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To: Dr. Erin McKean

From:

Michael	Geisser
Alan	Sugar
Robertson	Davenport

Cc:

Erin	McKean
Amy	Hurst

Subject: Notice of Exemption for [HUM00173791]

SUBMISSION INFORMATION:
Title: Antibiotic Use for TS/EEA Pituitary Adenomectomy
Full Study Title (if applicable): Antibiotic Use for Transsphenoidal/EEA Pituitary Adenomectomy: National Quality Data Analysis from the North American Skull Base Society (NASBS) Value-Based Healthcare Committee
Study eResearch ID: HUM00173791
Date of this Notification from IRB: 4/15/2020
Date of IRB Exempt Determination: 4/15/2020
UM Federalwide Assurance: FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)
OHRP IRB Registration Number(s):

Additional Supporting Documents:

IRB EXEMPTION STATUS:
The IRBMED has reviewed the study referenced above and determined that, as currently described, it is exempt from ongoing IRB review, per the following exemption category:

EXEMPTION 4(iii) at 45 CFR 46.104(d):

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(iii)The research involves only information collection and analysis involving the investigator's use of **identifiable health information when that use is regulated under 45 CFR parts 160 and 164,**

subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)

Note that the study is considered exempt as long as any changes to the use of human subjects (including their data) remain within the scope of the exemption category above. Any proposed changes that may exceed the scope of this category, or the approval conditions of any other non-IRB reviewing committees, must be submitted as an amendment through eResearch.

Although an exemption determination eliminates the need for ongoing IRB review and approval, you still have an obligation to understand and abide by generally accepted principles of responsible and ethical conduct of research. Examples of these principles can be found in the Belmont Report as well as in guidance from professional societies and scientific organizations.

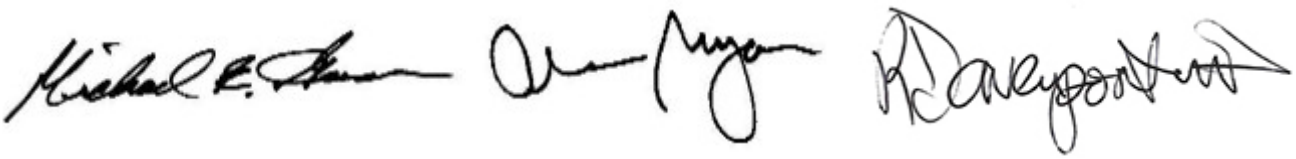
HIPAA REVIEW:
The IRB has reviewed the project referenced above and has granted a Waiver of HIPAA Authorization. The IRB has determined that the proposed project conforms with applicable regulations and policies. This project must be conducted in accordance with the description and information provided in the application and associated documents.

Note: This project is regulated under the HIPAA Privacy Rule, which requires you to account for certain disclosures of Protected Health Information (PHI).

SUBMITTING AMENDMENTS VIA eRESEARCH:
You can access the online forms for amendments in the eResearch workspace for this exempt study, referenced above.

ACCESSING EXEMPT STUDIES IN eRESEARCH:
Click the "Exempt and Not Regulated" tab in your eResearch home workspace to access this exempt study.

TERMINATION:
You will receive an annual message reminding you of your responsibilities to manage this research application. Terminate the application once you only hold or are analyzing deidentified data, or the research has ended.



Michael Geisser
Co-chair, IRBMED

Alan Sugar
Co-chair, IRBMED

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