Department: **UAMS Institutional Review Board**
Policy Number: **17.4**
Section: **Special Populations**
Effective Date: **July 31, 2002**
Revision Date: **October 10, 2002; June 24, 2004; February 8, 2005; January 24, 2011; February 15, 2016; July 16, 2020**

SUBJECT: Subjects in Long Term Care

POLICY
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: diminished functional capacity, 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 researchs involving persons with diminished functional capacity.

Historically, 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).

PROCEDURE
A. When a research study is to take place 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 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. This evidence should be included in the IRB e-system submission.

4. 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 Innovation 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.

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