

CLINICAL TRIALS AND RESEARCH

The Consumer's View

Reasons for participating

- Altruism - even if they don't benefit personally
- Access to currently unavailable treatments
- To please professionals or family
- The process is interesting or socially enjoyable

QUESTIONS TO ASK

- What is the purpose of the research?
- What does the research involve for the person with dementia, and will they benefit from participating?
- Will other people in the person's life (such as a carer) be involved – and if so, how?
- How will confidentiality be maintained?

QUESTIONS TO ASK

- Where will the research take place, with how many sessions and over what period of time?
- Who will have access to the data (such as questionnaires or interview transcripts), and will this information be destroyed once the research is complete?
- Will any necessary transport be arranged and paid for?
- Are there plans to tell people about the results of the research – and if so, how and when?

QUESTIONS TO ASK

- Is the research likely to cause any discomfort or distress?
- If the research involves treatment, what are the risks and likely side-effects?
- If the research involves treatment that appears to benefit the person with dementia, can they continue with the treatment once the research is completed?
- How can complaints be dealt with?

Consent

- Individuals with the capacity to make decisions as to whether or not to be involved in research may be involved only if they give consent.
- The ability of people with dementia to make decisions as to whether or not to participate in research should not be under-estimated.
- A person's capacity may fluctuate and may be able to make decisions if approached at the right time and in the right way.

WHEN THE PERSON DOES NOT HAVE CAPACITY

Under the **Mental Capacity Act 2005** research carried out on, or in relation to, a person lacking capacity can be lawfully carried out if an 'appropriate body' agrees that the following conditions are met

- The research must be safe.
- The research must relate to a condition that the person has.
- There must be reasonable grounds to believe that the research could not be carried out successfully if it were confined to individuals who had the capacity to consent.

WHEN THE PERSON DOES NOT HAVE CAPACITY

(Mental Capacity Act 2005)

- The research must produce a benefit to the person taking part that outweighs the risk or burden. or, if the research is to develop scientific knowledge, the risk to must be likely to be negligible, and the research must be carried out in a way that will not be intrusive or interfere with the person's privacy.
- Carers or nominated third parties must be consulted, and agree that the person would want to join a research project. If it appears that the person would not wish to be involved, then they must be withdrawn immediately unless withdrawing would provide a significant risk to that person's health.

WHEN THE PERSON DOES NOT HAVE CAPACITY

Clinical Trials Regulations

specify that there must be grounds to expect that administering a product to a person who lacks capacity will produce a benefit to the person that “outweighs” the risks, or will result in no risk at all.

www.alzheimers.org.uk

Factsheets

460 [Mental Capacity Act 2005](#)

409 [Volunteering for research into dementia](#)

www.nuffieldbioethics.org

Consultation paper on ethical issues in dementia
(to be published mid 2009)