Cure Glomerulonephropathy Network
Publication and Presentation Policy

Original: March 5, 2015
Updated: March 26, 2019
Edited: November 30, 2020
Approved: January 11, 2021
Edited: March 25, 2021

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1 OVERVIEW AND GENERAL PRINCIPLES

The CureGN Publication and Presentation Policy (PPP) seeks to ensure appropriate use of CureGN data, timely completion of manuscripts and presentations, equitable access to authorship, and adherence to established principles of authorship. These guidelines apply to manuscripts, abstracts, oral and poster presentations, letters to the editor, meeting proceedings, and reviews that include original CureGN study data not previously published.

This policy outlines membership, leadership, and responsibilities of the CureGN Publication and Presentation Committee (PPC) and the Writing Groups (WGs). CureGN seeks to provide support for broad and equitable participation of investigators in presentations and publications. CureGN also seeks to promote career development of trainees and junior faculty by providing opportunities for lead and co-authorship on CureGN publications.

Peer-reviewed publications are the principal mechanism by which CureGN communicates its scientific findings. Publications arising from CureGN should avoid overlap and/or conflicting representation of study findings. Research questions and hypotheses to be addressed using CureGN study data should be formulated *a priori* and stated clearly in the manuscript or abstract proposal to reduce the likelihood that study results are attributable to error. Publication of scientific findings from the CureGN study should proceed in a timely fashion once relevant analyses are complete. All publications and presentations using CureGN material must be accurate and objective and must not compromise the scientific integrity of CureGN.

Authorship on CureGN publications will adhere to the International Committee of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journal (ICMJE, http://www.icmje.org/recommendations/). Publications arising from the CureGN study will adhere to STROBE guidelines for reporting observational studies (www.strobe- statement.org). CureGN has a general preference to foster career development by providing authorship opportunities to junior faculty and trainees when appropriate.

Media releases should be timed to coincide with publication of findings and should respect any applicable publication embargoes. Media releases require Steering Committee (SC) approval.

No investigator may jeopardize the publication of CureGN analyses by releasing or presenting data prematurely or without CureGN SC approval. Disclosure of unpublished CureGN data should only occur in formal settings such as scientific meetings and always requires pre-approval by the CureGN SC.

All data derived from the CureGN project or from specimens collected for the study are collective intellectual property, not property of any individual investigator or participating site. While supporting the academic freedom of investigators to publish study results, it is necessary to provide limitations on publication from any one center that could threaten the integrity of collective data.

All CureGN publications and presentations will be stored electronically on the secure CureGN website, accessible to study personnel.

2 PUBLICATION TYPES

2.1 Manuscripts

Manuscript types:

- **Core Manuscripts** are based on analyses that utilize existing CureGN data, with goals that are within the scope of the core CureGN study aims. Core manuscripts are subject to approval via the PPC, but not the CureGN Ancillary Study Committee (ASC). It is expected that the DCC will provide principal statistical and methodological support.
  Authorship list should include "for CureGN" or "for the CureGN study/investigators"

- **Secondary Manuscripts** are based on analyses that utilize existing CureGN data, performed principally by CureGN site investigators, or external investigators with sponsorship from a CureGN site investigators, with goals determined by the writing group. Secondary manuscripts are subject to approval via the PPC, but not the ASC. The DCC will provide review of the proposal for feasibility at the submission stage. Analyses will be performed by the investigators or by the DCC, depending on DCC availability and interest.
  Authorship list could include "with CureGN" or "with the CureGN study/investigators"

- **Ancillary Study Manuscripts** originate from the specific aims of ancillary studies approved via the CureGN Ancillary Studies Policy. Ancillary studies typically propose new use of biospecimens or generation of new ideas, collection of additional data/biomaterials, additional recruitment, or an interventional study using the CureGN cohort as a basis for recruitment. Investigators may come from within or without the CureGN study sites. Ancillary studies require approval in accordance with the CureGN Ancillary Study Policy; manuscripts eventually derived from ancillary studies require approval via the PPC.
  Authorship list could include "with CureGN" or "with the CureGN study/investigators"

