

[REDACTED]

This Replaces

SUBJECT: Ethics Committee and  
Institutional Review Board

File: [REDACTED]

Date: 04-04

2/00

HEADING: 100. PATIENT POLICIES

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PERTAINS TO: All Departments

PREPARED BY: Patient Rights

**PURPOSE:** To provide a mechanism for discussion and resolution of ethical dilemmas which may arise regarding the provision of health care or within the healthcare setting.

**POLICY:** It is the policy of [REDACTED] to provide care that follows Federal and State Laws and current standards of medicine. However, patients, their spokespersons, physicians, nurses and other providers may encounter ethical dilemmas regarding treatment decisions or other aspects of patient care. The [REDACTED] Ethics Committee is a standing committee of the organization that is entrusted with the responsibility for considering these matters, as well as ethical dilemmas that may involve the business practices of the organization or the organization's relationship to other entities.

**DEFINITIONS:**

**Ethics Committee:** As set forth in the By-Laws of [REDACTED], the Ethics Committee will consist of at least nine members, including the following:

Senior Vice President for Medical Affairs

Chief Nursing Officer

Chaplain

Legal Counsel

One Member of [REDACTED] Board

One Member of [REDACTED] Board

2 Members of the active medical staff

Representative of Continuing Care Services

One Community Member-at-large (with no affiliation to [REDACTED])

"The Ethics Committee shall be responsible to identify and make recommendations to the Board of Trustees, Administration, and members of the Medical Staff regarding matters relating to termination/withholding of treatment, informed consent, surrogate decision-making, powers of attorney for health care, and other medical-moral issues, including the making of recommendations concerning policies and procedures and providing guidance to members of the Medical Staff as to specific patients. The Committee shall also perform the functions of an Institutional Review Board as defined in regulations of the U.S. Food and Drug Administration." ([REDACTED] By-Laws2003)

**Ethical issue or dilemma:** A situation where it is not clear what is the ethically sound action or course of action or when people disagree about what the course of action should be.

[REDACTED]

ADMINISTRATIVE POLICY

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**Institutional Review Board:** A board empowered to evaluate all proposed clinical trials or patient studies and assure that participation is voluntary and that the rights and welfare of human subjects of research are protected.

**Procedure for Ethics Consultation:**

Any person (associate, nurse, administrator, physician, patient, family member, or other) may request an ethics consultation by the following mechanisms: Contacting the Chaplain, or Vice President of Medical Affairs, or the Nursing Supervisor (who will contact an available member of the Ethics Committee).

An initial assessment of the situation will be made to clarify the issue(s), to identify the complexity of the situation, and to identify the persons or resources involved in resolution. Consultations typically fall into three levels:

- 1: Consultations that are simple and are resolved by answering questions (usually clarification or education regarding policy or law).
- 2: Consultations that require ongoing dialogue between the person(s) who placed the consultation and the ethics consultant, but do not require direct contact with other parties.
- 3: Consultations that may involve direct contact between the ethics consultant, other members of the ethics committee, and/or involved parties.

Assessments will include exploration of any or all of the following: medical indications, patient preferences, quality of life, and contextual features of the situation.

Following this initial assessment, all efforts will be made to resolve the situation as efficiently as possible. Documentation of the salient issues and resolution will be made in the clinical record.

If resolution is not possible, additional members of the Ethics Committee will be consulted, meet with the persons involved and make recommendations regarding resolution. Documentation will be maintained in meeting minutes, retained in the files of the Committee, and placed in the clinical record (if appropriate). Any recommendations will be conveyed to involved persons by personal contact and/or letter.

[REDACTED]

ADMINISTRATIVE POLICY

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**Procedure for Institutional Review:**

All proposed research studies will be submitted to the Ethics Committee/IRB prior to initiation of the research or enrollment of any patients. This includes prospective trials, retrospective analyses of data, or research conducted in collaboration with other institutions. (Exceptions to this procedure are oncology trials conducted through the Toledo Community Hospital Oncology Program.)

The proposal submission will be made using the form *Request for Approval of Research* and following the instructions indicated in this document. A blank form may be found on the CORE and submission will be made to the chair of the Committee by paper copy and including all required signatures.

Trials, data collection or patient enrollment will not begin until the IRB has reviewed and approved the proposal. This approval will be documented in Committee meeting minutes and a final copy of the proposal maintained in the Committee files.

The [REDACTED] Primary Investigator will notify the Committee if the research is terminated for any reason or when the study is concluded.

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President