Publications and Presentations (P&P) Policy

Contents

The success of the C4R Study will be judged largely on the number and quality of its scientific publications and presentations. The purpose of this policy is to encourage and facilitate data analysis and reporting, while providing guidelines to ensure correct use of C4R data, timely completion of manuscripts, and adherence to the ethical principles of authorship.

I. Administrative Structure

The C4R CCC will appoint a Publications and Presentations (P&P) Committee and select a chair and co-chair.

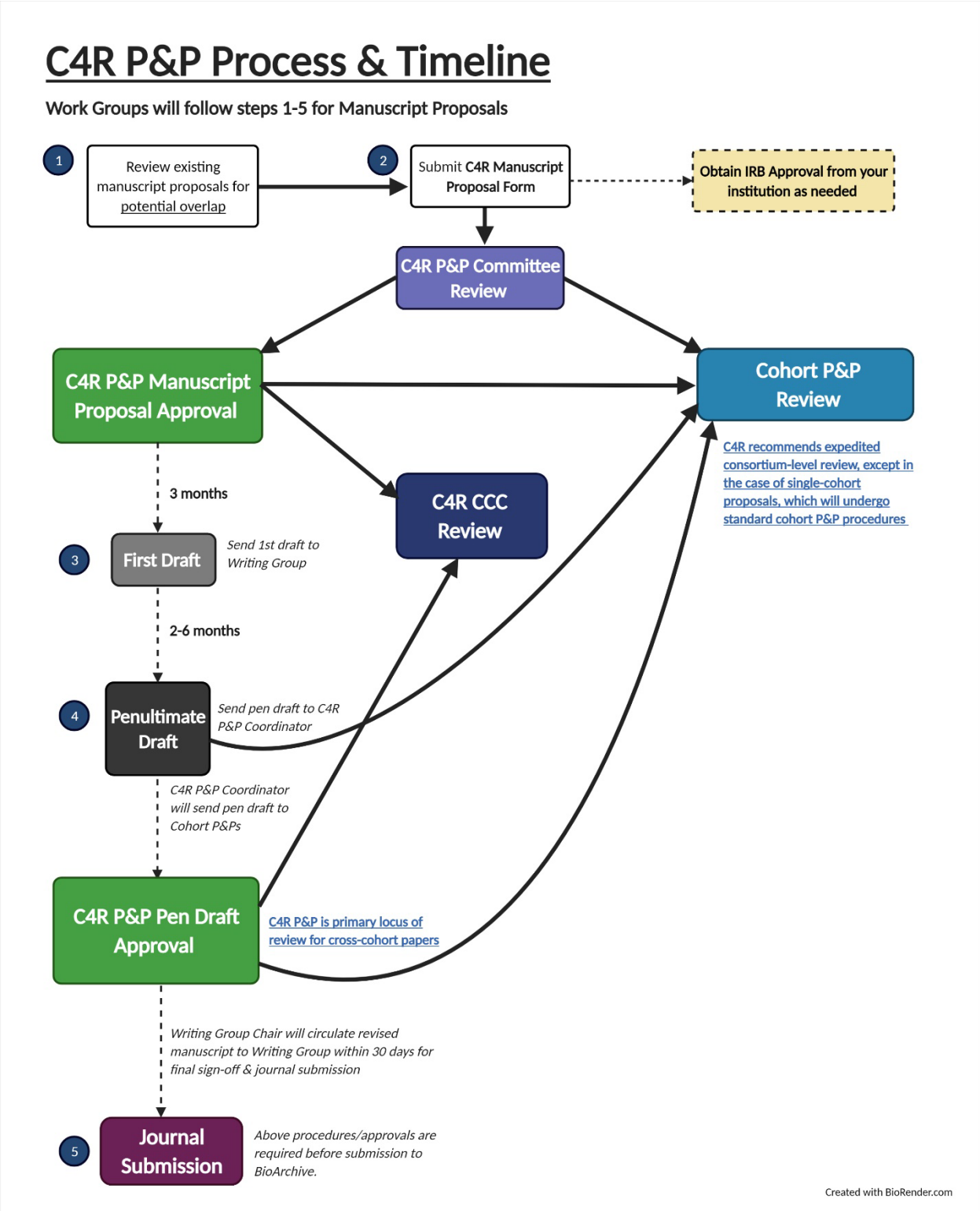
The P&P Committee will report to the C4R Cohort Coordinating Committee (CCC) on all matters relating to the publications or presentations of C4R material.

