

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

Determination Notice Research Activity Does Not Involve "Human Subjects"

RE: IRB File #

Dear :

The above research proposal was reviewed on . From the information you have provided, the proposed research does not appear to involve "human subjects", as defined in 45 CFR 46.102(f) and does not require IRB review.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may

readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

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.

Sincerely,

Chairman, Institutional Review Board

cc:

Department Chairman