

Template – Investigator Reporting to IRB Chair

[Print on Investigator’s Department/Office letterhead]

Date

*IRB Chair name
Institutional Research Review Committee
Research Oversight and Compliance
Sparrow Health System
1215 E Michigan Avenue
Lansing MI 48912*

Dear Dr. {IRB chair name}:

*Please regard this notice as a request for an IRB Emergency-Use Exemption for the use of the **drug xxxx** for one patient (**subject identifier**).*

According to the FDA regulations, in order to qualify for an emergency-use exemption, the situation must involve a “life-threatening situation in which no acceptable standard treatment is available and in which there is not sufficient time to obtain full IRB approval.”

*This situation complies with the definition because the **patient [describe why the patient needs the drug in a timely manner]**...*

Consent from the patient will be obtained... [explain the process so that the patient understands that the drug is not FDA approved for this use and if a consent form will be used state so and include with this memo].

The data for this patient will not be used as part of a prospective research protocol.

Sincerely,

Dr. XYZ