All communications to the P&P Committee should be sent to: c4r@cumc.columbia.edu.

II. Objectives

- To encourage and facilitate high quality data analysis;
- To stimulate scientific presentations and manuscript publication;
- To ensure and expedite orderly and timely reports to the scientific community of results from C4R;
- To ensure that abstracts, presentations, and publications based on C4R material are accurate and objective, and do not compromise the scientific integrity of this collective study;
- To ensure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide C4R papers;
- To establish procedures that allow the C4R CCC and NIH to exercise review responsibility in a timely fashion for C4R publications and presentations;
- To encourage manuscripts based on the information collected from all C4R study sites and cohorts;
- To prevent duplication of published material.
- To disseminate key findings to participants and the general public

III. Procedures



A. Papers

Potential Overlap

It is the first author's responsibility to avoid overlap with manuscripts already in progress or published. Approved manuscript proposals and published articles will be listed on the internal (investigator-only) C4R website to help investigators in their planning. Authors should review previously-approved proposals and C4R published manuscripts for potential overlap with a new proposal. They should indicate directly on the manuscript proposal form which (if any) proposals could potentially overlap with the new proposal, as well as those which are most similar. Authors should describe how the proposal is different from those with potential overlap (if any) or major similarities, in the space provided in the form. Collaboration among C4R members and proposals is strongly encouraged.

Submission of a Proposal for a Paper

Any proposal to use data funded by the C4R OTA should be submitted to the C4R P&P.

Submission will consist of a written manuscript proposal to the P&P Committee submitted via email attachment (word document) using the form available on the Publications page of the C4R website. See: C4R Manuscript Proposal Submission Form.

The form will be approved by the C4R P&P and the cohort P&P when a cohort's participants are involved. If a C4R cohort's participants are not included in an analysis, that cohort P&P will receive the proposal but approval will not be required. The C4R manuscript proposal form includes the following sections:

1. Project Title
   C4R policy requires that authors include the study name, "Collaborative Cohort of Cohorts for COVID-19 Research," at the end of their manuscript title. The only exception is when the Journal restricts the number of words allowed in the title or the paper combines data from multiple similar studies.
2. List similar C4R proposals and describe any potential overlap, as well as ways that the new paper is different
3. Writing Group Chair(s)
4. C4R Cohort inclusion table (includes listing of proposed co-authors)
5. Specific aims and hypotheses
6. Rationale (300 words maximum)
7. Data to be used (exposure(s), outcome(s), and covariate variables needed)
8. Analysis plan (primary analyst(s) and brief statistical plan, organized by specific aim)
9. Additional considerations of primary importance to C4R approval
    - Inclusion of women and minorities
        - Treatment of sex as a biological variable
        - Analysis and interpretation of differences by race and ethnicity when appropriate
    - Consideration of social determinants of health
    - Use (or non-use) of genetic data
    - Respect for data sharing restrictions on Strong Heart Study data

Important: proposals should be no more than 4 pages in length, excluding the references. Proposals exceeding 4 pages will not be accepted.

Authorship

For each cohort included in a proposal, at least one investigator must be included from that cohort. If a C4R cohort is not included in the sample for an analysis, inclusion of an investigator from that cohort is encouraged but not required. Investigators from the C4R DCHC and NIH C4R project officers should be offered the opportunity to participate as co-authors. In all cases, the CCC may nominate additional authors at its discretion. The CCC will also determine if "for the C4R Investigators" can be excluded at the end of the authorship block.

For each manuscript proposal, C4R requires a Senior author who will act as the responsible, sponsoring author. C4R expects that the Senior author will be an experienced investigator and familiar with P&P policies and procedures. The Senior author is responsible for advising the first author concerning these procedures and C4R P&P deadlines for submission of abstracts, proposals and manuscripts. (This role is only for the C4R review process. Once a pen draft receives C4R approval, any member of the writing group can assume the corresponding author role for submission to a journal.)

