

Print letter on SHS IRRC/Research letterhead

{date}

{name and address}

RE: EMERGENCY USE – *{drug name}*, *{date to be used}*, *{IRRC ID #}*

Dear

The office of the Sparrow Health System institutional review board (IRB) has received your written notification of the request for the one-time emergency-use exemption of the investigational drug, (*drug name*), for one patient, (*pt initials*).

Prior IRB review and approval are not required for the emergency use of a test article as described in 21 CFR 56.102(d) and 21 CFR 56.104(c). This memo is not a notification of IRB review or approval.

The notification you have provided to the IRB meets the requirements of our IRRC policy and federal regulations. Informed consent must be obtained, please refer to the attached FDA information.

In accordance with the regulations, you **must** send the IRRC office the following information within five (5) business days of the emergency use of this test article:

- Subject identifier,
- Date of event,
- Diagnosis,
- Summary of event,
- Investigational treatment used, and
- Outcome.

Please note, if subsequent use of drug { } is anticipated, please submit an application for review by the full IRRC before its next use. The data from this use should not be used for prospective research purposes.

If you require further assistance, or have any questions, please do not hesitate to contact us at 517.364.2150 or via email: irrc@sparrow.org. Thank you.

Sincerely,

George S. Abela, MD, Chairperson
Institutional Research Review Committee
Sparrow Health System

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Attach