



STATE OF TENNESSEE
INSTITUTIONAL REVIEW BOARD
DEPARTMENT OF HEALTH
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NASHVILLE, TENNESSEE 37243
TDH-IRB.Health@tn.gov

DATE: December 26, 2023

TO: Susan Guttentag

FROM: Tennessee Department of Health Institutional Review

PROJECT TITLE: Tennessee's Tiniest Babies: Prevention of Chronic Lung
Disease

SUBMISSION TYPE: Initial Submission

ACTION: Determination of Quality Improvement, Not Research

Thank you for your submission of materials for this project. The Tennessee Department of Health (TDH) IRB has reviewed your submission. It has been determined this submission is Not Research but Quality Improvement. This determination is based on an appropriate risk/ benefit ratio and a project design wherein the risks have been minimized. All work must be conducted in accordance with this designation.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office within 10 business days. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office within 10 business days.

We strongly encourage all communications regarding this project to occur within the iMedRIS system. However, if you have any questions and/or have difficulties using the iMedRIS system, please contact the TDH IRB at TDH-IRB.Health@tn.gov or (615) 253-2557. Please always include your project title and the assigned iMedRIS ID reference number.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Tennessee Department of Health (TDH) IRB's records.

Ramona Lainhart, PhD

Chair, TDH IRB

Signature applied by Ramona Lainhart on 12/26/2023 10:23:58 AM EST