Usually the manuscript proposer will be designated as the Writing Group Chairperson and first author of the paper. He/she will receive written notification of approval by the P+P and CCC of the proposal and the penultimate draft. The WG Chair responsibilities are found below. In general, an investigator should only have two study (active) proposals which haven't yet progressed to the pen draft stage in which he\she is the Writing Group Chairperson (first author).

All proposals from investigators are to be submitted with the knowledge of their PI.

All coauthors must have seen and **approved** the manuscript proposal prior to submission.

Timing

Proposals will not be considered by the committee unless it is feasible to begin data analysis within 6 months of proposal approval. C4R encourages proposals for manuscripts with data availability such that the manuscript can be completed in this time frame.

Types of manuscripts

Single cohort versus cross-cohort proposals

Manuscripts may include only one C4R cohort (single-cohort proposal) or two or more C4R cohorts (cross-cohort proposal).

Upon receipt of a single-cohort proposal, the C4R P&P then CCC will determine if it will recommend that additional C4R cohorts be added to the proposal, which would convert it into a cross-cohort proposal.

If the C4R recommends that the proposal should remain a single-cohort proposal, it will notify the authors and forward the proposal to the cohort-specific P&P for review according to their standard procedures.

The C4R P&P will be the primary locus of review for cross-cohort proposals. Nonetheless, proposals will be forwarded to all C4R cohort P&Ps for review. C4R cohorts with participants included in the analysis will be required to approve the proposal in order for publication to proceed. For efficiency, C4R recommends expedited cohort-level review, so as not to be duplicative with C4R review. It is hoped that cohorts will eventually cede full review to the C4R process, which has representatives from the cohort involved. Meanwhile, C4R cohorts without participants included in the proposed analysis will receive C4R proposals for information purposes, but their approval will not be required for publication to proceed.

COVID-19 pandemic papers versus non-pandemic papers

We anticipate that there may be three types of manuscripts that propose to use C4R data. First, there will be "COVID-19 papers," defined as manuscripts that treat SARS-CoV-2 infection and/or COVID-19 illness as an exposure or outcome. Second, there will be "pandemic papers" that propose to analyze pandemic impacts (e.g., pandemic-related changes in mood or behavior). Third, there will be "non-pandemic papers," or manuscripts that aim to use data harmonized by C4R to study conditions unrelated to the COVID-19 pandemic.

The C4R P&P will be the primary locus of review for COVID-19 and pandemic papers. The review procedures for non-pandemic papers that use C4R harmonization resources have not yet been established.

C4R-TOPMed papers

C4R proposals that require TOPMed data will be reviewed according to TOPMed P&P processes and guidelines. While the C4R P&P will not duplicate review of initial C4R-TOPMed proposals, a copy of these proposals should be submitted to c4r@cumc.columbia.edu for reference. Penultimate (pen) draft manuscripts must be approved by co-authors, TOPMed PIs, and cohort P&Ps prior to journal submission. In addition, we propose that the C4R P&P Committee retain the right and responsibility to review and approve the C4R-TOPMed pen draft prior to journal submission. The scope of the C4R P&P review of the C4R-TOPMed pen draft will include, but will not be limited to, confirmation of appropriate C4R authorship and funding acknowledgements. More information on TOPMed can be found here: https://topmed.nhlbi.nih.gov/.

Approval of manuscript proposals by the C4R P&P

The primary aims of P&P manuscript proposal review will be to assure appropriate inclusion of cohorts and authors, and assure the feasibility, interpretability, and validity of proposed analyses.

All P&P members will review each proposal. Approval will be determined by majority vote, supervised by the Chair. Comments and recommendations will be shared with the Writing Group.

Upon approval by the P&P Committee, the proposal will be assigned a manuscript number for a C4R database and will be visible on the internal, investigator-only website. Approval status will be forwarded to included C4R cohort P&Ps. The approved proposal will then be submitted to the C4R CCC for approval, which may include additional writing group nominations. Proposals with NIH co-authors will additionally require NIH approval.

