Chapter 2 Exercise Solutions

2-1
Ethics refers to a certain part of study, whereas morality refers to the distinctive object of study. The morality of a person, nation, culture, etc. consists of a body of moral judgments, which are based on moral standards. Examples of moral judgments in a medical area are as follows:

- Active euthanasia is wrong.
- Humans should not be involved in experiments without their consent.
- Information contrived in medical records should be held in confidence between patient and physician.

Ethics would involve a study of each of these issues resulting in a list of pros and cons for consideration by the person, nation, culture, etc. Ethics is concerned chiefly with determining which moral judgments are valued in various circumstances.

2-2
Beneficence and Non Maleficence are two moral norms that have remained constant (see page 44 for details).

2-3
Controversial moral judgments include the following examples:

- Individuals should have the sole authority to accept or reject medical treatment.
- Patients needing dialysis should have full access to their treatment.
- Brain death is the criteria for the end of human life.

2-4
The end justifies the means.

2-5
Respect the patient's rights.

2-6
A code of ethics for Clinical Engineers provides guidance in making specific judgments related to the care of patients and the integration of medical devices used in that process.

2-7
Brainstem death, defined as total and irreparable loss of brain function, is when an individual is legally indistinguishable from a corpse and so may be legally treated as one. Therefore, mechanical sustenance of a person in a state of brainstem death is merely postponement of the inevitable. Neocortical death is defined as a present vegetative state. In this case, although severe damage to the brain has occurred, there is sufficient brain function to make mechanical sustenance of respiration and circulation unnecessary.

2-8
For brain death to occur the EEG must be a flat line. It is critical that each hospital develop the appropriate guidelines for these cases.

2-9
The distinction between active euthanasia and passive euthanasia rests on the difference between helping a person die and letting a person die. Involuntary euthanasia is distinguished by acts that hasten an individual's death for his or her own good, but against their wishes. Voluntary euthanasia, on the other hand, requires that substantial evidence of prior consent or patient willingness exists.

2-10
ABSOLUTRLY NOT .This decision is a personal one and should only be initiated and signed by the individual patient.

2-11
It should be honored. In the presence of a living will, there need not be any further discussion.

2-12
Human experimentation occurs when the overall aim of the treatment is to acquire new knowledge that will be useful to medical science. It is permissible only if an informed consent is attached.

2-13
The use of animal experimentation is solely dependent on the question / hypothesis being asked (see page 55). Animal research should be conducted only if it leads to new knowledge that would benefit society as a whole (see page 38).

2-14
Risk/Benefit is a critical tradeoff. All treatment should follow low risk/high benefit principles.

2-15
The place to begin is with the health care professionals in charge of the care for their patient.

2-16
The steps include the following:

1. Proof of concept
2. Prototype development
3. Small Scale test to prove feasibility
4. Larger study to determine statistical accuracy
5. Refinement as a clinical device
6. FDA approval
7. Clinical use

2-17
Practice – devices accepted and approved by the FDA for clinical use.
Research – exploratory efforts to develop a new medical device (see Section 2.8.2).
Non-validated practice – patients volunteer to partake in a novel use of a medical device (see section 2.8.3).

2-18
(see Section 2.8.1)

2-19
Informed Consent provides the opportunity for self determination (see Section 2.8.1). The patient must receive full disclosure of all information.

2-20
A feasibility study would take place in a single institution, involve no more than ten patients, and be limited to investigation of new uses or modifications of either existing devices or temporary and permanent implants.

Emergency use, on the other hand, is the use of a device to save the life of a patient under circumstances where no alternative is available.

2-21
Student View.