ARIC Manuscript Proposal #3805

PC Reviewed: 03/09/21   **Status: _____**   **Priority: 2**
SC Reviewed: _____   **Status: _____**   **Priority: ____**

C4R Manuscript Number: 001
Submission Date: 25 Feb 2021

Project title: Collaborative Cohort of Cohorts for COVID-19 Research (C4R) Study: Study Design

Lead investigator(s):

    Writing Group Chair
        Name: Elizabeth Oelsner
        Email:eco7@cumc.columbia.edu
        Affiliation: Columbia University
    Senior C4 author
        Name: Elizabeth Oelsner
        Email:eco7@cumc.columbia.edu
        Affiliation: Columbia University

Potential overlap

- Among approved C4R proposals (see website), which ones are the most similar to this proposal?
    - Not applicable
- Is there any potential overlap with existing C4R proposals? Please explain and describe
    - If there is potential overlap, please summarize how this proposal is different
    - No overlap

C4R cohort inclusion table:

Cohorts	Include: Yes / No	Co-author*	Comments**
ARIC	Yes	Josef Coresh, Ryan Demmer, Aaron Folsom, David Couper, Anna Kucharska-Newton, Kimberly Ring	
CARDIA	Yes	Kelley Pettee Gabriel, Norrina Bai Allen, Veronique Roger, James Shikany, Beth Lewis	

COPDGene	Yes	Matthew Moll, Jessica Bon, Greg Kinney, University of Colorado School of Public Health, Elizabeth A Regan, Barry Make	
Framingham	Yes	Vasan S Ramachandran, Vanessa Xanthakis, Joel M Henderson, Sudha Seshadri	
HCHS/SOL	Yes	Robert Kaplan, Linda Gallo, Carmen Isasi, Greg Talavera	
Jackson Heart Study	Yes	Adolfo Correa, Yuan-I Min, Pramod Anugu, Karen Winters, Mario Sims	
MASALA	Yes	Alka Kanaya, Namratha Kandula, Arunee A Chang, Michael Schembri	
MESA	Yes	Wendy Post, Jerome I Rotter, Karen Hinckley Stukovsky, Alain Bertoni, Karol Watson	
NOMAS	Yes	Mitchell Elkind, Ralph L. Sacco, Jose Gutierrez, Tatjana Rundek, Clinton B. Wright, Deborah A. Levine	
PrePF	Yes	David A. Schwartz, MD, Joyce S. Lee, MD, and Alyssa Asaro	

REGARDS	Yes	Mary Cushman, Virginia Howard, Emily Levitan	
SARP	Yes	Sally E. Wenzel, MD; Bruce Levy, MD; Victor E. Ortega, MD, PhD; Wendy C. Moore, MD; Wanda Phipatanakul, MD,MS; Dave Mauger, MS, PhD	
SPIROMICS	Yes	Prescott G. Woodruff, David Couper, R. Graham Barr, MeiLan K. Han	
Strong Heart Study	Yes	Jason G Umans, Shelley A Cole, Amanda M Fretts, Tauqeer Ali, Ying Zhang, Kimberly Malloy	
C4R DCHC	Yes	Elizabeth C Oelsner, R Graham Barr, Pallavi P Balte, Howard Andrews, Akshaya Krishnaswamy, Yiyi Zhang, Jennifer Manly, Priya Palta	
C4R BCL	Yes	Russell Tracy, Rebekah Boyle, Monica Parker	
Other***	No		

*If you do not have a co-author identified to represent a cohort, we will be happy to assist you in identifying one.
**Please justify exclusion of any C4R cohort from your proposal.
***If you anticipate including data from another cohort, please indicate which one(s).

Co-authors not already listed above:

Specific aims and hypotheses:

Specific Aim	Hypothesis
To describe methodology for C4R data collection and analysis.	This is a descriptive report.

Rationale (300 words maximum):

Significance	The profound adverse effects of the COVID-19 pandemic on US health, economy, and society[1-3], especially the risk of long-term post-acute sequalae, necessitate development of longitudinal studies that would allow for the examination of COVID-19 outcomes overall and across diverse socio-demographic subgroups. The Cohort of Cohorts for COVID-19 Research (C4R) is a consortium of 14 longitudinal cohort studies, established to ascertain the burden of the SARS-CoV-2 infection and its sequalae in a large multiethnic sample of adults 18-108 years of age. The objective of this manuscript is to describe protocols employed by the study for ascertainment of COVID-19 events, to provide information on the standardization of event ascertainment protocols across contributing cohorts, and to outline study aims and overall study design protocols.
Relevant prior literature	Cited below
Summary of proposed study	N/A
Justification for use of C4R	Design paper

Data requests:
For this manuscript proposal, cohort data are included only to provide participant baseline demographic characteristics.

C4R Data Needed:

	Variables needed		Questions and comments*
	Variable name	Dataset	
Exposure(s)			N/A
Outcome(s)			N/A
Covariates			N/A

Version Date: 22Feb2021

*For meritorious proposals, we will work with you to assess the status of data harmonization of variables of interest.

Analysis plan:
- Primary analyst(s): N/A
  - Name:
  - Email address:
  - Affiliation:
- Brief statistical plan, organized by specific aim: N/A

Additional considerations of primary importance to C4R approval -- please comment:
- Inclusion of women and minorities
  - Treatment of sex as a biological variable
  - Appropriate analysis and interpretation of differences by race and ethnicity
- Consideration of social determinants of health
- Use (or non-use) of genetic data
- Respect for data sharing restrictions on Strong Heart Study data

N/A

References:

1. Kissler SM, Tedijanto C, Goldstein E, Grad YH, Lipsitch M. Projecting the transmission dynamics of SARS-CoV-2 through the postpandemic period. Science. 2020.
2. Woolf SH, Chapman DA, Lee JH. COVID-19 as the Leading Cause of Death in the United States. JAMA. 2021;325(2):123-124.
3. COVID Data Tracker. Centers for Disease Control and Prevention. https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days. Published 2021. Accessed February 24, 2021.