

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board
Telephone (601) 984-2815
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DHHS FWA #00003630
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Acknowledgement of One-Time Emergency Use

RE: IRB File #

Dear _____ :

Your notice of one-time emergency use was reviewed on _____. This letter provides my concurrence that immediate use of _____ is necessary and in compliance with FDA regulations for emergency use. You must notify the IRB immediately of any serious, unexpected toxicities or complications that occur with this use.

Please submit 1 copy of the following documents within ten (10) working days for review by the convened IRB at its next available meeting:

- A cover letter that includes a progress report;
- The original notice of emergency use;
- The research protocol and/or other documentation that supports the use;
- A copy of the signed consent document(s), with the signature of the participant or the signature and name of the participant's legally authorized representative redacted; and
- Any other pertinent information.

Please note that if you plan to use this _____ again a treatment protocol must be separately submitted for review by the convened IRB. The IRB may not approve additional one-time emergency use for this at this institution.

Sincerely,

Chairman, Institutional Review Board

cc: