

## Requirements for Penultimate Manuscript Draft Submission to PubExec

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1. After review and approval of the penultimate draft by writing committee members, the writing committee chair or designee will email the following documents to the SDCC project manager for review by the Pub-Exec Committee:
  - a. Penultimate manuscript draft
  - b. Cover letter
  - c. Completed Manuscript Submission Checklist (attached)
  - d. The applicable documents listed in #4 below

### Cover letter to include:

- a. Statement that penultimate draft is ready for review.
  - b. An explicit statement from the Writing Committee chair confirming that the manuscript is consistent with the scope reflected in the originally approved manuscript proposal. If the manuscript is not consistent with this scope an explanation for this must be provided. The Pub Exec SC will then review the scope approved in the original manuscript proposal to ensure that it is consistent with the current submission.
  - c. An explicit statement that the penultimate draft being submitted was circulated to all Writing Committee members.
  - d. An explicit statement describing the grants and grant numbers that are acknowledged in the body of the draft manuscript.
2. In accordance with the publications policy requirement, please add “**and the CRIC Study Investigators**” to your author list. This should be marked to direct readers to the list of authors provided below. If any of the individuals in this list are specifically listed as authors, only list the names of the individuals who are not.

Amanda H. Anderson PhD, MPH  
Lawrence J. Appel, MD, MPH  
Jing Chen, MD, MMSc, MSc  
Debbie L Cohen, MD  
Laura M Dember, MD  
Alan S. Go, MD

James P. Lash, MD  
Mahboob Rahman, MD  
Panduranga S. Rao, MD  
Vallabh O. Shah, PhD, MS  
Mark L. Unruh, MD, MS

3. Please include the NIDDK grant numbers for the CRIC Study as well as the grant numbers for the clinical centers involved in the collection of your data. Recommended text:

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Funding for the CRIC Study was obtained under a cooperative agreement from National Institute of Diabetes and Digestive and Kidney Diseases (U01DK060990, U01DK060984, U01DK061022, U01DK061021, U01DK061028, U01DK060980, U01DK060963, U01DK060902 and U24DK060990). In addition, this work was supported in part by: the Perelman School of Medicine at the University of Pennsylvania Clinical and Translational Science Award NIH/NCATS UL1TR000003, Johns Hopkins University UL1 TR-000424, University of Maryland GCRC MO1 RR-16500, Clinical and Translational Science Collaborative of Cleveland, UL1TR000439 from the National Center for Advancing Translational Sciences (NCATS) component of the National Institutes of Health and NIH roadmap for Medical Research, Michigan Institute for Clinical and Health Research (MICHR) UL1TR000433, University of Illinois at Chicago CTSA UL1RR029879, Tulane COBRE for Clinical and Translational Research in Cardiometabolic Diseases P20 GM109036, Kaiser Permanente NIH/NCRR UCSF-CTSI UL1 RR-024131, Department of Internal Medicine, University of New Mexico School of Medicine Albuquerque, NM R01DK119199.

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4. **If analysis was done locally, submit the documents listed below with the penultimate draft.** The SDCC will determine if the penultimate draft will or will not be selected for analysis verification according to pre-determined criteria.

Submission to a journal should not take place until the writing committee chair is notified whether or not the manuscript was selected for verification, and if selected, that the verification of analysis has been completed; and after notification of PubExec approval.

#### A. Summary of analysis, including:

1. Details on how to derive the final dataset from the dataset provided by the SDCC, including added variables, deleted records and changed data elements (e.g., out-of-range values set to missing).
2. Definitions for all derived variables, Including information on handling missing values

3. The dataset used, variables used (with variable names in the order that they appear), sample size and statistical methods used for each table, figure, and numerical or statistical claim in the text.
  4. Sample code for all statistical methods. For example, when two groups were compared, provide SAS (or STATA) code for calculating the p values. For models, provide code for the model. If there are multiple p values provided for the same statistical procedure, specify which p values were used.
  5. Note that the explanations in this summary should be clear and sufficiently detailed for another analyst to replicate all analysis accordingly. Unclear explanation may lead to delays in the completion of verification analysis.
- B. Final dataset(s):
1. All variables should be labeled
  2. Formats should be provided for all categorical variables
- C. Analytical programs that were used to generate all numbers that appear in the text, figures, and tables or support statistical claims.
- D. The manuscript to be submitted, including all tables, figures, appendices, and supplemental tables.

