# AMA *Code of Medical Ethics*

### *7.3.2 Research on Emergency Medical Interventions*

Emergency medicine often applies standard interventions that have not been scientifically evaluated for safety and effectiveness in the context of emergency care and may render unsatisfactory outcomes. However, in life-threatening situations, patients may not be able to give informed consent and a surrogate decision maker may not be readily available, making it challenging to carry out ethically sound research. Soliciting input from the community before a research protocol is approved can help address some concerns, but not all.

Given the insufficiency of standard treatment alternatives, it can be appropriate, in certain situations and with special safeguards, to provide experimental treatment without a participant's informed consent.

To protect the rights and welfare of participants in research on emergency medical interventions, physician-researchers must adhere to the following criteria:

(a) The experimental intervention has a realistic probability of providing benefit equal to or greater than standard care.

(b) The risks associated with the research are reasonable in light of the critical nature of the medical condition and the risks associated with standard treatment.

(c) Study participants are randomized fairly.

(d) The trial is overseen by an independent data and safety monitoring board.

(e) The prospective participant lacks the capacity to give informed consent at the time he or she must be enrolled due to the emergency situation and requirements of the research protocol and it would not have been feasible to obtain prospective informed consent because the life-threatening emergency situation could not have been anticipated.

(f) The window of opportunity to administer the experimental intervention is so narrow as to make it unfeasible to obtain consent from the prospective participant's surrogate or other legally authorized representative.

(g) Participants, or their representatives, are informed as soon as possible that the individual has been enrolled in the research and asked to give consent to further participation.

(h) The representative of a patient who dies while participating in the research must be informed that the individual was involved in an experimental protocol.

(i) Study results will be publicly disclosed.

***AMA Principles of Medical Ethics: I,V***