Type of Project	Core	Secondary	Ancillary
Aims	CureGN study aims, as determined by grant application, SC, or PPC	Determined by investigators	Determined by investigators
Data	Established CureGN data, or data derived as part of study aims	Established CureGN data	Established CureGN data *OR* New data generated by study
Biospecimen use	Per CureGN primary aims	None	As needed
Investigators	Principally CureGN	Principally CureGN	Anyone
Authorship	First and last authorship contingent on approval by SC or PPC	Determined by writing committee	Determined by writing committee
Analysis performed by	DCC	Investigator, with DCC review/assistance as bandwidth allows	Investigator
Concept approval	PPC	PPC	ASC
Manuscript approval	PPC	PPC	PPC
Suggested author line	"for CureGN" or "for the CureGN study/ investigators"	"with CureGN" or "with the CureGN study/investigators"	"with CureGN" or "with the CureGN study/investigators"

2.2 Abstracts

Abstracts submitted to scientific meetings can be based on either core or ancillary studies, and will typically follow a process of peer review (for admission to the scientific meeting) followed by either oral or poster presentation. Most abstracts will be derived from manuscripts in development and will follow the processes below. A principle will be one abstract per manuscript. There can be exceptions to this rule if science compels so.

2.3 Presentations

For the purposes of this policy, presentations include, for example, invited presentations, grand rounds, and talks to community physicians (not linked specifically to a scientific abstract or manuscript in development).

- Presenters are encouraged to present published CureGN data that have appeared in publications or abstract form at scientific meetings with appropriate acknowledgements.
- Presentation of data that are unpublished and otherwise not publicly available requires approval from the CureGN SC; these data will be limited to operational updates such as recruitment numbers that include basic patient characteristics. Materials should be submitted to the DCC for routing to the CureGN SC.
- Slide presentations given publicly will be made available, in a non-editable format, on the secure CureGN website. The presenter is responsible for sending the presentation to the DCC for posting. The DCC administration email (CureGN-Admin@arborresearch.org) should be used for all required DCC submissions and inquires.

3 SITE OF ANALYTIC ACTIVITIES

To ensure integrity of CureGN research output and thereby maximize overall scientific impact, the CureGN Consortium has agreed that the DCC would have the opportunity for oversight over the quality of design and analyses performed with CureGN data. This may be approached in one of three ways:

1. The DCC conducts the full analysis and is responsible for producing methods, tables, and figures for manuscripts or abstracts. Prioritization among approved projects will be brought to the Steering Committee as needed.

2. The proposing team designs the study and conducts the analysis. In this case, the team assumes responsibility for the integrity of their results. Upon review by the PPC, the results may undergo additional quality review by the DCC or other methodological experts. This may include review of the statistical code and re-analysis if recommended. The Steering Committee may also request review or re-analysis by the DCC.

   In the event the PPC or SC requests validation of selected statistical analyses, the analytic team will make relevant statistical code and analysis results available to the DCC for review before publication.

3. A hybrid approach, e.g., with some aims analyzed by the investigators and others by the DCC.

The proposed location of the analyses should be specified in the proposal. Qualifications of the

analytical team should be included, if not at the DCC. For analyses of clinical data, it is expected in most cases that work be performed, at a minimum, by a masters-level biostatistician or epidemiologist under the supervision of a PhD level biostatistician or epidemiologist. Investigators may provide a justification in the proposal if this standard is not met.

Note that for manuscripts derived from ancillary studies, decisions regarding site of analytic activities will have been made at time of AS approval, as specified in the CureGN ASP. The site of analytic activities for core CureGN analyses (i.e., analyses not subject to the ASP) is under the sole purview of the PPC.

