Department: **UAMS Institutional Review Board**
Policy Number: **17.4**
Section: **Special Populations**
Effective Date: **July 31, 2002**
Revision Date: **June 24, 2004**

SUBJECT: Subjects in Long Term Care

Aside from the regulatory requirement that IRBs provide additional protections for specially 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 (Cognitvely Impaired Persons) 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 needs to 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 significant participation of nursing home research staff, then the nursing home must file a Facility Wide Assurance (FWA) with the Federal Office of Human Research Protections and either create its own Institutional Review Board, or appoint the UAMS IRB to act on its behalf. If the study does not involve the significant participation of nursing home research staff, an FWA is not necessary and it is up to the nursing home's discretion how they 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 consent will be obtained from the responsible party, but that assent will be obtained from the resident. The procedures used to obtain consent and assent should be detailed in the protocol. Finally, the procedure to be used to obtaining consent to review nursing home records from resident/responsible party AND from physician should be described.

4. The IRB will define the need for non-affiliated investigator agreements and inter-institution agreements as needed.