

7.1.2019, version 2, Next of kin

Clinical Trial unique protocol ID 2017/12883-1

Invitation to participate in the research project

“Nutrition and Medication” part I

This is an invitation where we ask if you may be willing consent that your next of kin can be a participant in a research project concerning nutritional status and medication use among elderly persons receiving home nurse services. The aim of the project is to gain more knowledge about undernutrition in the elderly and the relationship between medication use and nutritional status. This is a part of a Ph.D.-project which will be done in collaboration with the Health Care Service in your municipality.

What does participation in the project imply for you?

If you accept participation, a qualified nurse or another health care worker from the Home Nurse Service will visit your next of kin at home. She/he will record data related to eating habits, appetite, possible weight loss, illnesses/diseases, and other factors that may possibly influence intake of food. The participant will also be asked about civil status and if living alone or not. The height and weight will be measured, and a photo of participant's medicines card will be taken. On that picture, also name and date of birth will be included.

Possible benefits and risks by participation

Participation in this project does not imply any risks. When visiting the participant at home, we will use approximately 15-20 minutes for collecting the health data mentioned above.

Voluntary participation and the possibility to withdraw consent

Participation in the project is voluntary. If you accept that your next of kin can participate, you will need to sign the declaration of consent (on the last page in this letter). At any time and without need for giving reason, you are free to withdraw your consent. This will not have any consequences for future provision of health care to the participant. If you decide to withdraw participation in the project, you are also free to demand that participant's data file in this project can be deleted, unless if anonymized data have already been analysed or used in scientific publications.

If you at a later point, wish to withdraw your consent or have any questions regarding the project, you can contact Ph.D.- candidate and nursing home physician Mari Fiske, University of Oslo, mari.fiske@medisin.uio.no, telephone 926 67 311.



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What will happen to recorded personal data concerning health?

Any personal data concerning health that has been recorded in this project, will only be used as described in the purpose of the project. You have the right to access the information that has been recorded about your next of kin and the right to see that any error(s) in the recorded data is/are corrected. You also have the right to know which security measures that have been/will be taken for processing personal data.

All information will be processed and used without participants' names or personal identification numbers, or any other information that is directly identifiable to the person. Linkage between the person and data concerning health will only be possible via a separate identifier list. Only the researchers, professors Jørund Straand and Anne Moen, and Ph.D. - candidate and nursing home physician Mari Fiske will have access to the list.

Follow- up project

The research project “Nutrition and Medication” consist of two parts. In the first part we will just describe the nutritional status among the participants living in two municipalities. Some of the participants in this first part of the project will later be asked for participation in part II.

Finance

The project is funded of The Norwegian Research Fund for General Practice and the County Governor in Buskerud, Norway.

Approval

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project. Reference number 2018/1045.

In accordance with the General Data Protection Regulation the University of Oslo, project manager professor Jørund Straand is independently responsible for ensuring that the processing of personal health data has a legal foundation. This project has a legal foundation in accordance with the EUs General Data Protection Regulation, article 6 no. 1a, Article 9 no. 2a and with your consent.

You also have a right to submit a complaint on the processing of personal health data to the Norwegian Data Inspectorate.

Contact information

If you have any questions regarding the research project, you can get in touch with Mari Fiske, University of Oslo, mari.fiske@medisin.uio.no, telephone 926 67 311
Jørund Straand, University of Oslo, jorund.staand@medisin.uio.no, telephone: 928 52 23
Anne Moen, University of Oslo, anne.moen@medisin.uio.no

I consent to participating in the research project and that my personal data concerning health can be used as described above

City/Town and date

Participant's Signature

Participant's Name (in BLOCK LETTERS)

I confirm that I have given information about the research project

City/Town and date

Signature

Role in the research project