P&P Membership

The P&P will include one member for each cohort. Inclusion of investigators serving concurrently on their cohort's P&P committee is strongly encouraged. A chair and co-chair will be nominated by the committee and may be rotating, if preferred.

The P&P Coordinator will review the proposal to verify that the P&P policies have been followed.

Writing Group Responsibilities

The Writing Group Chair is responsible for all phases of manuscript preparation, from conception through publication. These responsibilities include:

- Assure all C4R publication policies are followed;
- Prepare outlines and identify data analyses needed;
- Assign tasks to Writing Group members with clear deadlines for completion, and assure that tasks are completed on schedule;
- Prepare and circulate one or more drafts for approval by each member of the Writing Group before submission of a Penultimate Draft to the P&P Committee and before submission to a journal;
- Determine the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript. In most cases, if the data analyst is not the WG chair, they should be listed as second author;
- Choose the journal to which the manuscript will be submitted, with advice of coauthors;
- Correspond with coauthors, communicate with the DCHC and the P&P Committee, respond to the CCC and NIH reviews, and to journal editors.

Author responsibilities

The Writing Group Chairperson should communicate with each member of the Writing Group to discuss the outline of the paper, data analysis plan, and the responsibilities and assignments for each member. Members of the Writing Group are responsible for performance of tasks within the allotted time period as assigned by the Chairperson. Each member is expected to actively participate in the preparation of the manuscript.

All coauthors should let the Writing Group Chairperson know of a change in contact information. Failure to respond within a reasonable amount of time to a Chairperson's request for coauthor feedback, could result in removal from the Writing Group.

If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she may be removed from the Writing Group. The chairperson must send an email to the P&P Program Coordinator requesting the removal of non-contributing members; this request will be reviewed by the C4R P&P Committee.

If the initial results lead to a split of the original paper into more than one manuscript, a new proposal must be submitted to the P&P Committee and relevant cohort committees following the above procedures.

If the work plan is modified in a substantial way, an addendum to the approved manuscript proposal must be submitted to the C4R P+P and relevant cohort P+Ps with a cover note of brief explanation and relevant changes tracked.

Schedule for Manuscript Preparation

The expected schedule for the development of a manuscript is described below. Deviation from this schedule must be approved by the P&P Committee. Failure to adhere to this schedule will prompt a review of circumstances. If it is determined that a manuscript is delinquent, this could be the basis for replacing member(s) of the Writing Group responsible for the delay, or for disbanding the Writing Group.

For single-cohort proposals, approval by the cohort P&P is required prior to initiating data analysis. For cross-cohort proposals, approval by the C4R P&P will be sufficient to initiate data analysis, although approvals from all cohort-level P&Ps, and incorporation of relevant comments to the authors, will be a prerequisite to pen draft approval.

Draft. After notification by the P&P Committee of manuscript approval and the availability of data, the Writing Group will have three (3) months to prepare a first draft. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. This draft should be sent to the members of the Writing Group. A response deadline of 2-3 weeks for Writing Group members is recommended to prevent unnecessary delays.

Penultimate Draft. The penultimate draft is due no later than 6 months after the first draft is distributed to the Writing Group. Given the pandemic issues we are studying, we expect most manuscripts to be completed more quickly than 6 months. A penultimate draft should be sufficiently developed for submission to a journal. After review and approval of the penultimate draft by Writing Group members, the penultimate draft is sent to the P&P Coordinator as an email attachment. The C4R P&P will forward the pen draft to all included cohort P&Ps. As for manuscript proposals, the primary locus of review will be the C4R P&P for cross-cohort papers, and the single cohort P&P for single-cohort papers.

Authors must include the following required information with each new pen draft:

1. C4R manuscript number (examples: MC 001, AC 025)
2. Confirmation that all included cohort P&Ps have **approved** the manuscript proposal
3. Confirmation that all coauthors have **approved** the manuscript prior to submission
4. Specify the first target journal for submission

Review/Deadlines. The P&P Program Coordinator will include manuscript submissions in the next available P&P Committee teleconference. To allow sufficient time for processing and review, please submit all manuscripts by noon Eastern Time on Monday of the week before the next P&P teleconference. Refer to P&P Meetings and Paper Submission Deadlines located at the very top of the Publications page (on the internal website) for teleconference dates and deadlines.

