

Department: UAMS Institutional Review Board
Policy Number: 17.4
Section: Special Populations
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SUBJECT: Subjects in Long Term Care

Aside from the regulatory requirement that IRBs provide additional protections for especially vulnerable persons, there are no specific regulations governing research with elderly subjects. The elderly are, as a group, heterogeneous and not usually in need of special protections, except in two circumstances: cognitive impairment and institutionalization. Under those conditions, the same considerations are applicable as with any other, non-elderly subject in the same circumstances. See IRB policy 17.2 for discussion of cognitive impairment.

Institutionalization: In the past, persons in nursing homes or other institutions have been selected as subjects because of their easy accessibility. However, conditions in institutional settings increase the chances for coercion and undue influence because of the lack of freedom inherent in such situations. Research in these settings should therefore be avoided, unless the involvement of the institutional population is necessary to the conduct of the research (*e.g.*, the disease or condition is endemic to the institutional setting, persons who suffer from the disease or condition reside primarily in institutions, or the study focuses on the institutional setting itself).

IRB Considerations: When a research study is undertaken at a nursing home, all necessary parties are informed and all documentation is maintained in a manner that meets all local, state, and federal research requirements.

1. The researcher must provide evidence that permission has been obtained from the nursing home administrator and medical director. In a chain of nursing homes, permission could be obtained from a regional or national administrator and medical director, but contact and approval should still take place at the local level with both the local nursing home administrator and local medical director.
2. If the study involves the engagement of the nursing home staff in the research, then the nursing home must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections. The nursing home will need to identify the IRB that will serve as its IRB of record. UAMS may only be named the IRB of record with the approval of the Vice Chancellor for Research and an IRB authorization agreement with UAMS. If the study does not involve the engagement of the nursing home staff in the research, an FWA is not necessary and the nursing home management can decide how it will review the researcher's protocol for appropriateness.
3. The protocol should include documentation of how consent to participate in the study will be obtained. This description should state that if the resident is not competent to provide informed consent that the consent and assent requirements described in IRB Policy 17.2 will apply. The procedures used to obtain consent and assent should be detailed in the protocol. Finally, the procedure to be used to obtain consent to review nursing home records from resident/LAR should be described.