U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

April 18, 2024

Katherine Moran
NCCDPHP/OSH
rtq5@cdc.gov

RE: CDC IRB Initial Approval of CDC Research Study 7493, "Evaluation of Local Policies that Restrict Sales of Menthol-Flavored Tobacco Products"

Dear Katherine Moran:

On April 12, 2024, the CDC Institutional Review Board (IRB) reviewed and approved the research study titled "Evaluation of Local Policies that Restrict Sales of Menthol-Flavored Tobacco Products," and assigned it CDC Protocol Number 7493. The approval is effective as of April 12, 2024. The CDC IRB made the following findings in accordance with 45 C.F.R. Part 46:

- The research study was reviewed and approved in accordance with the expedited review process outlined at 45 C.F.R. §46.119(b)(1)), category 7
- Determined the research study does not involve more than minimal risk to subjects
- Determined the research study does not require continuing review. However, the CDC Human Protections Office requires an annual progress report, which is due by April 11, 2025.
- Approved the inclusion of pregnant women, human fetuses, and neonates
- Approved a waiver of informed consent documentation
- A Certificate of Confidentiality applies to this research study to protect the privacy of individuals who are subjects of this study, pursuant to subsection 301(d) of the Public Health Service Act

Please note that any changes to the research study including the protocol, informed consent process or materials, or any other aspect of the research study or research materials must be reviewed and approved by the CDC IRB before they can be implemented. Failure to obtain CDC IRB's approval may result in the suspension or termination of the research study. Unanticipated problems or noncompliance of a serious or continuing nature should be promptly reported to the CDC's Human Research Protections Office in accordance with CDC policies and procedures.

We appreciate your commitment to responsible conduct of research and your cooperation with the IRB review process.

If you have any questions or concerns regarding the conduct of the research study or the IRB review process, please do not hesitate to contact your Center Human Subjects Contact or Felecia Peterson, IRB Administrator, at 404-639-4961, or via email at fdp1@cdc.gov.

Sincerely,

For Robert Chirila, Lead
Human Research Protections Office