

Samuel, Lee (CDC/DDPHSIS/CGH/DPDM)

From: Brown, Natalie (CDC/DDPHSIS/CGH/OD)
Sent: Wednesday, May 20, 2020 8:38 PM
To: Sartin, Shannon (CMS/OA)
Cc: Samuel, Lee (CDC/DDPHSIS/CGH/DPDM); CDC IMS 2019 NCOV Response PRA Human Subject; Zirger, Jeffrey (CDC/DDPHSS/OS/OSI); Daneshvar, Maryam I. (CDC/DDPHSS/OS/OSI)
Subject: CDC Non Research Determination; COVID- 19 Pandemic Response, Laboratory Data Reporting Policy: CARES Act Section 18115
Attachments: Lab Data - CARES Act - Final Draft for OMB Clearance515.docx

Hello Shannon,

I am currently serving as the Human Subjects Lead for the CDC COVID-19 response and it is my understanding you are working with my colleagues to develop an OMB package for the activity entitled "COVID- 19 Pandemic Response, Laboratory Data Reporting Policy: CARES Act Section 18115". Below you will find a Human Subjects determination which can be used to document Human Subjects review at CDC for this activity:

Project title: COVID- 19 Pandemic Response, Laboratory Data Reporting Policy: CARES Act Section 18115

Purpose: This document outlines the requirements for data submission to the U.S. Department of Health and Human Services (HHS) as authorized under Public Law 116-136 § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying of supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.

This activity does not meet the definition of research as defined in 45 CFR 46.102(I). No further Human Subjects review is required.

Thank you,
Natalie

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