

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board

Telephone (601) 984-2815
Facsimile (601) 984-2961

DHHS FWA #00003630

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

Exemption Granted

RE: IRB File #

Dear _____ :

Your Claim of Exemption was reviewed on _____ and it was determined that your research protocol meets the criteria for exemption, as defined by the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects, 45 CFR 46.101(b),

You may now begin your research, which is approved to be conducted at:

Although this research is exempt, you have responsibilities for the ethical conduct of the research under state law and UMC policy, and must comply with the following:

Amendments: You are responsible for reporting any amendments or changes to your research protocol that may affect the determination of exemption and/or the specific category to the IRB. The amendment(s) or change(s) may result in your research no longer being eligible for the exemption that has been granted.

Record Keeping: You are responsible for maintaining a copy of all research related records in a secure location, in the event future verification is necessary. At a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to participants, all correspondence to or from the IRB, and any other pertinent documents.

Yearly Progress Report: You are responsible for completing a yearly progress report and submitting it to the IRB. The information in this form will keep us up to date on the progress of the study and help to ensure that the study continues to meet the requirements for exemption.

Final Report: You are responsible for submitting a final report to the IRB at the end of the study.

DELETE THE FOLLOWING IF EXEMPTION #4 IS THE ONLY CATEGORY CITED

UMC policy requires investigators to provide information about the research protocol to participants and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to participants in writing, or orally from a written script. When appropriate, the following information should be provided to all research participants of exempt studies:

The purpose of the research;

The extent of the participant's involvement and an explanation of the procedures to be followed;

Whether the information collected will be used for purposes other than the proposed research, and a description of those other purposes;

A description of the procedures in place to protect the privacy of participants and the confidentiality of the research information and data;

A description of any reasonably foreseeable risks;

A description of any anticipated benefits;

A statement that participation is voluntary and participants can refuse to participate or withdraw at any time;

A statement that the researcher is available to answer any questions that the participant may have. This statement must include the name and telephone number of the investigator(s), both during and after hours.

A statement that the Chairman of UMC's IRB is available to discuss the rights of a research participant. This statement should include the IRB's telephone number, 601 984-2815.

Please include the **IRB file number** () on any documents or correspondence sent to the IRB about this study.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

Sincerely,

Chairman, Institutional Review Board

cc:

Vice Chancellor for Health Affairs
Department Chairman