation** in terms of the use of colour, font size, pictures and animations;
- **Media** in terms of the relevance and usefulness of pictures and animations;
- **Navigation** so that users can move through the guidance easily;
- **Scenarios** in terms of relevance to inclusion;
- **Language** ensuring that meanings are clear and the fewest possible words are used;
- **Resources** of relevant tools and supports to help with inclusion.

Most of the changes suggested by people were made to the online guidance. People who looked at the new version found it easier to use and understand. The online guidance is **potentially a useful guide** about the law and ethics for research in relation to the **Mental Capacity Act (2005)**.