Department: UAMS Human Research Advisory Committee
Policy Number: 15.2
Section: Consent
Effective Date: July 31, 2002
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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 (46CFR 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 available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject

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 determination in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

The documentation required shall be submitted to the IRB within 5 working days after the use of the test article.