

RETROSPECTIVE CONSULTEE COVER LETTER

Study Title: Mouth cAre to Prevent Pneumonia in older people Study (MAPPS): a feasibility study

Study Sponsor: South Tees Hospitals NHS Foundation Trust

Chief Investigator: Dr Vicky Ewan, Consultant in Older Person's Medicine, South Tees Hospitals NHS Foundation Trusts

What is a consultee?

The Mental Capacity Act 2005 is a system to protect the rights of people who are not able to make decisions for themselves. The Act also includes safeguards for the conduct of research involving people who may not be able to consent due to a medical problem, for example because of learning disabilities, illnesses such as dementia, head injuries or mental health problems.

In particular, the Act requires that before a person who is unable to consent to be involved in a study, another suitable person must be identified who can act on their behalf as a consultee. This consultee can then advise the research team on whether the person who lacks capacity would want to be involved in the project.

Why have I been approached to act as a consultee?

You have been approached as the patient has been taking part in this study already

- Either by providing consent themselves
- or
- A nominated consultee who's part of the treating team has provided the approval on the patient's behalf.

We are now approaching you regarding their continued participation in this study either

- To act as a personal consultee on the patient's behalf. A nominated consultee initially provided approval in your absence as the patient lacked capacity to consent into the research
- or
- To act as a personal or nominated consultee. The patient previously provided consent to participate in the study however has now subsequently lost capacity.

A personal consultee may be someone who has a personal relationship with the patient but is not involved in their welfare in a professional capacity, research or for financial benefit. Examples of suitable people who might act as a personal consultee are:

- a family member, carer or friend
- a court appointed deputy who has a personal relationship with the participant

In instances when 'reasonable steps' have been made to identify a personal consultee and a personal consultee is unavailable then the researcher must nominate a person to act as a consultee. This person may be involved in patients care in a professional capacity but they must have no connection with the research project. A suitable person who might act as a nominated consultee is a:

- General practitioner or other doctor

What are the duties of a consultee?

The main responsibility of a consultee in this instance is to advise the research team whether or not the patient would be happy to continue taking part in the study. When making the decision, please consider any views the patient may have expressed previously, for example their original consent. You are not being asked to give consent on behalf of the patient; however, if you advise us that the patient would not want to continue to be part of the study then we will abide by this. We may also ask a personal consultee to complete some short questionnaires on behalf of the patient if you agree.

In order to help you make the decision about acting as a consultee and advise the research team about the patient's wishes please see attached prospective participant information sheet describing what is involved in the study. This information is the same as that given to patients who are able to make this decision for themselves.