The P&P Committee will review each manuscript followed by a discussion during a P&P Committee conference call. A primary reviewer will be assigned, and will complete a checklist and form with major points of criticism and advice about approval. Key factors in the review are that authors followed their proposed plan, study policies were followed, that all authors reviewed and approved the draft, that the manuscript reflects well on C4R and correctly interprets results with appropriate discussion of limitations, that there is no misrepresentation of C4R or the cohorts involved and that C4R and specific cohort funding sources and a standard acknowledgements section are included. Afterward, the Writing Group Chair (and the senior C4R author) will be sent a summary of any pertinent reviewers' comments. If a manuscript is not approved by the P&P Committee, the draft will be returned to the Writing Group Chairperson with comments regarding the necessary revisions requiring resubmission.

If it is approved, it will be forwarded to the C4R CCC for review within two and a half (2 ½) weeks. The CCC members will vote to approve, approve with revision or disapprove. Approval status will also be communicated via email to all included cohort P&Ps.

Funding Citations

All publications and abstracts using C4R data or having C4R support for any of the authors' contributions to the manuscript must include the statement below:

> "The research was, in part, funded by the National Institutes of Health (NIH) Agreement 1OT2HL156812. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the NIH."

Cohort-specific funding statements should be obtained from the individual cohorts.

CONNECTS/NHLBI Clearance for Manuscript Submission

Once reviewed and approved by the lead study investigators, C4R P&P, C4R CCC, and included cohort P&Ps, all manuscripts are to be submitted to NHLBI and the CONNECTS Administrative Coordinating Center (ACC) prior to journal submission.

- The P&P Coordinator will send penultimate version of manuscript to their CONNECTS ACC contact and to Tony Punturieri at NHLBI (punturieria@nhlbi.nih.gov).
- NHLBI will confirm clearance to submit.
- CONNECTS ACC will review accuracy of the funding citation.

NHLBI and CONNECTS ACC will provide a rapid response within no more than 3-5 business days.

Preprint server policy as of January 2021:
Authors can post to a preprint server after full approval is given for a pen draft by the C4R P&P, the C4R CCC, included cohort P&Ps, and CONNECTS/NHLBI. The C4R P&P should be notified.

Journal Submission. Within thirty (30) days of receiving CCC and P&P Committee comments and verification confirmation, the revised manuscript will be circulated by the writing group chair to the Writing Group for final sign-off.

The manuscript will immediately be submitted to a journal.

The Writing Group Chairperson must keep the coauthors informed as to the manuscript's progress through journal review. Upon publication of the manuscript, the Writing Group Chair must provide an electronic copy of the final publication to the P&P Committee. If there are substantive changes made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the P&P Committee for re-review.

In order to stay informed of findings and to prepare for press queries, the NIH Project Offices would like a courtesy copy of all manuscripts at the time of journal acceptance or before, for particularly for "high-profile" papers, which will be identified by the CCC review. These generally include the following:

- Main results or key secondary results
- Papers with direct clinical implications, particularly if they impact NIH policies
- Papers on potentially sensitive topics
- Papers published in high impact journals, such as Nature, Nature Genetics, Science, NEJM, JAMA, and Lancet.

Letters to the Editor. If an author chooses to write a letter to the editor instead of a manuscript, please contact the P&P Coordinator to get instructions. This is rare and will be handled on a case-by-case basis.

When the author already has an approved manuscript (pen draft), the following policy for additional letters to the editor and/or response letters is as follows:

As a general rule, P&P will not review letters to the editor, including response letters. New data should not be presented or published unless it is part of an approved paper that went through the standard C4R review/approval process. If new analysis is included since it was in the scope of the involved manuscript proposal, a copy of the letter should be submitted as informational to the P+P. Also, all coauthors (on the approved manuscript) need to review/approve a letter to the editor.

