Appendix A
Qualitative interviews – topic guide

Interview with Research Ethics Committee members

1. **Tell me about the involvement of adults with impairments in communication and/or capacity in research**

Follow up questions:
What do you think about researchers including adults with impairments in communication and/or capacity *in research? – Why, how, effects on the research*
What do you think about researchers excluding people because of their impairments in communication and/or capacity? – Why, how, effects on the research

2. **Tell me about how you work with the Mental Capacity Act (MCA) as a REC member.**

Follow up questions:
What works well in the MCA?
What works less well in the MCA?
What do you think about the four principles for assessing capacity within the MCA?
Is there anything you would change about the MCA?

3. **What do you think about the MCA Code of Practice (CoP)?**

What is your experience of using the CoP as a REC member?
What works well in the CoP?
What works less well in the CoP?
Is there anything you would change about the CoP?

4. **What do you think about the consultee process for people deemed to lack capacity?**

Follow up questions:
What is your experience of the consultee process being used in research?
What works well with the consultee process?
What works less well with the consultee process?
Is there anything you would change about the consultee process?

Is there anything else that you would like to add about including or excluding adults with impairments in communication and/or capacity in research?

Interview with researchers

1. **Tell me about the involvement of adults with impairments in communication and/or capacity in research**

Follow up questions:
What do you think about including adults with impairments in communication and/or capacity *in research? – Why, how, effects on the research*

What do you think about excluding people because of their impairments in communication and/or capacity? – Why, how, effects on the research

2. **Tell me about how you work with the Mental Capacity Act (MCA) as a researcher.**

Follow up questions:
What works well in the MCA?
What works less well in the MCA?
What do you think about the four principles for assessing capacity within the MCA?
Is there anything you would change about the MCA?

3. **What do you think about the MCA Code of Practice (CoP)?**

What is your experience of using the CoP as a researcher?
What works well in the CoP?
What works less well in the CoP?
Is there anything you would change about the CoP?

4. **What do you think about the consultee process for people deemed to lack capacity?**

Follow up questions:
What is your experience of the consultee process being used in your research?
What works well with the consultee process?
What works less well with the consultee process?
Is there anything you would change about the consultee process?
Is there anything else that you would like to add about including or excluding adults with impairments in communication and/or capacity in research?

<u>Interview with practitioners, gatekeepers and supporters of adults with impairments in communication and/or capacity</u>

1. **Tell me about your role in relation to AwICC taking part in research**

Follow up questions:
If they had a role – why, how, effects on you/person with AwICC
What do you think about people with understanding and/or communication difficulties taking part in research?
What do you think about people with understanding and/or communication difficulties being left out of research – why, how, effects on the research
In what ways can people take part in research?
What is good about AwICC being included in research?

2. **Tell me about your experience of the MCA.**

Follow up questions:
What do you think about the assessment of capacity for AwICC to take part in research?
You told me about a project that had a role in, what did you have to do?
What did you perceive your role to be?
How was it for you?

Supplemental material

BMJ Publishing Group Limited (BMJ) disclaims all liability and responsibility arising from any reliance placed on this supplemental material which has been supplied by the author(s)

BMJ Open

Have you ever stopped research taking place? Why did you make that decision? Tell me more about that experience?

3. **Consultee process**

I would now like to talk to you about the consultee process for people who lack capacity.
Have you heard of the consultee process? (If yes – ask for their understanding, if no – explain it to them)
Have you ever acted as a consultee? If they have - What did you have to do? What was your experience of the process? Would you change anything about the process?
If they haven't - If someone that you know is deemed to lack capacity, how would you feel about advising on their wishes and feelings about taking part in research?

Interview with adults with impairments in communication and/or capacity

1. **Have you ever taken part in research?**

Follow up questions
If they did take part- tell me about your experience of taking part in research?
Why did you take part in research?
How did you take part in research?
What were the effects of taking part in research on you?
What do you think about people with understanding and/or communication difficulties being left out of research – why, how, effects on the research
In what ways can people take part in research? Prompt - what could be put in place to help people take part in research?

2. **Have you heard of the Mental Capacity Act 2005?**

Follow up questions
what do you know about the MCA 2005?
What is it about?
What does it have to do with research?
Can you tell me any words you have heard that relate to the MCA?
What has the MCA got to do with you?
If they answered yes to question 1:
You told me about a project that you took part in, what was the research about?
How was it for you?
Were any accommodations or reasonable adjustments made? Please tell me about this in more detail
Have you ever been stopped taking part in research? Tell me about this in more detail.

