

To: Seleda Perryman
NIH/OD

From: Richard L. Gorman, MD
Associate Director for Clinical Research
DMID/NIAID/NIH

Date: February 9, 2015

Re: Emergency OMB Clearance for the study entitled "Human Influenza Surveillance of Health Care Centers in the United States and Taiwan"

We are requesting an emergency review of the study entitled "Human Influenza Surveillance of Health Care Centers in the United States and Taiwan" because public harm is reasonably likely to result if the normal clearance procedures are followed. This study will identify individuals with influenza through focused surveillance in key region of the United States and Taiwan, rapidly identify circulating influenza strains to identify those with pandemic potential and create an invaluable bank of human samples from patients with influenza to characterize the basis of severe disease - a critical knowledge gap impacting effectiveness of decision-making around patient care.

The 2014-15 influenza season is unique because the dominant circulating strain is an H3N2 strain that is not sensitive to the immunity induced by the influenza vaccine formulation administered to the general public. This distinct influenza season could not have been reasonably anticipated when this protocol was under development. Our study combines serology with an analysis of the whole genome sequence of the circulating viruses which will provide insight into other viral determinants that may be contributing to the severity of influenza and associated morbidity and mortality. Capturing samples from this influenza season is essential for understanding the public health implications the virus may have in the future and discerning the reasons behind the severity of the disease it causes.

The normal OMB clearance process timeline will not allow for the collection of samples during this influenza season in the Northern Hemisphere, potentially resulting in harm to the public health. Given the significant public health implications of this novel strain of influenza, the impact it has already had on the US population, the pressing and immediate nature of the influenza season we are in the midst of and the critical public health value of this work, we are respectfully requesting emergency approval of this work to begin by February 16, 2015.