MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Rahul Kashyap
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Devang Sanghavi
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Timothy Weister

Re: **IRB Application #:** 20-002610
Title: Viral Infection and Respiratory illness Universal Study[VIRUS]: COVID-19 Registry and Validation of C2D2 (Critical Care Data Dictionary)

IRBe Protocol Version: 0.02
IRBe Version Date: 3/23/2020 10:46 PM

IRB Approval Date: 3/23/2020
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.

The Reviewer approved waiver of HIPAA authorization in accordance with applicable HIPAA regulations for subjects accrued at Mayo.

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

The investigator is reminded that the application does not include sharing information with external parties. If information is later requested to be sent to an external party a modification would be required.

The investigator is reminded to contact Legal Contract Administration regarding appropriate agreement(s).

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