



METROWEST MEDICAL CENTER

Framingham Union Hospital • Leonard Morse Hospital

April 20, 2022

Nitin Trivedi, MD
Saint Vincent Medical Center
123 Summer Street
Worcester, MA 01608

Re: IRB#2022-035: Assessment of the Association of Inflammatory Markers and Hyperglycemia in COvid-19 Patients without Diabetes Mellitus

Dates: 07/01/2021 to 03/30/2022

Jurisdiction: Saint Vincent Medical Center, 123 Summer Street, Worcester, MA 01608

Dear Dr. Trivedi,

This is to inform you that on April 20, 2022 MetroWest Medical Center Institutional Review Board (IRB), via Expedited Review by the IRB Chair, has approved the above-referenced research protocol and the participation of the above-referenced investigative site in the research. Your study number is 2022-035. Please be sure to reference this number and the name of the principal investigator in any correspondence with MetroWest Medical Center IRB.

The following items were included in the submission of April 15, 2022:

- Site Submission form
- Protocol
- HIPAA Waiver of Authorization
- PI Attestation
- Questionnaire
- CV, MA License and Training Certificates for Drs. Trivedi, Abraham, Gogtay and Geetha

Specifically your request was approved as "expedited review" under the following category:

- Secondary research uses of identifiable private information or identifiable biospecimens that are not exempt under §__ .104(d)(4) because (a) the identifiable private information or identifiable biospecimens are not publicly available; (b) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained directly or through identifiers linked to the subjects, or the investigator intends to contact the subjects or will re-identify subjects; (c) research use of identifiable health information not regulated under 45 CFR parts 160 and 164, subparts A and E.

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- A waiver of documentation of consent was approved in accordance with 45 CFR 46.117(c).
- The following must be promptly reported to the IRB: changes to the study site, and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.
- Approval is valid for enrollment of the number of subjects indicated on your submission form.
- Advertisements, letters, internet postings and any other media for subject recruitment must be submitted to the IRB and approved prior to use.
- All publications and communications related to this research are subject to Tenet Policy AD 2.16 related to the substantiation of all data/claims with reliable scientific evidence.
- Compliance with all federal and state laws pertaining to this research

If data is collected or shared with another institution/facility a data use agreement must be in place

If you have any questions regarding this determination, please feel free to contact me at mary.oster@mwmc.com or 508-383-8786.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mary Oster', with a stylized, cursive script.

Mary Oster
IRB Administrator