

Notification of Approval

Date: May 24, 2021

Principal Investigator: Shitij Arora

Study Title:	Mucormycosis in COVID-19	Reference #:	076596
IRB #:	2021-13086		
Type of Submission:	Submission Response for Initial Review Submission form		
Approval Date:	05/24/2021	Expiration Date:	05/23/2022

The above titled submission was reviewed and approved by expedited review under 45 CFR 46.110 and 21 CFR 56.110 as the research fits into the following category:

- Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

This submission was approved with the following stipulation:

- The waiver of informed consent and HIPAA authorization were approved.

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.

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

Data Use Agreements: If you are releasing data to an external site/entity/collaborator, you are required to obtain a DUA (Data Use Agreement). This may be obtained through the Research Agreement Request Portal (https://einsteinmed.co1.qualtrics.com/jfe/form/SV_8fgVaus0Bpcpeux).

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 04/23/2022. 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.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

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).