4 PUBLICATION AND PRESENTATION COMMITTEE (PPC)

4.1 Charge

The CureGN PPC is responsible for:

- Implementing the Publication and Presentation Policy and facilitating related processes.
- Proposing amendments to the Publication and Presentation Policy as needed; all amendments require SC approval.
- Quarterly review and approval, by the PPC co-chairs, of an updated list of published papers, abstracts, presentations, and manuscripts in development. The DCC will assemble this list for PPC review, and will post the approved list on the CureGN Website.
- Reviewing the progress of established writing groups during quarterly PPC meetings. Writing group co-chairs will be invited to present and discuss progress on manuscripts in development.

4.2 Membership and Chairs

The PPC consists of two members from each of the four PCCs and the DCC, and at least one member from the NIH- NIDDK. Please refer to the CureGN Committee Membership and Chairs policy for further details.

4.3 Meetings

PPC conference calls will be scheduled on a quarterly basis, and on an ad hoc basis at the discretion of the Co-Chairs..

4.4 Voting

The PPC voting body consists of members of the PPC, with votes assigned as follows:

- 1 vote per PCC (4)
- 1 vote from the DCC
- 1 vote from the NIH/NIDDK
- 1 vote from the SC Chair on an ad hoc basis

Each site may designate an alternate to participate if PPC members are not available. A quorum consists of one representative from four of the six voting groups. Decisions are based on a majority vote of a quorum.

If a PPC member proposes a manuscript, substantially collaborates on a manuscript proposal, or has a perceived or real conflict of interest in the outcome of a vote, he/she will be excused from

reviewing and voting on that manuscript proposal, similar to NIH peer review policies for avoidance of actual or perceived conflicts of interest. In the event that such conflicts result in a quorum not being reached, the definition of a quorum will be modified such that only those without a conflict can participate in the vote, and a majority vote of the present members is necessary to reach consensus.

4.5 Disputes

The PPC will mediate and is expected to settle disputes and conflicts over publication issues such as prioritization, authorship, etc. Investigators who perceive inequities or other problems relating to authorship should address these concerns with the PPC Co-Chairs. If the matter cannot be settled in this manner, the investigator should submit a letter to the CureGN Steering Committee Chair outlining his/her concerns.

5 NEW PROPOSALS

This section pertains to new proposals for manuscripts, abstracts, or presentations. The following processes will be followed:

5.1 Submission and Review Process

All concept proposals must be submitted to the CureGN DCC for circulation and review as per procedures below. Each step will include interaction with the proposing team as necessary.

1. Submission
    a. When considering a publication, investigators are highly encouraged to make use of the tranSMART resource to gain understanding of available data, study feasibility, and preliminary analyses. Investigators are also welcome to contact the DCC for these purposes. Contact CureGN-Admin@arborresearch.org to gain secure access to tranSMART or to submit a request for analysis.
    b. The proposing team will submit the concept proposal using the Publication and Presentation Proposal Application form in Appendix A. The form will be submitted to CureGN-Admin@arborresearch.org.
    c. The proposal should include a roster of proposed WG members for the manuscript who have had the opportunity to review, contribute and approve the proposal. When preparing a proposal, the co-chairs should email the relevant work group members (if applicable) as well as the PPC liaison for each PCC and the DCC. The PPC liaison is responsible for dissemination of proposals in preparation to their respective investigators and relaying interested co-authors to the co-chairs. If there is an excessive number (eg. >20) or imbalance (according to DCC/PCCs) of interested coauthors, the cochairs can contact the PPC for assistance with appropriate and fair co-author selection. Upon receipt and review of the proposal, the PPC will review the coauthor list to ensure that investigators with relevant expertise are included and that there is equitable authorship across the DCC/PCCs and individual investigators. The PPC will track first/last/coauthor positions across manuscripts to assist with this task. Key authorship positions (first, second, third and last) should be stated provisionally upon submission of the proposal, contingent on eventual manuscript contributions. See Section 5.6 (Authorship) for details.

d. The proposal must include "Summary Information" and "Proposal Details"

e. The proposal should indicate whether the DCC will analyze the data or whether the data will be analyzed at a local center. Justification for data analysis outside the DCC must be included here.

f. Proposals should list conflict of interests by any of the WG members.

