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To:

Anne O'Connor, MS, MT(ASCP)
National Center for Preparedness, Detection, and Control of Infectious Disease
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS C12
Atlanta, Georgia 30333
Phone: (404) 639-1042
Email: aoconnor@cdc.gov

Anne,

I have reviewed the Information Collection Request package for the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacteria drug susceptibility testing. I have determined that it does not constitute research. IRB review is not required.

Data to be collected are not meant to be generalized or to contribute to the scientific understanding of specific infectious diseases. As such, this data collection would be considered public health practice. This data collection does not meet the definition of research under 45 CFR 46.102(d), and IRB review is not required.

Please let me know if you have any questions and if this information is sufficient.

Regards,

Shambavi Subbarao, Ph.D.
Acting Associate Director of Science
Division of Laboratory Systems
National Center for Preparedness, Detection, and Control of Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd USPS
MS G25
Atlanta, GA 30333
Ph: 404-498-2253