

Attachment E

Research Data Center Proposal is not considered research with human subjects, and therefore Institutional Review Board (IRB) approval is not required. See email below from the National Center for Health Statistics' IRB.

New Protocol #2021-09 Research Data Center Protocol Form (20211018.03)



Wise, Kyle (CDC/DDPHSS/NCHS/OD)

To: McNeill, Tabatha (CDC/DDPHSS/NCHS/DRM); Russell, J Neil (CDC/DDPHSS/NCHS/DRM)

Cc: Craver, James (CDC/DDPHSS/NCHS/OD); O'Connor, Kathy (CDC/DDPHSS/NCHS/DHCS); Buie, Verita (CDC/DDPHSS/NCHS/OD); Miller, Donna M. (CDC/DDPHSS/NCHS/OD); Branum, Amy M. (CDC/DDPHSS/NCHS/OD)

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Wed 12/8/2021 11:59 AM

Date: December 8, 2021

From: James M. Craver, MAA
Chair, NCHS ERB

Kathleen S. O'Connor, MPH
Vice Chair, NCHS ERB

To: Tabitha McNeill MPH
J. Neil Russell Ph.D.

Subject: New Protocol #2021-09 Research Data Center Protocol Form (20211018.03)

The NCHS Human Subjects Contact determined that New Protocol #2021-09 Research Data Center Protocol Form, is a public health surveillance activity under the 2018 requirements of the Common Rule (45 CFR 46.102(l)(2)). All collected information will be used for administrative purposes only and is not consistent with the definition of human subjects research.

The NCHS Ethics Review Board reviewed the request for approval of New Protocol #2021-09 Research Data Center Protocol Form, using the expedited review process based on 45 CFR 46.

New Protocol #2021-09 Research Data Center Protocol Form is approved.

Any problems of a serious nature should be brought to the attention of the ERB, and any additional proposed changes should be submitted for IRB approval before they are implemented.

Please contact me or Kyle Wise, if you have any questions.

James Craver, MAA
Chair, NCHS ERB

Kathy O'Connor
Vice Chair, NCHS ERB