2. DCC Review and SC Notification
    a. The CureGN DCC will review the proposal for completeness and data availability at the Research Meeting following the submission to the DCC.
        b. The proposal will be shared with the SC. While this is principally for informational purposes, members will have one week to provide comments if desired, e.g., preference to route proposal first through Ancillary Study Committee.
    c. DCC comments will be provided to the PPC and/or the submitting team for consideration. Complete, revised proposals will be distributed by the DCC to the PPC.

3. PPC review and recommendation
    a. The PPC will review proposals, with focus on study goals rather than detailed study methods (under purview of WG, once established). PPC review should focus on expected scientific impact, data availability, and overlap with other papers or abstracts in process.
    b. In cases of overlap, the proposing investigator may be encouraged to collaborate with the existing WG.
    c. PPC determines if there is a pathology component.
        i If it is a core manuscript and there is a pathology component, PPC refers the proposal to the Pathology Committee for review of pathology methods for feasibility, consistency with approach in prior CureGN studies, and scientific rigor. If there are pathologists involved in the development of the proposal, they will be queried about the pathology component to inform the decision-making of the Pathology Committee.
        ii The Pathology Committee makes recommendations regarding the pathology component of the manuscript to the PPC, and these are included with the recommendations to the Steering Committee from the PPC.

5.2 Vote on Approval by Steering Committee

1. The PPC recommends for or against endorsement of the proposal to the SC, which will then vote on approval of the proposal.
2. The DCC will post approved proposals on the secure CureGN website. Information will include title, authors (with email of corresponding author), and date of approval.

5.3 Timelines

- Manuscript proposals should be submitted in a timely fashion, e.g. within a reasonable timeframe after data become available for core or ancillary studies.
- For established WGs (manuscript proposals), requests to the DCC for data or analysis should be made within 2 months of proposal approval; first draft of manuscript circulated within 6-8 months of proposal approval, and submission of manuscript to the PPC within 12-18 months of

proposal approval. WG's unable to meet this time frame should notify the PPC (via the DCC) for further discussion including if an action is necessary.

- Abstract proposals should be submitted at least 6 weeks in advance of the submission deadline for the scientific meeting.
- Proposals for invited presentations at scientific meetings should be submitted as early as possible and at least 6 weeks in advance of the scheduled presentation.

5.4 Agreement to Follow CureGN Policies

As part of the email confirmation to participate on a WG, proposed members must agree to the following statement regarding the use and disclosure of any CureGN data and analyses:

I will abide by all requirements of the CureGN Publication and Presentation Policy and CureGN Ancillary Studies Policy. I will not use or disclose CureGN data or analyses for any purpose other than accomplishing the approved scientific aims of the manuscript. I will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality and integrity of all CureGN data and analyses, as well as prevent their inadvertent use or disclosure.

5.5 Responsibilities

- Writing Group Co-chairs

The WG Chairs should be the first and senior authors and are responsible for ensuring frequent communication and soliciting feedback from the WG as the manuscript progresses. Chairs are encouraged to connect with the WG after preliminary analyses are obtained, when analyses are considered 'final' and to circulate both a first and final draft for edits/comments and approval, prior to submission to the PPC.

