



Not Human Research Determination

Date: November 08, 2019

Protocol Number: 1910007425
Principal Investigator: Longjian Liu, MD, PhD
Review Date: November 08, 2019
Committee: IRB 1
Sponsor: National Institute on Aging
Project Title: "Association of Cardiometabolic Syndrome and Cardiovascular Diseases with Risk of Cognitive Decline and Alzheimer's Disease: A Time-to-Event and Machine Learning Analysis Approach"

The proposed activity is not human subjects research as defined by DHHS or FDA regulations. Consequently, **Drexel IRB review and approval is not applicable**. You are welcome to pursue the activity, obtaining any applicable administrative or departmental (non-IRB) approvals.

This determination applies only to the activities described in this IRB submission and does not apply should any changes be made. Changes could affect this determination. Please contact the IRB for guidance.

DHHS Definitions:

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

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

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

FDA Definitions:

Research – any experiment that involves a test article and one or more human subjects, and that either: a) must meet the requirements for prior submission to the Food and Drug Administration; or b) the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for research or marketing permit.

Human subject – an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

Please contact the IRB at (215) 762-3944 or HRPP@drexel.edu if you have any questions.