3. **Have you heard about the consultee process?**

If they answer yes ask: what do you know about the consultee process?
If they answered no: explain the consultee process to them briefly.
How would you feel if someone else had to advise on your wishes and feelings about taking part in research?
How would you feel if someone that you did not know very well advised on your feeling about taking part in research? Prompt - for example your GP or neighbour?

Appendix B

Results – Interview and Online Researcher Survey

Interviews

The results from the interview data are grouped in the 6 organising themes that emerged: inclusion, impact of exclusion, understanding of the Mental Capacity Act (2005), consultee process, stereotypes and assumptions and accommodations. The key findings, organised by group, are given in Table 3.

Inclusion

Participants from all groups were clear that adults with capacity-affecting conditions and/or communication difficulties should be included in research for the quality of the research, in order for research to have a more comprehensive picture and range of opinions, and for research to improve understanding of the various conditions; '*I think it is essential, because how else are we going to learn, to help people who have those difficulties?'* (Adult with head injury 04). There were also seen to be potential benefits for individuals from taking part in research, but only the adults with difficulties in capacity or understanding talked about the benefit that came from a sense of helping others through their own participation in research.

Impact of exclusion

Adults with difficulties in capacity or understanding expressed anger about people with their difficulties being excluded from research, a sense of being 'disregarded', 'locked out' and that their issues would not be recognised. '*..you would be cutting off a, not generation, whole group of society.'* (Adult with aphasia 01). It was described as 'discrimination'. There was a sense that to be left out of research increased invisibility associated with some disabilities, with one person going so far as to equate this with a lack of democracy.   Those in support or practice roles thought that exclusion led to research making inaccurate assumptions about peoples' experiences. '*… if we don't speak to people with disabilities and impairments, we run the risk of just getting it so wrong and not only will people just not get the services, they … could be further damaged or further impaired by receiving the wrong services.'* (gatekeeper/supporter 03)

Understanding of the Mental Capacity Act

Around half of the participating adults with capacity-affecting conditions and/or communication difficulties had not heard of the Mental Capacity Act, and those who had were more familiar with it

4

Supplemental material

BMJ Publishing Group Limited (BMJ) disclaims all liability and responsibility arising from any reliance placed on this supplemental material which has been supplied by the author(s)

BMJ Open

in relation to health and social care provision rather than research. REC members had some areas of weaker understanding of the Act, such as one participant who thought that family members made proxy decisions for adults without capacity, and some who thought consultees were considering 'best interests' (which in the MCA is not used in the sections governing research).   Researcher understanding was also varied. Only a minority of respondents appreciated that the MCA's criteria for involvement of adults lacking capacity is that research of comparable effectiveness cannot be carried out without their involvement (s.31 (4)). The MCA Code of Practice (CoP) was not a well-used resource, and there was limited evidence that researchers were making use of the full range of methods outlined in the MCA CoP for supporting people to make autonomous decisions. Researchers views and experiences of working with the MCA and ethical review processes appeared to relate to their specific field of research. This appeared more straightforward in biomedical settings in relation to investigations of services or experiences where notions of capacity, consent and participation seemed more contentious between researchers and ethics committees.

Consultee process

Of the participants with health conditions, one participant had direct experience of the consultee role and 3 others had some related experience. None of the gatekeepers, supporters or practitioners had direct experience of the consultee role. While some adults with capacity-affecting conditions and/or communication difficulties were positive about the consultee process if it led to more inclusion, others were not comfortable about the process. They said they would want to be involved as much as possible in the process and that the consultee should be someone who knew them well, although this was not necessarily straightforward.

'Interviewer: So, let's say a researcher, wants to do some research, and the doctor thinks you can't say you want to take part?

Participant: (shouting and sitting upright) What? Please.

Interviewer: Oh, you would be cross?

Participant: Yes. God.

Interviewer: Why would that make you so cross?

Participant: Unhappy.' (Adult with aphasia 02)

Many of the researcher participants did not appear to understand that under the MCA people should be actively supported to make autonomous decisions and that where a person is judged to lack capacity he or she should still be involved in the decision-making process. For researchers in community and residential settings it could be challenging to find potential consultees. The

responses from some supporters could throw light on this as they expressed reluctance to 'speak for someone else' by being a consultee.

Stereotypes and assumptions

Adults with capacity-affecting conditions and/or communication difficulties were clear that researchers should not assume they don't want to take part in research. They thought researchers might assume that it would be too difficult to include people with difficulties in research, or that people would not want to be involved because of finding it difficult or boring.

