CHRONIC KIDNEY DISEASE EPIDEMIOLOGY COLLABORATION GFR ESTIMATING EQUATION DEVELOPMENT AND VALIDATION

Organizational Structure, and Publications, Presentations, and Ancillary Studies Policies

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Section A: Background and Organization

The CKD Epidemiology Collaboration (CKD-EPI) is a research group with interests in measurement and estimation of GFR (CKD-EPI GFR) and evaluation of surrogate endpoints for clinical trials in CKD (CKD-EPI CT). CKD-EPI was founded by Dr. Andrew S. Levey who served as Director from 2004 to 2018 and continues to serve as co-director. Dr. Lesley A. Inker has been the Director of the Data Coordinating Center (DCC) from 2004 and Co-Director since 2018.The goal of the CKD-EPI GFR is to develop and validate accurate GFR estimating equations for use in clinical practice across diverse populations of age, GFR, disease, race, ethnicity and geography.

The purpose of this document is to detail plans for the manuscripts and presentations and ancillary studies by CKD-EPI group.

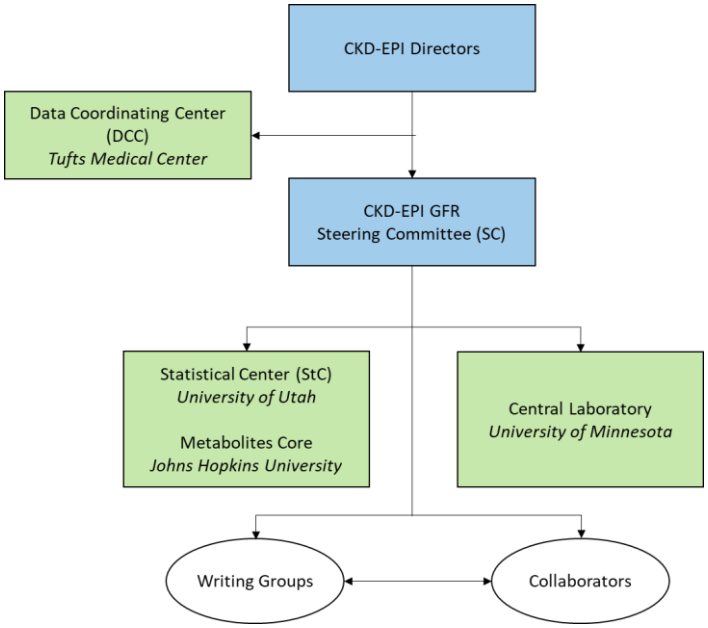

Figure 1. Organization of CKD-EPI

The Steering Committee (SC) guides the overall direction and policies. Drs. Lesley A. Inker, Andrew S. Levey, Josef Coresh, and Tom Greene are members of the SC. The Data Coordination Center (DCC) is at Tufts Medical Center. The Statistical Core (StC) is at the University of Utah. Ben Haaland PhD joins Dr. Greene at the StC. The Central Laboratory is at the University of Minnesota. Dr. John Eckfeldt was the previous Director of the Central Laboratory, while Dr. Amy Karger is the current director.

Section B. Selection of Topics for Analyses

B1. Main topics

The main topics are that which are described in the grant application funding the current work. The steering committee will vet specifics manuscripts that arise from the main topics and also consider related analyses that were not specified in the grant application but are related to the overall goals.

B2. Ancillary topics

Ancillary topics are those proposed for the use of CKD-EPI CT data. The analyses require additional funding to the DCC to perform analyses. The role of the SC will be to consider the scientific merits of the proposal, to determine the nature of the StC input required, to ensure that the DCC and StC have adequate time to perform the analyses without detracting from the main analyses, and that a robust publication plan has been considered. If the SC determines that these criteria have been met, the proposal will be forwarded to the StC for their review and comments. If the SC does not determine the proposal has merit, it will not be forwarded for StC for review.

All collaborators will have the opportunity to opt in or opt out of every analysis.

A detailed description of the procedure to submit proposals for ancillary studies is given in Section D3 of this document.

