



Institutional Review Board
19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE: July 22, 2021

TO: Michael Baracy, MD
FROM: Ascension St. John Hospital IRB

STUDY TITLE: [1783486-1] COVID-19, Universal Masking, and the Unintended Impact on Febrile Neutropenia

IRB REFERENCE #: 1783486

SUBMISSION TYPE: New Project

ACTION: **DETERMINATION OF EXEMPT STATUS**

DECISION DATE: July 22, 2021

REVIEW CATEGORY: Exemption category # 4(iii)

Thank you for your submission of New Project materials for this exempt research study. The Ascension St. John Hospital IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

Any change in the protocol which may raise the project from exempt to an expedited or full review category must be presented to the IRB. If there is any question about a change in protocol the Principal Investigator should consult the IRB Office. Failure to submit changes which raise the protocol out of the exempt category will be considered non-compliance and will be subject to investigation and action by the IRB.

We will put a copy of this correspondence on file in our office.

If you have any questions, please contact Lee Bowen at (313) 343-3863 or lee.boozebattle@ascension.org. Please include your study title and reference number in all correspondence with this office.

Sincerely,

A handwritten signature in black ink, appearing to be 'R. Dunne', followed by a long horizontal line.

Robert B. Dunne, MD, Chairperson
Institutional Review Board
Ascension St. John Hospital