B. Abstracts

Preparation and Submission of Abstracts for Submission to Conferences

New abstracts must be based on an approved C4R proposal or submitted or published manuscript.

An abstract based on an approved proposal should be submitted to the P&P Committee for review no less than 2 weeks before the conference (abstract) submission deadline. It is strongly advised that authors submit abstracts well before this deadline, in order to allow sufficient time for revisions. **There is no guarantee that abstracts submitted after the P&P deadline will be approved prior to the conference deadline**.

New abstracts must be submitted as an email attachment (word document) to c4r@cumc.columbia.edu.

The P&P Coordinator will notify the first author (via email) when P&P Committee approval is received.

If the abstract is accepted, a copy of presentation materials (including tables and graphs) and text are to be submitted to the P&P Program Coordinator as an email attachment for informational purposes.

C. Data Requests

Special analysis requests to the C4R DCHC by an investigator for the purpose of development of a grant application, hypothesis generation and power calculations should be submitted to the P&P Chair for review and approval by the C4R P&P and CCC.

Data analysis requests for theses or dissertations should go through the P&P Committee with the above processes as for a manuscript and it is expected the work will be published.

IV. C4R Common Proposal Form

Project title:

Lead investigator(s):
Writing Group Chair:
Senior C4R author:

Potential overlap
- Among approved C4R proposals (see website), which ones are the most similar to this proposal?
- Is there any potential overlap? Please explain and describe
    - If there is potential overlap, please summarize how this proposal is different

IRB Approval
- Does your institution have IRB approval for C4R?
    - If yes, are you included on your institution's IRB?

Funding
- Is there any funding anticipated for this proposal?
    - Source of funding and date of submission:
    - Timeline:

C4R cohort inclusion table:

Cohorts	Include: Yes / No	Co-author*	Comments**
ARIC			
CARDIA			
COPDGene			
Familial Interstitial Pneumonia/PrePF			
Framingham			
Jackson Heart Study			
HCHS/SOL			
MASALA			
MESA			
NOMAS			

REGARDS			
SARP			
SPIROMICS			
Strong Heart Study			
Other***			

*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

Do these aims relate to any of the C4R core research questions listed below? Please check all that apply.

☐ What are the major determinants of incidence and clinical severity of SARS-CoV-2 infection, and related disparities, across the US general population?

☐ What subclinical cardiopulmonary disorders increase the risk of severe COVID-19?

☐ What are the pulmonary complications of SARS-CoV-2 infection and COVID-19 illness and the risk of their occurrence?

☐ What are the risks of cardiovascular and cerebrovascular complications following SARS-CoV-2 infection?

☐ What are the neurological, cognitive, and psychiatric complications, including stroke, cognitive decline, and dementia, of COVID-19, and what are the predictors of persistent or delayed symptoms from COVID-19?

☐ How does lung structure associate with COVID-19 severity?

☐ Does COVID-19 cause long-term changes in lung structure?

☐ How do features of the innate and adaptive immune systems affect SARS-CoV-2 susceptibility?

☐ How do thrombo-inflammatory and endothelial activation profiles associate with risk of severe COVID-19 illness?

Rationale (300 words maximum)

Significance	
Relevant prior literature	
Summary of proposed study	
Justification for use of C4R	

Data: Please indicate what C4R, cohort, or de novo data will be needed to accomplish the Aims.

- **C4R data** is defined as data collected under the C4R OT agreement: the wave 1 and wave 2 questionnaires, COVID events ascertainment, and the dried blood spot serosurvey.
- **Cohort data** is defined as data collected by the C4R cohorts as part of funded exams and ancillary studies. Ancillary study data use must be discussed with the relevant PI.
- ***De novo* data** is defined as data that you would like to collect as part of a new study. This requires ancillary study approval by C4R and also each included cohort and should be discussed with the C4R PI prior to proposal submission.