Accommodations

A wide range of accommodations[1] were suggested by adults with capacity-affecting conditions and/or communication difficulties, including for example on the delivery of information, the physical and social environment, use of supporters and arrangements. Supporters thought that research should be made more engaging, and methods devised for learning from observations of people's daily lives. Researchers were most familiar with adapting written information to an easy read format. Some researchers felt the ethical review of consent is overly focused on written information and signatures, "*…they have templates about the GDPR stuff, they almost say that you have to be word for word in the information sheet.*" (Researcher 04) although one REC member indicated alternatives were considered, "*often I'll say well look, if the study is low-risk, then maybe you don't need a written information sheet, maybe you don't need a written consent form, maybe there are better ways of communicating with people and gaining their consent.*" (REC member 02).

---

[1] Accommodations in this context are alterations of the environment, communication, materials or processes, or use of additional materials or equipment with the aim of supporting the inclusion of a person with a disability or impairment.

Table 4: Findings from interview data presented in participant groups

Adults with capacity-affecting conditions and/or communication difficulties	Supporters and gatekeepers	Researchers
Adults with impairments of capacity or communication should be included in research in order that research is comprehensive, representative of the actual experience and needs of adults with impairments of capacity or communication.	Adults with impairments of capacity or communication should not be excluded from research as inaccurate assumptions will be made about their experiences.	The inclusion of Adults with impairments of capacity or communication in research is important in order that people are heard and research encompasses the range of experiences.
From the perspective of adults with impairments of capacity or communication research excluding Adults with impairments of capacity or communication is partial and flawed.	More should be done to make research participation accessible.	Not all participants demonstrated detailed understanding of the MCA research provisions.
Adults with impairments of capacity or communication have the view that involvement of Adults with impairments of capacity or communication in research can give a voice to these groups of people.	Researchers should use methods that are more engaging.	Participants were aware that potential research participants should be supported to make autonomous decisions about taking part in research.
Participation in research gives the opportunity for altruism for Adults with impairments of capacity or communication.	Researchers should use methods that make use of observation of people's everyday lives.	The MCA Code of Practice is not much used by researchers.
Participation in research offers benefits to the individual such as sense of achievement, feeling useful, increasing confidence.		Participants were aware that under the MCA capacity is decision specific.
Adults with impairments of capacity or communication perceived the exclusion of Adults with impairments of capacity or communication from research as discrimination leading to lack of recognition of their needs and issues.	People in gatekeeping roles do not necessarily see themselves as having this role.	Participants were aware that where a person lacks capacity to make an autonomous decision the consultee process can be used.
There is concern about having someone else speak for a person using the Consultee process.	There was concern over the consultee process as there was reluctance to speak for someone else.	It was not generally understood that under the MCA people judged to lack capacity to give consent should still be actively involved in the decision-making process where a consultee is used.
If the Consultee process is used, the participant should be involved as much as possible in the process.		The setting in which research was conducted had a bearing on the level of difficulty of contacting those who could take the role of personal consultee.
If the Consultee process is used the consultee should be someone who knows the participant very well.		Health related research is a diverse activity, and researchers in different fields have varying levels of understanding of the MCA.
The consultee process could be beneficial if it leads to more inclusion of adults with impairments of capacity or communication.		It was not generally understood that under the MCA people should be actively supported to make autonomous decisions.
People who can't communicate are thought not to understand.		
People who can't communicate are not noticed.		Participants were committed to presenting written information in easy read format.
Researchers should have the knowledge and experience to make adaptations to processes and to communication in order to include Adults with impairments of capacity or communication.	Researchers assessing capacity should have the communication skills to be able to adapt the information to the individual.	Researchers are concerned that the HRA is too focussed on written information and the use of signatures

Supplemental material

BMJ Publishing Group Limited (BMJ) disclaims all liability and responsibility arising from any reliance placed on this supplemental material which has been supplied by the author(s)

BMJ Open

Online researcher survey

Closed questions

Fifty-one percent of researchers said they had been working in research for more than 10 years using a variety of methods. The majority (50%) reported that they made use of mixed methods research, while 26% reported mainly using qualitative methods, and 24% reported that they used quantitative research methods. The most commonly used research design reported was an interview study (29%; Table 4). Considering public engagement in research, 34% reported that they had made use of co-production, while 39% engaged with user groups, and 24% had made use of some type of community-based engagement. The location of research activity undertaken by researchers is found in Table 4. Researchers reported working with participants with a variety of conditions, with dementia being the most frequent (Table 5).

