Boston Medical Center • School of Medicine • School of Public Health • Goldman School of Dental Medicine





Institutional Review Board 72 E. Concord St., Robinson 4 – Suite 414 Boston, Massachusetts 02118-2307 Tel: 617-358-5372

Title of Study: Comparing Utilization, Outcomes, and Choice between VHA and non-VHA Health Care Systems **IRB Number:** H-42700

RE: Initial Review Submission Form **Review Type:** Exempt **Action:** Exempt Determination

Date of Action: 04/15/2022 Status Check-In Due Date: 04/14/2025

Funding Source: Dept/Internal

April 15, 2022

Dear Christine Yee,

A qualified member of the Institutional Review Board (IRB) staff has reviewed the above referenced submission and has determined that the study qualifies for an exemption determination under the policies and procedures of the Human Research Protection Program (http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#10.2.4) under category (4).

This exemption determination is valid through the expiration date indicated above. You may close the study at any time when research activities are complete. You will be asked to file a brief status report prior to the above expiration date to indicate whether research activities are ongoing to renew this exemption determination.

This determination corresponds with the versions of the application and attachments in the electronic system most recently given an outcome of 'Reviewed' as of the date of this letter.

All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan that would possibly change this exempt determination or that meet the criteria for amendment submission as outlined in Section <u>10.2.4.1</u> (for example, changes in recruitment procedures, confidentiality protections, or use of PHI) must be submitted to the IRB for review and confirmation of continued exempt status prior to initiation of the change.

As principal investigator, you are reminded that you must comply with the responsibilities listed here <<u>http://www.bumc.bu.edu/irb/maintaining-irb-approval/responsibilities-of-the-principal-investigator/</u>> with the exception of point #13. PLEASE NOTE: Minor changes to the study that do not affect the exempt determination do not need to be submitted to the IRB. You will be asked to

summarize such changes if and when you renew the exemption determination.

Sincerely yours,

Matthew Ogrodnik, OHRA Director