



# Right of Long-Term Care Residents/Tenants to Participate in Research Studies



Long-term care facilities (LTCFs) and assisted living programs (ALPs) are sometimes approached by researchers and other interested parties with requests to recruit residents and tenants as research study participants.

While these opportunities can be useful in representing the views of these populations, LTCFs and ALPs must be mindful of potential ethical and practical issues associated with involving residents/tenants as research subjects.

If you have concerns about the rights of Iowa's long-term care residents and assisted living program tenants as research study participants, please call the Office of the State Long-Term Care Ombudsman at 866.236.1430.

Depending on the situation and where the resident/tenant lives, you may be connected with the Local Long-Term Care Ombudsman who monitors programs and homes in that region of Iowa, or you may be referred to another staff member who can assist you with understanding the right of residents/tenants to participate in research studies.

The Office of the State Long-Term Care Ombudsman supports the right of long-term care residents/tenants to voluntarily participate in research studies that demonstrate proper guidance and measures for ensuring an appropriate level of advanced, informed consent from participants.

## GUIDELINES FOR PARTICIPATION

Consideration of the following guidelines is recommended for safeguarding the health and welfare of residents and tenants as research subjects:

- Does the researcher have documented permissions from a governing university or an oversight agency that explain the purpose of the study and provide contact information should participants have questions about the research or their rights?
- Is a full description of the study presented that includes the responsibilities of the researcher; the role and expectations of the research subject; the length of participation; and the option to end participation at any time throughout the process?
- Can the researcher present all materially relevant facts about the study to potential research subjects in a manner that is clearly written and in an appropriate format for those with various impairments (e.g., hearing, visual)?
- Can the researcher explain the comparative benefits and harms that may arise from study participation, as well as steps taken to minimize these risks, and discuss them with residents or tenants?
- Does the research interfere with resident's or tenant's right to be treated with consideration, respect and full recognition of personal dignity and autonomy, or their right to be free from mental and physical abuse?
- How will the research subjects' privacy and confidentiality be ensured?
- Does the study address research subjects' capacity to consent? (When a resident's or tenant's capacity to consent to participation in a study is in question, the OSLTCO recommends involving a family member, guardian or physician to assist in making this decision.)
- Does the study indicate if/how the role of the resident or tenant might change or end if he/she were to experience diminished capacity during the study period?
- Will residents' and tenants' consent be obtained only once prior to participation, or will their role continue to be clarified in a frequent and ongoing process throughout the study?
- Does the LTCF or ALP have a policy that addresses resident/tenant participation in research studies and has it been shared with residents, staff, family members and other relevant parties?