Researcher Decision Making About Inclusion and Exclusion. Considering the rationale for the inclusion of adults with capacity-affecting conditions and/or communication difficulties within research, the most commonly reported reason (25%) given by researchers was that this group were the target population within the actual research study. The next most common reason for inclusion was to give this group a voice (16%) or to improve the quality of research (16%). Researchers also reported that they included this population for ethical reasons (12%), only this group could provide the data needed (11%), or to help ensure autonomy (6%) or for advocacy (4%; Table 5).

Considering the rationale for the exclusion of adults with capacity-affecting conditions and/or communication difficulties, 64% of the total responses for this question were "non-applicable" suggesting that most researchers did not feel they had a rationale for the exclusion of this population from research. The most frequently indicated reason for excluding this group was because they were unable to provide responses to questions (10%), unable to provide consent (8%), another reason not listed (7%), unable to meet the requirements of the Mental Capacity Act (4%), or due to a lack of funding, training, resources, or time (combined at 7%; Table 5).

Strategies, Resources, and Accommodations. Most researchers reported that their knowledge and understanding of the Mental Capacity Act, and confidence in working with a consultee, while others thought this was poor (Table 4). A majority of researchers said that they did not use communication tools when working this this group, while others made use of easy read information (21%), hand or body gestures (16%), easy text (13%), or other types that were not listed within our survey (21%). Very few used audio, British sign language, video, translators, and interpreters. Just over a fifth of

researchers said they tried to be flexible with this group, while others said they enquired about the needs of their research participants, offered breaks, gave various choices, and made use of alternative communication (Table 5).

Open questions – Content Analysis

Six key semantic categories emerged, and the associated referents are found in Table 6. The first was "knowledge and understanding the Mental Capacity Act". Researchers tended to refer to the use of the MCA within clinical settings, reported information about learning and training, and some stated they had limited knowledge and experience. The second was "confidence including adults with communication difficulties and/or capacity-affecting conditions in research". Some researchers commented that they had included this group in research studies, and were confident, while others were less confident and required training and support. Others described the barriers that led them to exclude this group from research. The third category was, "confidence in working with a consultee", and while some researchers indicated they were confident, others were inexperienced or did not understand the role of a consultee. The fourth category was, "role of the consultee" and many researchers indicated they did understand this role, but a significant proportion were unable to describe it correctly or confused it with a best interest meeting which would occur when making decisions within a clinical setting, rather than a research setting. Within our fifth category, "confidence in assessing capacity", researchers indicated having confidence with assessing capacity in clinical settings, but this was not the case for everyone. Notably, some researchers thought this was someone else's responsibility, normally a clinician. In our final category, "other comments", researchers indicated that the inclusion of this group in research is important, but there are barriers.

Table 5: Descriptive statistics summarising responses to the closed questions within the research survey

	Frequency	Percentage		Frequency	Percentage
	n	*%*		*n*	*%*
Gender			**Research experience**		
Male	41	32	0	8	6
Female	85	67	1-2	16	13
Transgender	1	1	3-5	22	17
			6-10	16	13
Ethnicity			>10	65	51
White – English/Welsh/Scottish/Northern Irish/British	100	78			
White – Irish	3	2	**Knowledge and understanding of the MCA**		
Asian/Asian British – Indian	6	5	Excellent	23	18
Asian/Asian British – Pakistani	1	1	Very good	51	40
Asian/Asian British – Chinese	2	1.5	Good	33	26
Black/African/Caribbean/Black British - African	2	1.5	Fair	13	10
Black/African/Caribbean/Black British – Caribbean	1	1	Poor	8	6
Other	13	10			
Experience working with AwICC			**I feel confident working with a consultee**		
0	11	9	Strongly agree	52	42
1-2	11	9	Agree	48	38
3-5	17	13	Neither agree/disagree	13	10
6-10	21	17	Disagree	8	6
>10	67	52	Strongly disagree	5	4
Age	21	16			
25-34	28	22			
35-44	37	29			
45-54	42	33			
>54					

