

Yale University

*Institutional Review Board
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To: Merceditas Villanueva
From: **Yale University Institutional Review Board**
Date: 10/19/2015
IRB/HSC#: 1510016672
Title: The Cooperative Re-engagement Controlled Trial (CoRECT)_

The IRB is in receipt of your request for review for your proposed study. We have determined that this study is not considered to be Human Subjects Research and does not require IRB review, pursuant to the Office of Human Research Protections (OHRP) definition of human subject, 45 CFR 46.102 (f), as follows:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

OHRP has issued guidance regarding Institutional Review board (IRB) review and approval processes for research involving coded private information or human biological specimens; this guidance can be found at **<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>**.

The Guidance provides specific mechanisms by which coded information or specimens can fall outside of the definition of human subjects research. OHRP considers this guidance to apply not only to existing information and specimens but to materials to be collected in the future if the purpose of collection is for reasons other than the contemplated research project. The Guidance states that research does not involve human subjects if 1) the data or specimens were/will not be specifically collected for the current research project, and 2) there is a documented mechanism in place that prevents the investigator from obtaining access to identifiers. Examples of acceptable mechanisms include a simple Memorandum of Understanding between the provider and recipient that identifying information will neither be provided nor requested.