Section C: Dissemination of Results, Publications and Presentations Policy

C1. Authorship – general principles

All publications from the CKD-EPI follow approved authorship formats, as described below. All abstracts and manuscripts will be written by a writing committee, with initial drafts by first and last authors and DCC. All collaborators of the CKD-EPI whose data were included in a manuscript may participate in writing committees. StC and DCC members may participate as appointed by SC. All authors and collaborators have full access to the results from all analyses. Other collaborators (up to 4 per study in addition to the author) will be acknowledged in the manuscript as CKD-EPI collaborators. Subject to specific journal policies, the goal is to have CKD-EPI collaborators indexed in PubMed. All authors are expected to review all manuscripts. Manuscripts will also be sent to the CKD-EPI collaborators who are not included in the writing groups, from whom data have been used for the analyses, for review and comment.

C2. Formation of Writing Committees

Main topics

The DCC will send out a questionnaire inviting volunteers for writing groups. All CKD-EPI collaborators who contributed data to a specific manuscript may volunteer to participate in the writing committee for each paper. SC, DCC, and StC members' interest will also be elicited. Writing groups for secondary topics can also include other interested parties, such as statisticians engaged in the research area or investigators with

experience in this topic. The DCC will compile the list of volunteering investigators and will review with the SC, who has the final authority on the composition of the writing committee. If there are more volunteers than able for a particular study, we will give consideration primarily to those with submitted their requests first, but also with consideration to those investigators with prior work or publications in the field.

The SC will assign the first or last author of the writing committee and its members. The exception will be if a paper highlights selected studies, then one collaborator from each of those studies will be included even if they or other collaborators from that study are already participating in a writing group.

Ancillary topics

CKD-EPI collaborators may submit written proposals to the SC, as detailed in the Ancillary Studies Policy (Section D).

If approved, the "proposer" of the ancillary manuscript shall be the chair of the writing committee, unless decided otherwise by the SC. Reasons for a change will be discussed with the proposer prior to a decision. The DCC will notify CKD-EPI collaborators, who may volunteer to participate in the writing committee.

The DCC will assign the other members of the writing committee, after discussion with the chair, and based on the volunteers. Members of the DCC or StC will be included in the ancillary study writing committees.

A more detailed description of the formation of writing committees and the procedure to submit proposals for ancillary studies is given in Section D of this document.

Authorship format

Writing committee members will be listed as authors in the front page. The SC chooses the first and last authors based on the volunteers. In general, our philosophy is that credit should correspond to work and effort into a particular manuscript and the order of authors should reflect that. The base scenario for author order is first author, second author if this has been specified, the DCC members, alphabetical listing of the collaborating trial representatives, alphabetical listing of other members of the SC if appropriate, and the last author, however this will be modified depending on work contributed. "The Chronic Kidney Disease Epidemiology Collaboration" could be chosen as sole author or as last author.

CKD-EPI collaborators are listed in the acknowledgements. Editors of journals / PubMed will be requested to index all collaborators individually. In general, there is a maximum of 4 collaborators per collaborating trial (including members of the writing committee) and this can all be acknowledged in the manuscript.

Acknowledging funding of individual studies

A list of the key grants supporting the data collection in the individual cohorts will be included in manuscripts, either in the main paper or as web appendix.

C3. Manuscript Generation and Review

The same rules apply to all manuscripts.

Main papers will be written by the first and last author for each topic, with the methods section drafted by the DCC and StC. The DCC will develop, tables, and figures for review by the first and last author and will work together to finalize a draft for review by the Writing Group.

Ancillary papers will be similar to the main papers but there will be additional responsibility for the overall design and methods of the paper for the Ancillary study PI. The chair of the writing committee will involve designated StC and/or DCC members in the review of each manuscript emanating from an approved ancillary topic, and ensure their approval of the manuscript before submission to journals. To ensure that this occurs, each manuscript that arises from an ancillary study will need to be sent to the DCC as part of the analytical process. The goal is to ensure that the final manuscript ready to be submitted has input from the DCC and StC investigators.

C4. Abstract Generation and Review

The same rules apply to abstracts about main and ancillary topics.

Approved writing committees may submit abstracts to national and international meetings, in accordance with rules governing the meeting.