The WG Chairs are responsible for the timeliness and integrity of all phases of manuscript or abstract preparation, including:

- Contacting WG members to review the outline, data analysis plan, and responsibilities and assignments for each member
- Determining order of authorship athe time of WG proposal submission and as the manuscript evolves. Assignment of the first three authors and the senior author should rely on significance of contribution and the PPC suggests assigning all other authorship positions according to alphabetical order.
- Developing the analysis plan in collaboration with the analytic team (typically at the DCC)
- Seeking consensus from the WG on the following:
  - Analytic approach
  - Mock tables and figures shells
  - Proposed timeline for each stage
- Preparation of drafts
- Circulation of drafts to WG members
- Submitting interim status reports, if requested by the PPC
- Determining order of authorship at start of WG and as manuscript evolves
- For manuscripts, selecting a journal for submission; for abstracts, selecting a scientific meeting for submission

  - Corresponding with co-authors, communicating with the DCC and the PPC, responding to the PPC and NIDDK reviews and to journal editors
  - Assuring adherence to timelines outlined in this policy
  - Documenting each author's contribution to the manuscript (e.g., design, conception, analysis, etc.)

- Writing Group Members
  - WG members are responsible for timely completion of tasks assigned by the Chair. These are expected to include, for example, detailed review and approval of analytic approach and draft text.

5.6 Authorship

Authorship inclusion and order will be proposed by the WG co-chairs, based on expected effort and contributions made by each member of the WG. Proactive communication is encouraged so that consensus among WG members is achieved. A working plan should be established at WG inception (ie. before proposal submission), and reviewed in view of actual contributions periodically and before the final draft manuscript is submitted to the PPC. If necessary the WG chair or any member may ask the PPC to mediate disagreements, and the PPC may call on SC for final decision-making authority. The PPC recommends that WGs meet regularly during the analysis and writing process (as per section 5.5) to ensure all members have an opportunity to provide significant contributions.

1. Author inclusion:

   In most cases, authors will comprise the WG members. WG membership does not guarantee authorship, which requires adherence to ICMJE standards. Authors must satisfy authorship criteria as specified by ICMJE:

   - Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
   - Drafting the work or revising it critically for important intellectual content; AND
   - Final approval of the version to be published; AND
   - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

   All those who should meet all four ICMJE criteria for authorship should be identified as authors. Those who meet some but not all four criteria should be acknowledged as contributors.

2. Author order:

The consortium recognizes that the largest contributions to manuscript content are made by a relatively small number of individuals. In addition to the first and senior authors (co-chairs), consideration of key authorship positions may include significant contribution from biostatisticians, content experts and other individuals whose involvement provided significant support to the subject matter of the manuscript. If indicated, the WG chairs will consider these individuals for 2nd, 3rd and 4th authorship positions. For all others, authorship order shall be determined randomly (i.e. alphabetically). A principle of the CureGN consortium is to strive to provide key authorship opportunities to junior investigators, subject to ICMJE criteria.

3. SC authorship on core manuscripts:

SC members including the PCC and DCC PIs, the SC chair, and the NIDDK project scientist will be given an 'opt out' opportunity for authorship on core CureGN manuscripts, and in keeping with ICMJE authorship criteria. For core manuscripts, priorities for authorship should be as follows:

   a. Author list should include at least one representative from each PCC and the DCC, assuming participation in keeping with ICMJE criteria.

   b. First authorship should *preferably* go to a junior or mid-level investigator

   c. First and senior authors should be *encouraged to* come from different PCCs or DCC

   d. CureGN investigators who have not yet participated on core CureGN manuscripts as first or senior authors will be provided every opportunity possible. This determination would typically be made by the relevant working group prior to proposal submission.

