Department: **UAMS Institutional Review Board**
Policy Number: **15.2**
Section: **Consent**
Effective Date: **July 31, 2002**
Revision Date: **August 24, 2004**

Subject: Consent Exceptions: **Emergency Use of a Test Article**

The obtaining of informed consent shall be deemed feasible unless, before use of the test article, both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following (21 CFR 50.23):

1. The human subject is confronted by a life-threatening situation necessitating the use of the test article

2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject

3. Time is not sufficient to obtain consent from the subject's legal representative

4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject

The Principal Investigator (PI) should obtain consent from a legally authorized representative (LAR), if possible.

If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent physician's determination that the four conditions above apply, the physician should make the determination and in within 5 working days after the use of the article, have the determination reviewed and evaluated in writing who is not participating in the clinical investigations. .The documentation required shall be submitted to the IRB within 5 working days after the use of the test article. (21 CFR 50.23(c).

Data From emergency use of a test article should not be used as research.

More information regarding Emergency Use of Test Articles and Emergency Research can be found in Section 18.