

# **MICHIGAN STATE UNIVERSITY**

## **DETERMINED NOT “HUMAN SUBJECTS” Revised Common Rule**

September 1, 2022

To: Zichun Cao

Re: **MSU Study ID:** STUDY00008137  
**Principal Investigator:** Zichun Cao  
**Determination Date:** 9/1/2022

Title: Mediation Analysis in Case-Control Study with Secondary Outcome

The activity described in this submission was determined not to involve “human subjects” as defined by the Common Rule as codified in the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human research subjects.

### **Definition of Human Subject**

For DHHS, “*Human subject*” means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” [45 CFR 46.102(e)(1)]



**Office of  
Regulatory  
Affairs  
Human Research  
Protection Program**

4000 Collins Road  
Suite 136  
Lansing, MI 48910

517-355-2180  
Fax: 517-432-4503  
Email: [irb@msu.edu](mailto:irb@msu.edu)  
[www.hrpp.msu.edu](http://www.hrpp.msu.edu)

### **Determination**

**This project involves only secondary data analyses of de-identified data from the NIEHS Sister Study. Data are de-identified and MSU PI and data analyst do not have any personal identifiable information by which study participants could be linked or located.**

Hence, the activity does not involve human subjects.

Therefore, the federal regulations for the protection of human subjects would not apply to this activity and Michigan State University (MSU) Institutional Review Board (IRB) approval is not needed to proceed. However, please note that while MSU IRB approval is not required, other federal, state, or local regulations or requirements or ethical or professional standards may still be applicable based on the activity.

**Modifications:** If any of the activities described in this submission change, please contact the IRB office as the activity may involve human subject research and require IRB approval. For example, this determination is not applicable to activities

that may be regulated by U.S. Food & Drug Administration (FDA), such as those involving drugs, medical devices, human food additives, color additives, electronic products, or any other test articles regulated by the FDA.

**Modifications to Funding: Changes in funding may alter this determination.**

For example, MSU IRB review and approval is required if MSU receives an award through a grant, contract, or cooperative agreement directly from a federal agency, even where all non-exempt research involving human subjects are carried out by employees or agents of another institution. In addition, the new funding source may have additional or different requirements.

**For More Information:** See HRPP Manual Section 4-3, Determination of Human Subject Research (available at [hrpp.msu.edu](http://hrpp.msu.edu)).

**Contact Information:** If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at [IRB@msu.edu](mailto:IRB@msu.edu). Please visit [hrpp.msu.edu](http://hrpp.msu.edu) to access the HRPP Manual, templates, etc.