### **If selected for analysis verification**

After penultimate draft approval and journal submission:

- If reviewers' comments necessitate analyses revisions that require Biostats effort, send the reviewer comments and due date to journal to the SDCC project manager, biostat faculty, and biostats analyst as soon as possible.
  - During the journal submission/resubmission process, any revisions made to address reviewer comments or for resubmissions to other journals must be submitted to the Biostats faculty and analyst for re-verification.
5. All manuscripts that include ESRD and/or death outcomes include data obtained from USRDS and are subject to USRDS requirements. Attached please find the Planned USRDS Publications: Checklist for Approval Requests for your review. Per the USRDS checklist, the following requirements must be met prior to submission to a journal:
1. The manuscript should include the following USRDS citation  
U.S. Renal Data System. 2022 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2022.
  2. The manuscript should include the following USRDS disclaimer  
"A portion of the data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government."
  3. Manuscripts using USRDS data must be submitted for privacy assurance review to the USRDS Coordinating Center (CC) at [USRDS@niddk.nih.gov](mailto:USRDS@niddk.nih.gov). The email should include the following:
    - Please use the subject line: "USRDS manuscript"
    - Please include the name of the journal for planned submission
    - Indicate the USRDS Data Use Agreement number: 2019-11b
    - Indicate if the USRDS CC has a copy of your current IRB approval, or attach the current approval letter in your email to USRDS (local approval if applicable)
    - Indicate the funding source, specifically NIH funding and grant number in your email to USRDS

## CRIC Manuscript Submission Checklist

| <b>Summary Information</b>  |             |
|---|-------------|
| <b>Date:</b>  | <b>MS#:</b> |
| <b>Full Proposal Title:</b>   |             |
| <b>Elements Required for Review</b>   |             |
| <input type="checkbox"/> Manuscript title includes “ <b>CRIC</b> ” acronym (if possible)  |             |
| <input type="checkbox"/> List of authors includes “ <b>and the CRIC Study Investigators*</b> ” and lists the following authors:<br><i>Amanda H Anderson PhD, MPH; Lawrence J. Appel, MD, MPH; Jing Chen, MD, MMSc, MSc; Debbie L Cohen, MD; Laura M Dember, MD; Alan S. Go, MD; James P. Lash, MD; Mahboob Rahman, MD; Panduranga S. Rao, MD; Vallabh O Shah, PhD, MS; Mark L. Unruh, MD, MS.</i>   |             |
| <input type="checkbox"/> <b>Acknowledgments include a description of the grants and grant numbers</b><br>(e.g., grants to the SDCC, to all clinical centers whose data were included)   |             |
| <input type="checkbox"/> Acknowledgments include grant numbers for site-specific CTSA/GCRCs   |             |
| <input type="checkbox"/> Confirmation that a minimum of 1 writing committee conference call was conducted   |             |
| <input type="checkbox"/> Confirmation that a minimum of 2 manuscript drafts were circulated to the writing committee  |             |
| <input type="checkbox"/> Confirmation that the writing committee members both received and approved the penultimate draft   |             |
| <input type="checkbox"/> Cover letter submitted stating that the penultimate draft is ready for review including: <ul style="list-style-type: none"><li><input type="checkbox"/> an explicit statement from the Writing Committee chair confirming that the manuscript is consistent with the scope reflected in the originally approved manuscript proposal (if manuscript is not consistent with original scope an explanation must be provided)</li><li><input type="checkbox"/> an explicit statement confirming that all co-authors were provided with the penultimate draft being submitted for PubExec review</li><li><input type="checkbox"/> an explicit statement describing the grants and grant numbers that are acknowledged in the body of the manuscript (including CTSA/GCRC grant numbers)</li></ul>   |             |
| <input type="checkbox"/> Name of journal to which the manuscript is being submitted   |             |
| <input type="checkbox"/> Statement that contributing authors have adhered to the authorship guidelines outlined by the target journal   |             |
| <input type="checkbox"/> Statement confirming that you have reviewed the Planned USRDS Publications:<br>Checklist for Approval Requests and have satisfied the following requirements: <ul style="list-style-type: none"><li>• Submitted the penultimate draft for privacy assurance review to the USRDS Coordinating Center (CC) at <a href="mailto:USRDS@niddk.nih.gov">USRDS@niddk.nih.gov</a>. <b>The email should include the following information:</b><ul style="list-style-type: none"><li>○ Please use the subject line: “<b>USRDS manuscript</b>”</li><li>○ Name of the journal for planned submission</li><li>○ Indicate the <b>USRDS Data Use Agreement number: 2019-11b</b></li><li>○ Indicate if the USRDS CC has a copy of your current IRB approval, or attach the current approval letter in your email to USRDS (local approval if applicable)</li><li>○ <b>Indicate the funding source, specifically NIH funding and grant number in your email to USRDS</b></li></ul></li><li>• Manuscript includes USRDS citation</li><li>• Manuscript includes USRDS disclaimer</li></ul> |             |
| <b>Upon Journal Review/Publication</b>  |             |
| <input type="checkbox"/> Copy of the journal’s letter of acceptance, request for revisions, or letter of rejection provided to the Pub Exec Subcommittee  |             |
| <input type="checkbox"/> Reprint or copies of the final publication provided to Pub Exec subcommittee   |             |