

SPARROW HEALTH SYSTEM
INSTITUTIONAL RESEARCH REVIEW COMMITTEE

POLICY: EMERGENCY USE

Emergency use of an investigational product, drug or procedure may be granted by the Chairperson of the Institutional Research Review Committee (the "Committee") and may be considered exempt from Committee review. A researcher may request exempt status for emergency use if the investigational product, drug or procedure meets the following guidelines from the Code of Federal Regulations ("CFR").

According to Federal regulations (21 CFR § 56.102.d and .l), the terms "Emergency Use" and "Test Article" are defined as:

Emergency use means the use of a test article 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.

Test article means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.

Furthermore, the CFR definition (21 CFR § 56.104.c) allowing for exemption from IRB (i.e. Committee) requirements is as follows:

Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review. ("Emergency use" is to be interpreted as the initial treatment course. "Subsequent use" means any use of the test article that occurs after its initial emergency use.)

Procedure for obtaining Exempt Status for Emergency Use:

1. Researcher is to contact the Chairperson of the Committee and explain the situation for which the researcher is requesting exemption. If the Chairperson is not available, the request for exemption shall be made to the Vice-President of Medical Affairs of Sparrow Hospital. The Committee Chairperson (or, if applicable, the Vice-President of Medical Affairs) shall have absolute discretion to grant or deny a request for exempt status for emergency use.
2. If an exemption is granted, the Committee Chairperson will immediately send researcher an acknowledgement letter along with a copy of this policy.
3. In emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. Special procedures for documenting the infeasibility of obtaining consent are in the attached regulations and policies guide or in 21 CFR § 50.23(a).
4. Researcher must submit IRRC approval documentation to all departments effected by the Emergency Use of this test article.
5. Researcher must send the Committee Chairperson the following information (per Federal guidelines – 21 CFR § 56.104.c) within five (5) working days of the first emergency use of the test article:

Patient name, date of event, diagnosis, summary of event, investigational treatment used, outcome.