

**Department:** UAMS Institutional Review Board  
**Policy Number:** 17.4  
**Section:** Special Populations  
**Effective Date:** July 31, 2002  
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**SUBJECT: Subjects in Long Term Care**

**POLICY**

No specific regulations govern research involving subjects in long-term care facilities, such as nursing homes. Individuals in long-term care are a heterogeneous group and may not require special protections, except in two circumstances: (1) when they have diminished functional capacity, and (2) when the mere fact of being in such an institution may unduly influence their decision to participate in research. See IRB Policy 17.2 for a discussion of research involving persons with diminished functional capacity.

Historically, individuals in long-term care or other institutional settings have been selected as research subjects due to their easy accessibility. However, conditions in institutional settings increase the risk of coercion and undue influence because of the inherent lack of freedom. Research must not be conducted in these settings solely for the convenience of access to potential participants. Research targeting an institutionalized population should only be conducted when such a setting is essential to the research—for example, if the disease or condition is endemic to the institution, if individuals with the condition primarily reside in institutions, or if the study focuses on the institutional setting itself.

Individuals in long-term care facilities must not be excluded from research that may offer potential benefits to them solely because of their living situation.

**PROCEDURE**

- A. When a research study is to take place in a nursing home or a similar setting, the researcher and the IRB must ensure the following steps are taken:
1. All involved parties are informed of the research, and all documentation is maintained in a manner that meets all local, state, and federal requirements related to research.
  2. The institution in which the research is being conducted may have additional requirements for documentation or for other aspects of the research. The investigator shall work with the institution to ensure these requirements are met.
  3. The researcher must provide evidence that permission has been obtained from the nursing home/institution administrator and medical director. When the institution is part of a chain, 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 administrator and local medical director. This evidence should be included in the IRB e-system submission.
  4. If the institution's involvement constitutes engagement in the research AND the study is federally funded, supported, or conducted, the nursing home/institution must be covered by a Federalwide Assurance (FWA). The nursing home/institution may either obtain its own FWA from the Office for Human Research Protections or enter into an unaffiliated investigator agreement extending another institution's FWA to the nursing home/institution.
  5. The submission shall fully describe the informed consent process and include any supporting documentation. The consent process should address any issues that may arise if potential participants' functional capacity is in question or may fluctuate during participation, as described in IRB Policy 17.2.

**REFERENCES**

AAHRPP Element II.4.A, III.1.C  
OHRP Guidance on Engagement