April 11, 2014

To:
Christine Hercik
Department of Microbiology and Immunology
Georgetown University

From:
Julianne Nelson, MPH
Senior IRB Program Coordinator
Georgetown University, Institutional Review Board
MedDent Bldg., SW 104
Washington, DC 20007

Re: An Examination of Exposure and Risk Factors for Emerging Infectious Disease at the Animal-Human Interface

Your project, (An Examination of Exposure and Risk Factors for Emerging Infectious Disease at the Animal-Human Interface) does not require IRB review and approval, as it is not viewed by the Georgetown University Institutional Review Board (GU IRB) to be human subject research within the meaning of Georgetown University policies and procedures and the Common Rule (Title 45 Code of Federal Regulations Part 46).

Under the applicable human subjects regulations (45 CFR Part 46) research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]. A human subject is "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" [45 CFR 46.102(f)].

The IRB has been informed that the above listed investigators will analyze pre-existing, de-identified, coded data from the CDC. The data utilized by the GU investigator(s) will not contain any identifiers, the CDC has agreed to not release the code to the GU investigator(s) and the GU investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain. Therefore, this
project does not meet the definition of human subject research defined above as it does not involve the collection of data through intervention or interaction with the individual or collection of identifiable information per HHS regulations 45 CFR 46.102(f).

No further IRB review is required for your project at this time.

You must submit your project to be reviewed by the GU IRB if any project changes occur that will involve the following:

- obtaining data about living individuals for research purposes through intervention or interaction with them;

- obtaining individually identifiable private information for research purposes (45 CFR 46.102(d),(f));

- obtaining informed consent of human subjects;

- if research meets the above criteria, you must obtain IRB review if you receive a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution.

No further IRB review is required for your project at this time. Please contact the IRB office at 202-687-6553 if you have any questions.