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Albert Einstein College of Medicine

Office of Human Research Affairs

Montefiore

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Institutional Review Board

Albert Einstein College of Medicine
FWA #00023382

Montefiore Medical Center
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FWA #00000140

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West Campus IRB
Montefiore Medical Center
3308 Rochambeau Avenue
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Notification of Reapproval

Date: August 06, 2021

Principal Investigator: Sumit Kapoor

Study Title:	Characteristics and outcomes of adult patients with Stress Cardiomyopathy in ICU.		
IRB #:	2019-10754	**Reference #:**	079260
Approval Date:	08/06/2021	**Study Expiration Date:**	08/05/2022

This is to inform you that the Einstein IRB has reviewed and reapproved the above referenced human research project for the period noted above by expedited review under 45 CFR 46.110 and 21 CFR 56.110.

Expiration Notice: IRB approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report by 07/05/2022. To facilitate this, iRIS will send an email reminder 60 days prior to the due date. When this project is completed, submit a final Progress Report to close the file.

To prevent lapses in IRB approval the IRB recommends the following:

- Submission of Progress Report in iRIS 6 weeks prior to the expiration date
- Setting up a calendar reminder to submit the Progress Report (automatic iRIS notifications are often sent to SPAM).
- Maintaining a list of COI disclosures and CITI training for all Key Personnel, and proactively updating the disclosures and training on a regular basis. We recommend that COI disclosures be updated on a quarterly basis.
- Notifying the PI by phone or email to sign off on the Progress Report submission (automatic iRIS notifications are often sent to SPAM).
- Proactively tracking the Progress Report submission in IRIS to make sure the it is progressing in the system in a timely manner. You may track the status of your submission by going to Study Assistant > My Studies > Click on the notepad > Click on the colored icon under "Track Location" (right hand side of the page) and note the location of the submission by the first row in the list.

Reminders

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

All changes to a study must receive IRB approval before they are implemented. The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(b)(4), 21 CFR 56.108(a)). In such cases, report the actions taken as a reportable event.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

Consent form posting requirement for federally sponsored clinical trials receiving initial approval from the IRB after January 20, 2019
The revised Common Rule requires that for each clinical trial conducted or supported by a Federal department or agency (such as the NIH), one IRB-approved informed consent form used to enroll subjects must be posted by the awardee on a publicly available Federal Web site.

The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

At this time, there are two publicly available federal websites that will satisfy the consent form posting requirement: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

If additional information is needed, please contact the Administrative Office at 718-430-2237.