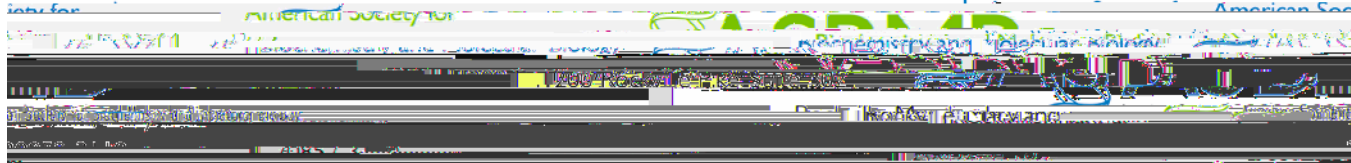




Responses submitted: May 30, 2019

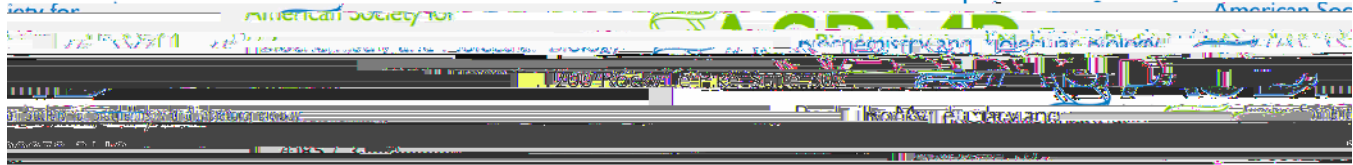


to sensitive information not available to outside researchers and groups. A second study (Charette et al., 2016, PLOS ONE, dx.doi.org/10.1371/journal.pone.0168511) featured authors who were exclusively employees of the Department of Health and Human Services (NIH and CDC employees). The authors examined demographic changes, particularly changes in the age of grantees over time. Again, the privileged access to sensitive data used in this study is not normally available for external researchers. These two examples are not meant to be exhaustive, but rather as exemplars of the types of high quality and high value research that can be conducted using data that would be available through a data enclave. It is disheartening to imagine the vast array of research and analyses that could be carried out by qualified external researchers at academic institutions and scientific societies and the insights and lessons we are missing because this research cannot be done in the current regulatory climate.

II. Whether the benefits of the proposed data enclave are worth repurposing NIH research funds to establish, maintain and operate the data enclave.

The research that will be made possible by the proposed data enclave will provide the opportunity for independent analyses of the NIH funding process, making the effort worth funding. Analyses can be paired with the history publiclaira10.19 0 Td [(p)-14 (02 Tw 3.39 0 Td [(w)-6 (ill)]TJ 0 Tc 0 Tw ()Tj 1.91 0 Td [(pr) ta tA opportunity a (((7)Tn(T2 ()TjTJ0.35T()2TmT00 T4Ttw[0,]900 TdTc[3-40 -1.15wTd 1[(78)) 0 Tc 0.0d t s(Tc u (ill 004 T2.6 -1.15 Td [(0 Tc 0.0d t) 0 Tc 0 Tw 1.78 0 Td 4 (pe)4 (nde)4 (nt) ()T8Twv Tc (.00b o Tab Tcc 0 Tt .ooo Tw 2.49



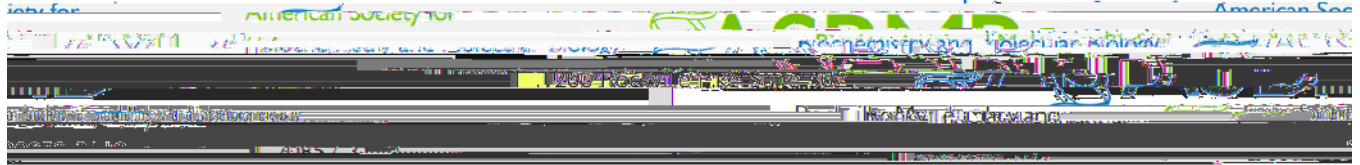


could be dedicated toward directly supporting research. A virtual location for the data enclave would also eliminate access issues for researchers who could not reasonably make accommodations to travel to a central physical location.

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IV. Quantity of seats desired if NIH decides to make a substantial investment to sponsor access to sensitive data as allowable under the applicable federal laws in a secure virtual or physical environment.

Initially NIH may want to set the number of available seats to 10, particularly when piloting the data enclave with early users. Once the data enclave is fully running, NIH should evaluate the necessary number of seats and adjust seat availability based on demand from the community. Quarterly or biannual analyses of demand may be sufficient.



VII. Examples of outputs from approved research and how these may be shared with NIH

As described in our response to question V, we expect outputs from approved research to primarily take the form of published manuscripts.