

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

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Institutional Review Board

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DHHS FWA #00003630

IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Determination Notice
Activity Does Not Meet the Definition of "Research"

03/05/2013

Tibor Fulop, MD
Medicine - Division of Nephrology
University Of Mississippi Medical Center
2500 North State Street
Jackson, MS 392164505

RE: IRB File #2013-0036

Desmopression for Hyponatremia Overcorrection: an Effective Adjunct Treatment for Reversing Rapid Overcorrection and Preventing Osmotic Demyelination Syndrome

The above research proposal was reviewed on 03/05/2013. From the information you have provided, the proposed activity does not meet the definition of research, as defined in 45 CFR 46.102(d), and is not subject to oversight by the Institutional Review Board.

45 CFR 46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

If the intent of this project changes and/or you decide to measure outcomes please notify us of the change. At that point in time we will reconsider the project and if it requires an additional level of review.

A copy of this letter is being provided to your Department Chairman for the department's research files. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

IRB 2

CC: Shirley Schlessinger, MD