4. Consortium acknowledgement and list of contributors:

a) Publications will include the acknowledgement, 'on behalf of the CureGN Consortium." Consortia members not meeting authorship criteria shall be listed under this banner and will be searchable on PubMed. The list of consortia members on manuscripts shall be drawn from the standing list of CureGN contributors, maintained by the DCC. Each PCC and DCC will review and attest to the accuracy of the list of CureGN investigators semiannually, by March 15 and September 15.

b) Responsibility for this review will fall to the members of the PPC and subsequent sign-off by each PCC PI and lead coordinator

c) The DCC will maintain this record of CureGN membership and will be used to track contributions and identify potential participants for WG invitation.

a) This list will be queried for interest in active WG participation for core CureGN manuscript proposals

b) CureGN investigators who change employment to a non-CureGN institution will be removed from the active investigator list. If they have specific expertise relevant to a project, they may still be invited to participate by the WG chairs as above.

c) CureGN investigators who change employment to a non-CureGN institution while members of a WG for an accepted proposal will be allowed to complete participation in that/those manuscript(s).

d) The DCC should maintain, for each investigator, a running count of first, middle, and senior authorship roles from completed manuscripts and active WGs.

5.7 Removal of Members

A WG member may be removed from the WG if he/she does not accomplish his/her assigned tasks and has not contributed, or is no longer expected to contribute, and per the following procedures:

- The WG co-chairs contact the member in writing with a request for participation or performance

of a task, and indicates that non-response within 2 weeks will be considered notice that the WG member no longer wishes to participate in the writing activity.

- The WG co-chairs then send notification to the PPC requesting the non-contributing member's removal.
- Recommendations to remove a WG member must be approved by the SC.

6 PROCESSES FOR DEVELOPMENT OF MANUSCRIPTS, ABSTRACTS, AND PRESENTATIONS

This section outlines centralized processes occurring after approval of new proposals and assembly of the WG, and involving the PPC and/or SC.

6.1 Manuscripts

6.1.1 Review and Approval

1. The draft for submission is due to the PPC for review within 4 months of WG receipt of the complete analyses from the DCC (if applicable). This draft should be nearly complete for journal submission.
2. Review of draft will occur by the PPC and CureGN SC. The PPC will each assign two members for primary review. The CureGN SC and PPC will simultaneously be given access to the penultimate draft manuscript for approval prior to submission to the journal. Members of both committees will be given one week to comment, with comments provided to the Writing Group Chair who will decide if this input should lead to modification in the manuscript prior to submission. The review should focus on major concerns with methodology, interpretation of findings, and inaccuracies regarding the CureGN study.
3. The PPC will collate PPC and SC feedback in a summary document to be provided to the WG Chair within 2 weeks. In the case of major concerns, an ad hoc conference call may be suggested by the PPC or SC with the WG Chair.
4. The WG will consider the feedback provided and make modifications to the draft manuscript based on his/her judgment.
5. The WG Chair will re-submit the updated draft to the PPC; the PPC will forward to the SC.
6. Vote on approval of the manuscript by the SC is required within 2 weeks of re-submission.
7. The results of the SC vote will be communicated to the WG Chair via the PPC.

6.1.2 Journal Submission

The following processes pertain to core CureGN manuscripts. Once approved by the Steering Committee, draft manuscripts will be prepared for journal submission by either the WG Chair or the DCC editorial team (at the discretion of the WG Chair). If the DCC assumes responsibility, then the DCC editorial team will conduct an editorial review and copy edit, ensure that all journal submission requirements are met, complete all administrative details, formatting, etc., according to journal submission guidelines, solicit duality of interest/financial conflict of interest/author copyright assignment/other required journal disclosures and forms from all authors, and submit the manuscript to the journal. It is expected that the time from receipt by the DCC editorial team until submission will occur within 10 working days.

The DCC or the WG Chair will keep the PPC and co-authors informed as to the manuscript's

progress through journal review. Copies of letters of acceptance, requests for revisions, and letters of rejection will be shared. Upon acceptance for publication, the WGG chair will notify the DCC and PPC and co- authors and ensure that the manuscript is submitted to PubMed Central.

For core manuscripts, the DCC will cover standard publication fees, but not fees for open access. For submission to open access journals, it is expected that the senior author will pay publication fees.

6.1.3 Tracking Manuscripts

As agreed on a case-by-case basis, the Writing Group Chair or the DCC will keep the Publications Committee and co-authors informed about manuscript progress through journal review.