Completed abstracts will be subject to review by the SC and will be sent to collaborators, from whom data have been used for the analyses, for comment.

Abstracts cannot be submitted for publication without approval of the SC. The goal will be to approve drafts within 1-2 weeks.

C5. Presentations

Use of unpublished meta-analyzed data (including analyzed data of individual studies as a form of forest plots or tables with similar concept) for presentations will be limited and need prior approval by the SC. Acceptable reasons to present unpublished meta-analyzed data are (1) the use for other scientific workgroups, where gain is mutual to CKD-EPI and materials are kept to within the group, (2) Official CKD-EPI presentation where showing upcoming progress is important for CKD-EPI funding/continuation, (3) presentation by the writing group of submitted abstract. Reviews/invited talks should focus on materials published or in press. Key presentations of CKD-EPI meta-analyzed data will be made available on the CKD-EPI website for use by all collaborators.

C6. Abstract/Manuscript Submission

Unless otherwise specified and agreed upon, DCC will submit abstracts and manuscripts on behalf of the writing groups.

The corresponding author for all CKD-EPI manuscript submissions will be listed as follows:

> "Chronic Kidney Disease Epidemiology Collaboration Data Coordinating Center
> Principal Investigator, Lesley Inker, MD, MS,
> Division of Nephrology,
> Tufts Medical Center,
> 800 Washington Street,
> Box 391,
> Boston, MA 02111
> Tel: 617-636-2569
> linker@tuftsmedicalcenter.org"

CKD-EPI will pay or reimburse for the submission fees and publication cost of CKD-EPI abstracts and manuscripts but not ancillary studies.

Section D: Ancillary Studies Policy

D1. General Policy

We welcome proposals for ancillary studies from investigators and collaborators in CKD-EPI. Ancillary studies can enhance the value of CKD-EPI and encourage interest of the overall goals. To protect the integrity of CKD-EPI and ensure adequate resources, such ancillary studies must be reviewed and approved by the SC before their inception Ancillary studies require outside (non-CKD-EPI) funding to support coordination and statistical analyses.

D2. Requirements for approval of an ancillary study

Before an ancillary study can be approved, it must be shown to have scientific merit and that it will not do any of the following:

1. Interfere with the completion of the main objectives of CKD-EPI CT
2. Adversely affect collaborator cooperation in CKD-EPI CT
3. Create a diversion of study resources (personnel, equipment, or study samples), neither locally nor centrally, and
4. Jeopardize the public image of CKD-EPI CT.

D3. Preparation of Request for Approval of an Ancillary Study

The CKD-EPI will utilize a two-step process for reviewing ancillary study proposals. Step 1 involves the submission of a brief description of the ancillary study for "concept approval". Step 2 requires the submission of a more complete technical proposal. Submission materials must be in an electronic format. Steps 1 and 2 can be consolidated with written approval by one of the Directors.

Step 1: Letter of Intent: Submit a request for concept approval to the CKD-EPI Steering Committee. Include a brief (2-4 page) description of the proposed ancillary study that specifies:

1. Title
2. Identification of the principal investigator of the ancillary study
3. Names of definite or possible co-investigators/collaborators, including DCC and StC members (Please see Section C2)
4. Proposed funding sources
5. Timeline of grant application or analyses as applicable
6. Objectives/specific aims
7. Scientific merit and rationale of the study
8. Study design
9. Indication of which studies or group of studies will be requested and methodology for new data collection, if applicable
10. Name of the statistician(s) or analyst(s)
11. Discussion of impact on CKD-EPI investigators and collaborators
12. Agreement that all ancillary data (clinical information, laboratory assay results) will be shared with the CKD-EPI DCC
13. Agreement to follow CKD-EPI publications policy for ancillary topics

Step 2: Ancillary Study Proposal: If concept approval is granted, the SC will invite the Principal Investigator to submit a complete proposal. Approval of the technical proposal is required prior to submission to the funding agency or study initiation. The proposal should be submitted to the SC and should include the items listed below. A grant application can be used for items 11-16.

