

Overcoming Therapeutic Inertia Among Adults Recently Diagnosed With Type 2 Diabetes

NCT ID not yet assigned

September 7, 2022



Kaiser Permanente Northern California
Institutional Review Board
FWA# 00002344 IRB# 00001045

1800 Harrison Street, 10th Floor
Oakland, CA 94612
(510) 625-4588
KPNC.IRB@kp.org

DATE: September 7, 2022

TO: Lisa Gilliam, MD, PhD
FROM: Kaiser Permanente Northern California IRB

PROJECT TITLE: [1857661-2] Overcoming therapeutic inertia among adults recently diagnosed with Type 2 Diabetes

REFERENCE #:
SUBMISSION TYPE: Amendment/Modification

ACTION: RESEARCH - NOT HSR
DECISION DATE: September 7, 2022
REVIEW TYPE: Administrative Review
ADMINISTRATIVE CHECK- IN DUE DATE: Not applicable

Dear Dr. Lisa Gilliam:

On September 7, 2022, the Kaiser Permanente Northern California (KPNC) Institutional Review Board determined that your project is Not Human Subjects Research as defined by federal regulations and institutional policies (45CFR46.102).

The activity does not meet the regulatory definition of research at 45 CFR 46.102(d):

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Note: The word "research" should not appear in any posters or publications resulting from this project. Also, the word "clinical trial" should not appear in any posters or publications resulting from this project. Lastly, the study team may not store any identifiable data or conduct any future research use without IRB review and approval.

This determination is based on the information provided to the IRB. If the scope or nature of the project changes in a manner that could impact this review, you are required to notify the IRB Office prior to implementing this change.

You are expected, however, to implement your study or project in a manner congruent with accepted professional standards and ethical guidelines as described in the Belmont Report

(<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>).

Additionally, you are responsible for keeping a copy of this determination letter in your project files as it may be necessary to demonstrate that your project was properly reviewed.

Provide this approval letter to the Physician in Charge (PIC), Area Manager, and/or Chief of Service, to determine whether additional approvals are needed.

If you have any questions, please contact the KPNC IRB at KPNC.IRB@kp.org. Please include your project title and reference number in all correspondence with this committee.

Sincerely,

Kaiser Permanente Northern California IRB