In filling out the following table, please review the **C4R data dictionary**, which includes C4R collected-data and selected cohort data. Inclusion of specific variable names from the data dictionary will expedite review. **Papers that do not include a COVID-related exposure or outcome are not suitable for review by the C4R P&P.**

	Variables needed	Details, questions and comments*
Outcomes	**COVID-Related outcomes** ☐COVID Infection ☐Acute COVID symptoms ☐COVID Severity ☐COVID Hospitalization ☐Death due to COVID ☐SARS-CoV-2 serology ☐Recovery from COVID ☐Reinfection with SARS-CoV-2 ☐Testing for SARS-CoV-2 ☐COVID Vaccine ☐Medications for COVID ☐COVID attitudes and beliefs ☐Behavior related to COVID ☐COVID exposures and risk mitigation ☐COVID pandemic effects on healthcare and finances ☐COVID Information sources ☐Psychosocial effects of COVID	*Please provide as much detail as possible regarding your primary and secondary outcomes and the population(s) in which they will be classified (e.g., infected participants only).*

	☐Other COVID-related outcome: please comment in detail in the box on the right **Other outcomes** ☐Cardiovascular ☐Pulmonary ☐ Neurocognitive ☐Renal ☐Biomarkers ☐Psychosocial ☐Behavioral ☐Other non-COVID outcome: please comment in detail in the box on the right	
Exposures	**COVID-Related exposures** ☐COVID Infection ☐Acute COVID symptoms ☐COVID Severity ☐COVID Hospitalization ☐Death due to COVID ☐SARS-CoV-2 serology ☐Recovery from COVID ☐Reinfection with SARS-CoV-2 ☐Testing for SARS-CoV-2 ☐COVID Vaccine ☐Medications for COVID ☐COVID attitudes and beliefs ☐Behavior related to COVID ☐COVID exposures and risk mitigation ☐COVID pandemic effects on healthcare and finances ☐COVID Information sources ☐Psychosocial effects of COVID ☐Other COVID-related outcome: please comment in detail in the box on the right **Other exposures** ☐Cardiovascular ☐Pulmonary ☐Neurocognitive ☐Renal ☐Biomarkers	*Please provide as much detail as possible regarding your primary and secondary outcomes and the population(s) in which they will be classified (e.g., infected participants only).*

	☐Psychosocial ☐Other non-COVID exposure: please comment in detail in the box on the right	
Covariates		

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

Analysis plan

- Primary analyst(s):
- Brief statistical plan, organized by specific aim

Table Shells

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 & Jackson Heart Study data

References:

V. Checklist for Authors

Senior Author	Writing Group Chairperson/First Author	Co-Authors
Experienced investigator familiar with P&P policies and procedures ❑ Advises the first author concerning procedures and C4R P&P deadlines for submission of abstracts, proposals and manuscripts	*Manuscript proposer will (usually) be designated as Writing Group Chairperson & first author* ❑ Responsible for avoiding overlap with manuscripts already in progress or published ❑ Submits a manuscript proposal to the C4R P&P ❑ Assures all C4R publication policies are followed; ❑ Prepares outlines and identifies data analyses needed; ❑ Assigns tasks to Writing Group members with clear deadlines for completion, and assures that tasks are completed on schedule; ❑ Prepares and circulates one or more drafts for approval by each member of the Writing Group before submission of a Penultimate Draft to the P&P Committee and before submission to a journal; ❑ Determines the order of authorship on the manuscript ❑ Chooses the journal to which the manuscript will be submitted, with advice of coauthors; ❑ Corresponds with coauthors, communicate with the DCHC and the P&P Committee, respond to the CCC and NIH reviews, and to journal editors	❑ Responsible for performance of tasks within the allotted time period as assigned by the Chairperson ❑ Actively participates in the preparation of the manuscript ❑ Lets the Writing Group Chairperson know of a change in contact information ❑ Responds within a reasonable amount of time to a Chairperson's request for coauthor feedback ❑ Approve manuscript prior to submission

VI. Checklist for Primary Reviewers of Pen Drafts

Primary Reviewer Responsibilities
❑ Confirm appropriate inclusion of cohorts and authors ❑ Confirm all coauthors have reviewed and approved the manuscript ❑ Confirm authors have followed the proposed plan and study policies ❑ Confirm manuscript reflects well on C4R and correctly interprets results with appropriate discussion of limitations ❑ Confirm inclusion of specific cohort funding sources and a standard acknowledgments section