The Institute for Ageing and Health
Newcastle University

The Newcastle

Study

Guidance To Assessing General Understanding and Capacity with Consent Checklist

Participant Name_____

Opening Question: Guidance To Assessing General Understanding and Capacity

- **This should be done prior to signing the consent form.**
- **The person must be able to hear the statements and questions.**
- **Check that the person has read the information leaflet.**
- **Identify that they can ask questions at any time.**

'I know that you have read the information leaflet, but one of the things we need to check is that people understand the study and what it will involve for them if they choose to take part. So if I can read you a small section of the information leaflet and then check your understanding of it. Is that all right?

Q1.

"We are asking you to take part in a research study to investigate the health and needs of older people and find out why some people stay healthy and independent whilst others are not doing so well. If you take part I would ask you questions about your life and to carry out some medical tests with you." (explain tests)

'Are you happy to do this?'

- **Yes**……go to Q2 ☐
- **No**……..'Is there anything I can explain that might make you willing to take part, or any questions I can answer?' If refusal is adamant: end interview. ☐ If explanations can be given (without compulsion) and the person agrees to take part, proceed to Q2.

Q2.

'So, in a few words, can you tell me what the study is about?'

- If answer implies or includes: Investigate health of older people to find out why some people stay healthy and independent whilst others are not doing so well. Go to Q3. ☐

- If answer is muddled or confused on <u>first 'pass'</u>, return to Q1.
  If answer is muddled or confused on <u>second 'pass'</u>, return to Q1.
  If answer is muddled or confused on <u>third 'pass'</u>, discuss with relative/main carer to decide if the interview should continue. Given that the person at this stage has said "yes" (Q1), if the relative/carer and interviewer feel it appropriate to continue, and presuming there is no resistance to continuing, a decision could be made at this stage that the person seems to be consenting to their level of understanding and the relative/main carer could then be asked for consultee approval. Ensure that details are documented. The rest of the questions below could still be asked to check further understanding or any overt objections. ☐

Q3.

'From what I said earlier, can you tell me what would happen to you if you agreed to take part in this study?'

- If answer implies or includes: An interview or questionnaire and medical test go to **. ☐

- If answer is incorrect go to **Q4.**

Q4.

'Just to remind you, I said we would need to ask you questions about your life and to carry out some medical tests. Are you still happy to take part in the study?'

- **Yes**……go to Q5. ☐

- **No**……..'Is there anything I can explain that might make you willing to take part, or any questions I can answer?' If refusal is adamant: end interview. ☐ If explanations can be given (without compulsion) and the person agrees to take part, proceed to Q5.

Q5. **'So, can you tell me what would happen to you if you agreed to take part in this study?'**

- If answer implies or includes: An interview or questionnaire and medical test go to **. ☐
- If answer is muddled or confused on <u>first 'pass'</u>, return to Q4.
  If answer is muddled or confused on <u>second 'pass'</u>, return to Q4.
- If answer is muddled or confused on <u>third 'pass'</u>, discuss with relative/main carer to decide if the interview should continue. Given that the person at this stage has said "yes" (Q1), if the relative/carer and interviewer feel it appropriate to continue, and presuming there is no resistance to continuing, a decision could be made at this stage that the person seems to be consenting to their level of understanding and the relative/main carer could then be asked for consultee approval. Ensure that details are documented. The rest of ** below still applies. ☐

******The interviewer should continue to check that the participant is willing to take part throughout all of the interviews, checking that he or she is comfortable and offering to pause or stop if the person seems distressed. The reason and description of all tests should be explained again before completion. No test should be taken unless the person agrees freely for example after explaining about the blood sample the person freely offers his or her arm.

Comments_____

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CONSENT CHECKLIST FOR INVESTIGATORS

1. Has the consent protocol been adhered to?		Yes – No
2. Has the participant/relative/carer/consultee read the 'Participant Information Booklet' (Circle all who apply).		Part: Yes – No – N/A Rel: Yes – No – N/A Car: Yes – No – N/A Cons: Yes – No – N/A
3. Have you given an oral explanation to the participant/representative, including:		
	▪ this is a research study?	Yes – No
	▪ participation is voluntary?	Yes – No
	▪ the aims of the study?	Yes – No
	▪ the likely duration of the participant's involvement?	Yes – No
	▪ the legal requirement of a consultee should the participant lose/lack capacity during the course of the research?	Yes – No
	▪ If the participant has lost capacity have you requested approval for continued use of data	
	▪ the expected benefits to the participant and/or others?	Yes – No
	▪ what risks, inconvenience, discomfort or distress may reasonably be anticipated for this participant?	Yes – No
	▪ that a refusal to participate or withdrawal from the whole or part of the study may be given without reasons and will not affect the usual care?	Yes – No
	▪ that personal information will be treated as strictly confidential only available to ▪ the research team?	Yes – No
	▪ whom to contact and how?	Yes – No
	▪ for permission to inform the GP of important health findings?	Yes – No
4. If you have answered NO or not answered any of the above Questions record why:…… ……		
5. Have you allowed the participant/representative sufficient time to consider the matter, discuss with others if wished, and ask you any questions?		Yes – No
6. In your opinion, has the participant/consultee understood and given informed consent/ approval to this study?		Yes – No
8. Has the participant/consultee signed and dated the consent/ approval form?		Yes – No
9. Has the participant/consultee received a photocopy of this form?		Yes – No

Investigator name:…… Designation:…….
Signature:…… Date:…….