Emergency research is a planned clinical investigation of an intervention that may have direct benefit to human subjects in a life-threatening situation for which available treatments are either unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of the intervention under study.

Emergency research is a special category of human subject research, because there is a high likelihood that the subjects may not be able to provide informed consent due to the nature of the emergency, i.e., they may not be conscious, they may be conscious but in a state of shock, or there is insufficient time for thoughtful consideration of potential risks and benefits. Further, there is a high likelihood that a legally authorized representative is not available to provide consent for subjects who are not able to consent for themselves.

The regulations governing the release from a requirement for informed consent for human subject research appear to conflict. The Common Rule permits a waiver of informed consent only if the research is minimal risk. The U.S Food and Drug Administration (FDA) regulations permit an exception from the requirement of informed consent for emergency research if the intervention may benefit the subject and there is community consultation and disclosure, i.e., in essence the community “consents”. There is no FDA requirement for minimal risk for this exception.

Michigan State University does not permit emergency research involving human subjects unless informed consent is obtained from the subject or the legally authorized representative. This does not restrict the emergency use of investigational drugs or devices as described in the Human Research Protection Program Manual 7-3, “Emergency Use of Investigational Drugs and Devices.”

Excerpt from the Federal Regulations
The Common Rule, which governs human subject research supported by a federal department or agency, e.g., the Department of Health and Human Services, permits an IRB to “waive the requirement to obtain informed consent” only if several criteria are met, including:
“The research involves no more than minimal risk to the subjects” 45 CFR 46.116(d)(1)

The FDA regulations, which govern human subject clinical investigations of a test article that is subject to FDA, e.g., medical drugs and devices, foods or supplements that have a nutrient or health claim, permit an IRB to approve an “exception from informed consent requirements for emergency research” (as defined above) only if several criteria are met and the IRB, in consultation with a licensed, unaffiliated physician, finds and documents that specific criteria are met including, but not limited to, the following:

“Participation in the research holds out the prospect of direct benefit to the subjects...” 21 CFR 50.24(a)(3)

“Additional protections of the rights and welfare of the subjects will be provided, including, at least:

Consultation ... with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;” 21 CFR 20.24(a)(7)(i)

“Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;” 21 CFR 20.24(a)(7)(ii)

“Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;” 21 CFR 50.24(a)(7)(iii)