	Frequency	Percentage		Frequency	Percentage
	n	*%*		*n*	*%*
Study Method			Setting for Study		
Qualitative	33	26	Hospital	64	29
Quantitative	31	24	Residential care home	36	16
Mixed	63	50	Participant home	50	23
			Community	25	12
Study Design			University	25	12
Laboratory experiment	15	7	Laboratory	4	2
Field experiment	14	6	Other	13	6
Interview study	66	29			
Questionnaire	46	21	Study Location		
Observational	49	22	Northeast England	17	13.3
Case study	8	4	Northwest England	28	21.9
Case series	5	2	Yorkshire and the Humber	18	14.1
Other	20	9	East Midlands	18	14.1
			West Midlands	12	9.4
Public involvement			East of England	17	13.3
Coproduction	62	34	London	33	25.8
User group engagement	71	39	Southeast England	30	23.3
Community engagement	44	24	Southwest England	21	16.4
Other	6	3	Scotland	9	7
			Wales	16	12.5
			Northern Ireland	4	3.1
			Other	4	3.1

11

Supplemental material

BMJ Publishing Group Limited (BMJ) disclaims all liability and responsibility arising from any reliance placed on this supplemental material which has been supplied by the author(s)

BMJ Open

	Frequency	Percentage		Frequency	Percentage
	n	*%*		*n*	*%*
Target population			Rationale for exclusion		
Post-stroke communication difficulties	23	16	Restricted time	4	3
Dementia	54	38	Lack of funding	2	1
Head injury	6	4	Lack of training	3	2
Mental health conditions	18	13	Lack of resources	1	1
Learning disability	11	8	Unable to meet the MCA requirements	5	4
Autistic spectrum conditions	7	5	AwICC unable to provide responses	13	10
Other	24	17	AwICC unable to consent	11	8
			Other	10	7
Groups included as participants			Not applicable	88	64
Post-stroke communication difficulties	29	18			
Dementia	56	34	Use of communication tools		
Head injury	10	6	Easy read	41	21
Mental health conditions	22	14	East text	24	13
Learning disability	13	8	Audio	2	1
Autistic spectrum conditions	8	5	British sign language	2	1
Other	25	15	Hand and body gestures	30	16
			Braille	0	0
Rationale for inclusion			Video/DVD	3	2
Giving people a voice	53	16	Translator	1	1
Ethical reasons	39	12	Interpreter	3	2
Advocacy	15	4	Other	40	21
Autonomy	19	6	Did not use	45	24
Target population of the research	84	25			
Improved quality of research	51	16	Use of accommodations		
Only AwICC could provide the data	35	11	Enquiring about needs	83	64.8
Other	9	3	Offering regular breaks	71	55.5
Not applicable	22	7	Participant choice of location	68	53.1
			Flexibility	84	65.6
			Alternative communication	53	41.4
			Other	13	10.2

12

Table 6: Findings from online researcher survey – content analysis of open questions

Nodes	References	Nodes	References
	n		*n*
Knowledge and understanding of the MCA		**Confidence working with a consultee**	
Clinical application	27	Has experience of consultee process	7
Research application	11	No experience of consultee process	6
Training and personal study	10	Did not understand our question	2
Teaching the MCA	4	Difficulties identifying a personal consultee	2
Clinically	4	Not relevant to research project	2
Research-focussed	2	Clinical application	1
Personal experience with family member	1	People lacking capacity were excluded	1
Rarely use the MCA	1		
Level of knowledge and understanding		**Role of the consultee**	
Limited	7	Unable to answer our question	7
Good	1	Issues with the consultee process	3
Familiar with research provisions	1	*Description of consultee role*	
Has improved over time	1	Correct	46
Has worked with others who are familiar with the MCA		Incorrect	26
Clinical setting	4	Sees consultee as an advocate	8
Legal setting	1	Partially correct	
		Partially describes role	12
Confidence including AwICC		Confusion with best interests meeting	9
Inclusion of AwICC	10		
Support from multi-disciplinary team	5	**Confidence assessing capacity**	
Exclusion of AwICC	4	Clinical application	15
Barriers to inclusion	3	Other people's responsibility	7
Communication impairments does not mean impaired capacity	1	Support from the multi-disciplinary team	4
Broad range of impairment	1	Tools to support assessment	3
Experience working with AwICC		Training course	2
Clinical setting	4	*Confidence*	
Research setting	1	Confident	7
Confidence		Limited confidence	2
Confident	7	Dependent on individual being assessed	2
Requires training	3	*Issues with assessment*	
Limited confidence	3	Assessment is decision-specific	2
		Translating the principles of the MCA	2
Any other comments			
Support for inclusion	14		
Barriers to inclusion	14		
Exclusion of AwICC	6		
Personal experience of relative who lacks capacity	5		
Importance of training, research experience and appropriate support	2		
Multifaceted methods of communication	1		
Current guidance is clear	1		

13

14