Emergency Use of a drug or device

Overview
The FDA defines "emergency use" as the use of a test article (an unapproved drug, device, or biological product) on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21CFR 56.102 (d)]. The FDA regulates use of all investigational drugs and devices, including emergency use. The IRB must be notified of all emergency use, even though it is not considered research.

Any subsequent use of the test article is subject to IRB review and approval. Only one emergency use of the test article is permitted at a given institution and any subsequent use needs to have an IRB approved protocol in place for the use. However, FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

Submission Requirements
Effective July 2016, any request for use of an unapproved test article for the treatment and care of a patient in a life-threatening situation at Banner-University Medicine requires IRB oversight from Banner Health IRB.

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