**Section 280.3000 Research or Experimental Programs**

Each hospice shall have a written policy concerning initiating and participating in research studies or experimental programs. Studies conducted only for the hospice quality assurance/performance improvement program are not considered to be research or experimental programs prior to initiation. The policy shall require that the Director approve any research study or experimental program.

a) Hospice policies regarding research studies or experimental programs initiated by the hospice shall include the following:

1) The establishment of appropriate written policies and procedures for all participants, including staff and patients affected.

2) Requirements for written informed consent signed by each subject or patient representative or legal guardian.

3) Procedures for full disclosure to subjects, including disclosures of conventional and experimental procedures, risk and/or potential discomfort, purposes or potential benefits, and alternative procedures.

4) A statement that subjects shall be permitted to withdraw consent and to discontinue participation at any time and for any reason.

5) A statement that subjects shall not be made, or requested, to waive any of their legal rights.

6) A statement that confidentiality shall be maintained regarding identity and clinical records of all participants.

7) A statement that control groups in treatment modalities shall be considered as participants in research and experimentation.

8) The establishment of an interdisciplinary research committee or human rights committee that is composed of both program staff members and persons who are not staff members. This committee shall include hospice patients or their representatives, or family members of former hospice patients, and persons from outside the facility, such as doctors, nurses, lawyers, parents, friends and advocates. All deliberations and decisions of the committee shall be documented.

9) A written review procedure for approval by the Institutional Review Board of the sponsoring organization or approval of the hospice Interdisciplinary Review Committee established by the hospice program to assure compliance with the policy for protection of human subjects of the U.S. Department of Health and Human Services (42 CFR 2.52 (2004)).

b) The Director will base approval of research studies or experimental programs upon compliance with the requirements of subsection (a).

(Source: Amended at 32 Ill. Reg. 2330, effective January 23, 2008)