6.1.4 Accepted Manuscripts

Upon publication of a manuscript, it will be listed on the publically-interfacing CureGN website, and publication materials will be made available to the extent allowed by journal copyright policies.

6.2 Letters to the Editor

- Letters to the Editor submitted to scientific journals should, in most cases, be limited to rebuttals in response to a CureGN publication.
- All letters must be approved by the PPC and SC before journal submission.
- Drafts are to be submitted to the PPC for review at least 2 weeks before the intended submission date.
- The PPC and SC will provide feedback within 1 week of receipt; the WG Chair may choose to modify and then resubmit the letter to the PPC.
- Vote by the SC on approval of the final draft is required within 1 week of receipt.

6.3 Abstracts

6.3.1 Review and Approval

1. A working draft from the WG Chair is due to the PPC for review at least 4 weeks before submission date.
2. Review of draft will occur by the PPC. The PPC will assign two members for primary review. The review should focus on major concerns with methodology, interpretation of findings, and inaccuracies regarding the CureGN study.
3. Feedback will be provided to the WG Chair within 1 week. In the case of major concerns, an ad hoc conference call may be suggested.
4. A final version must be submitted to the PPC at least 1 week before the abstract submission deadline.
5. Vote on approval of the final abstract by the PPC is required within 1 week after receipt.
6. The results of the PPC vote will be communicated to the WG Chair.

6.3.2 Abstract Submission

The abstract will be formatted and submitted in adherence to meeting requirements. Most abstracts will be submitted by the DCC, and in these cases, the DCC will incur any costs associated with abstract submission. The PPC and co-authors will receive a copy of the submitted abstract. The DCC will keep the PPC and co-authors informed as to decisions about the abstract. Copies of acceptance or rejection notifications will be shared.

6.3.3 Accepted Abstracts for Presentation

Abstracts to be presented at scientific meetings, either via oral or poster presentation, will be submitted to the PPC for review at least 4 weeks prior to the presentation. The PPC will provide feedback to the authors within 1 week of receipt. Formal PPC approval by vote is not required.

The PPC will collaborate with the DCC to ensure that presentation materials include the CureGN logo and are formatted according to study standards. Printing, transportation, and display of posters are the responsibility of the presenting author.

6.4 Presentations

6.4.1 Requirements for Review

- Unpublished CureGN data presented at meetings must be approved by the PPC. Refer to Section II (Publication Types) for additional information regarding the appropriate use and scope of unpublished data.
- The presentation of published CureGN data is generally not subject to CureGN approval, except as follows:
    - Talks at scientific meetings that are centered on CureGN (e.g., symposia or lectures with CureGN in the title or learning objectives) are subject to PPC approval. In these cases: (1) the lead speaker must obtain PPC approval prior to accepting the invitation; and (2) lecture materials should be submitted to the PPC for review at least 4 weeks prior to the presentation date. The PPC will vote on approval within 2 weeks.
- PPC approval is not required for local (e.g., CureGN site) presentations and accompanying syllabus material of published CureGN data for purposes such as grand rounds lectures, research seminars, medical school lectures, etc.

Investigators are expected to consult the PPC Co-Chairs with any questions related to the propriety of CureGN material for presentations, or if other questions arise. If the Co-Chairs cannot address such questions readily, the issue should be considered by the entire PPC by way of conference call or written communication.

6.4.2 Formatting

The PPC will collaborate with the DCC to ensure that presentation materials include the CureGN logo and are formatted according to study standards.

6.4.3 Reproductions

Requests for permission by meeting organizers, industrial sponsors, etc. to videotape or audiotape presentations, and/or to publish written summaries of these presentations must be submitted to the PPC by the speaker. The PPC will vote on approval of the material, and will ensure that previously unpublished data are protected. Vote on approval by the PPC will occur within 2 weeks of submission.

