

MICHIGAN STATE UNIVERSITY

DETERMINED NOT “HUMAN SUBJECTS” Revised Common Rule

February 7, 2019

To: Furqan Bin Irfan

Re: **MSU Study ID:** STUDY00002083
Principal Investigator: Furqan Bin Irfan
Determination Date: 2/7/2019

Title: Healthcare Cost and Utilization Project (HCUP)

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**

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Determination

You have indicated that you will be analyzing deidentified healthcare from a public database.

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).

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. Please visit hrpp.msu.edu to access the HRPP Manual, templates, etc.