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; August 15, 2022

SUBJECT: Subjects in Long Term Care

POLICY
No regulations specifically govern research involving subjects in long-term care facilities, such as nursing homes. People in long term care are, as a group, heterogeneous and may not need of special protections, except in two circumstances: diminished functional capacity, and when the mere fact of being in such an institution may unduly influence the decision of whether or not to participate in research. See IRB policy 17.2 for discussion of research involving persons with diminished functional capacity.

Historically, persons in long term care or in other institutional settings 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 may not be done in those settings solely because of easy access to potential participants. Research targeting an institutionalized population should only be if this condition 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. Individuals in long-term care settings shall not be excluded from research that may potentially yield some benefit to them solely because of their living situation.

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/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