7 ACKNOWLEDGEMENTS

Manuscripts should include:

- "CureGN" in title, when permissible.
- "The CureGN Investigators" as part of the list of authors, when permissible.
- All grants (and grant numbers) which supported the work.
- The following statement – "Acknowledgement: Funding for CureGN has been provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) [grant number]. The views expressed in written materials or publications do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Additional support for CureGN is provided by NephCure Kidney International."
- If any data in a manuscript were presented at a scientific meeting, the meeting name, location, and date should be noted in an Acknowledgement.

7.1 Data Sharing Statements

1. If CureGN investigators are involved in authorship, the statement below should be used:
   "*Data are available upon request through the CureGN Ancillary Studies program. Data access is governed by the CureGN Steering Committee and NIDDK. Additional data sets will be provided to the NIDDK Central Repository after completion of study recruitment, which is currently ongoing. After data are deposited, the data will be available through the NIDDK Central Repository (https://repository.niddk.nih.gov/home/).*"
2. If CureGN investigators are not involved in authorship and this is part of a requirement for ancillary study investigators, use:
   "*The CureGN longitudinal cohort study was conducted by the CureGN Investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The data* [and, if applicable samples] *from CureGN reported here were supplied by the NIDDK Central Repositories. This manuscript was not prepared in collaboration with the CureGN Investigators and does not necessarily reflect the opinions or views of the CureGN study, the NIDDK Central Repositories, or the NIDDK.*"

8 DEVIATIONS

8.1 Deviations in Schedule

For approved manuscript proposals, schedule deviations require PPC approval and will prompt PPC review. If it is determined that a manuscript is delinquent, this could be the basis for replacing WG members or for disbanding or reconstituting the WG.

8.2 Deviations in Scope

For approved manuscript proposals, changes in scope will be communicated by the WG Chair to the PCC. The PCC will review and submit to the SC for approval. Changes include, for example:

- **Changes in Specific Aims**
  If the WG decides that a change in the approved specific aims for a manuscript is warranted, the Chair will communicate this, along with a brief rationale to the PPC.

- **Development of More Than One Manuscript from a Single Proposal**
  If initial analyses suggest that a proposal should be split into two manuscripts, the rationale for this split should be submitted by the WG Chair to the PPC. WG members will typically remain the same for both manuscripts, though the Chair may be re-assigned for the second manuscript.

- **Withdrawal of an Approved Manuscript**
  If the WG concludes that it will not produce a manuscript or will combine its analyses with those of another WG to generate one integrated manuscript, the WG Chair will submit the rationale for these changes to the PPC.

9 ADHERENCE TO NIH PUBLIC ACCESS POLICY

The PPC will ensure that appropriate NIH regulations are followed, including adherence to NIH Public Access Policy:

- The NIH Public Access Policy requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. It applies to any manuscript that is peer-reviewed and is accepted for publication in a journal on, or after, April 7, 2008.
- It is the responsibility of the submitter (either WGWG Chair or DCC) to make sure that the publication is submitted to PubMed Central. Instructions related to the submission process can be found at http://publicaccess.nih.gov/.

10 SOURCE DOCUMENTS

This policy was developed with the use of the Nephrotic Syndrome Study Network (NEPTUNE), Adult to Adult Living Donor Liver Transplantation Cohort Study (A2ALL), and Chronic Renal Insufficiency Cohort Study (CRIC) publications policies as reference. A2ALL is supported by the NIH-NIDDK. NEPTUNE is supported by the NIDDK, the NIH Office of Rare Diseases Research (ORDR), and NephCure Kidney International (NKI). CRIC is supported by the NIH-NIDDK.

11 APPENDICES

A. Publication and Presentation Proposal Application
B. CureGN First Author Form
C. CureGN Authorship Form
D. Proposal and Writing Group Process Flowchart
E. Abstract Processes Flowchart
F. Manuscript Processes Flowchart