1. Title
2. Identification of principal investigator of the ancillary study
3. Names of definite or possible co-investigators/collaborators
4. A brief description of the nature of the involvement of DCC and StC members
5. Agreement that all ancillary data (clinical information, laboratory assay results, analytical data on individual patient and summary data) will be shared with the CKD-EPI DCC.
6. Agreement to follow CKD-EPI Publications Policy for ancillary topics.
7. Proposed funding sources
8. Budget for data coordination, if applicable.
9. Budget for laboratory coordination, if applicable
10. Budget for statistical analysis.
11. Objectives/specific aims
12. Scientific merit or rationale of the study
13. Study design and hypotheses
14. Methodology for data collection, if applicable
15. Proposed statistical analyses
16. Power calculations (if applicable) and
17. Proposed publications including tentative timeline and target journals

D4. Review of Ancillary Study Proposals

Proposals will be sent to the SC for review, who may confer with collaborators with expertise on the topic. The SC will approve, reject, or request modification of the ancillary study proposal. The key criteria for approval of proposals are scientific merit and impact on the main CKD-EPI goals. If the ancillary study is approved by the CKD-EPI SC, the SC Chair will write a letter to the principal investigator of the ancillary study indicating approval and support of CKD- EPI SC. This letter can be used to document approval and support in submission of grant applications for funding or local IRB approval. If the SC does not provide approval, the proposal will be rejected.

D5. Selection of Investigators/Collaborators in Ancillary Studies

If concept approval is indicated by the SC, the DCC will circulate a notice with a request for CKD- EPI collaborators, in addition to those submitting the proposal, to participate in the ancillary study (opt-in / opt-out procedure), which CKD- EPI collaborators would like to be part of the writing committee (investigator) and whether there are comments / suggestions on the proposal. CKD- EPI collaborators must indicate their willingness in writing (electronically) to the SC. The DCC will compile the list of volunteering investigators. The SC shall have final authority on the composition of the ancillary study investigators. The DCC will keep track of volunteering investigators and those investigators submitting proposals for all ancillary studies.

D6. Progress Reports

The Principal Investigator shall provide a written annual report on the progress of the ancillary study. Based on progress achieved, the SC will recommend approval or disapproval for continuation of the ancillary study. In the case of disapproval, permission to continue the ancillary study may be granted to another co-investigator/collaborator (subject to approval by the funding agency).

D7. Analysis of Ancillary Studies

The investigator of the ancillary study, and if necessary the SC, will consult with the DCC and StC during data analysis to ensure that all study data used in analysis of ancillary study results are consistent with data in the main study database. In general, the individual person data of participating cohorts is provided to the DCC for analysis without permission for transfer to other places. Therefore arrangements will need to be made to fund analysts or access the data at the DCC. The investigator of the ancillary study will receive analyzed results, but not individual person data, from the DCC.

D8. Publications from Ancillary Studies

Publications from ancillary studies shall follow the CKD-PC EPI Publication Policies related to ancillary topics as listed in Section C. In particular, each manuscript emanating from a given ancillary study will should be sent to the DCC prior to analyses. The goal is to ensure sufficient input from StC and DCC investigators in the analyses and interpretation of the data.

D9. Dissemination of results including presentations, abstracts and publications from ancillary studies

Publications from ancillary studies shall follow the CKD-EPI Publication Policies related to ancillary topics as listed in Section C. In particular, each manuscript emanating from a given ancillary study will should be sent to the DCC prior to analyses. The goal is to ensure sufficient input from StC and DCC investigators in the analyses and interpretation of the data.

Section E: Policy on Individual Study Publication

The CKD-EPI encourages the activity of individual studies. If authors believe they have gotten ideas from CKD-EPI work (e.g., study design, statistical code) and deem it appropriate to do so, acknowledgement of the collaboration would be appreciated. The DCC aims to continue to share methods and expertise and respond to requests by individual cohorts as much as possible.

While the Collaboration generally encourages individual studies publishing, groups forming small multi-study collaborations may not be beneficial for the Collaboration. CKD-EPI encourages collaborators thinking to form a small collaboration to consider the possibility to proceed with their projects in the entire Collaboration whenever possible.