Cheungpasitporn, Wisit, M.D.

From: IRBe <irbe@mayo.edu>
Sent: Tuesday, July 27, 2021 8:49 AM
To: Cheungpasitporn, Wisit, M.D.
Subject: 21-007353 - A study has been deemed Exempt by the IRB

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Wisit Cheungpasitporn
CC: Wisit Cheungpasitporn
Charat Thongprayoon

Re: **IRB Application #:** 21-007353
Title: In-hospital mortality of hepatorenal syndrome in the United States: Nationwide inpatient sample 2005-2015

IRB Approval Date: 7/27/2021
IRB Expiration Date:

The above referenced application was reviewed by expedited review procedures and is determined to be exempt from the requirement for IRB approval (45 CFR 46.104d, category 4). Continued IRB review of this study is not required as it is currently written. However, requests for modifications to the study design or procedures must be submitted to the IRB to determine whether the study continues to be exempt.

As the Principal Investigator will be in receipt of a limited data set, HIPAA authorization is not required in accordance with 45 CFR 164.514.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer