Cure Glomerulonephropathy Network
Publication and Presentation Policy

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1 OVERVIEW AND GENERAL PRINCIPLES

This policy 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 Committees (WCs).

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

2.1.1 Core Study Manuscripts

A "Core Study" is a study (may be funded as an Ancillary Study) that fundamentally extends from the core CureGN aims. Core Study Manuscripts are based on analysis of biospecimens and/or data collected as part of the core CureGN data set, as agreed upon by CureGN leadership.

2.1.2 Ancillary Study Manuscripts

Ancillary Study manuscripts originate from the specific aims of ancillary studies approved by the CureGN Ancillary Studies Committee. For example, these may be based on new use of data/biospecimens that have already been collected (or are already planned to be collected), collection of additional data/biomaterials, an analysis not included in the core CureGN study, or an interventional study using the CureGN cohort as a basis for recruitment

For more information regarding core and ancillary data/studies, refer to the CureGN Ancillary Study Policy.

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.
- 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.

3 PUBLICATION AND PRESENTATION COMMITTEE (PPC)

3.1 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.
- Maintaining an updated list of published papers, abstracts, presentations, and manuscripts in development.
- Reviewing core research and ancillary studies in progress to anticipate potential manuscripts to be developed, as well as possible WC members.

3.2 Membership

The PPC is composed of the following members:

- CureGN Consortium members (10), consisting of two members from each of the PCCs and the DCC. Members are determined by the respective PCC and DCC Principal Investigators (PIs).
- Members will serve 2-year terms, staggered annually to ensure overlapping representation. At the discretion of PPC members, with input from their respective PCC or DCC PIs, membership may be updated on a more frequent basis.
- NIH-NIDDK representatives (one to two)

3.3 Leadership

Two PPC Co-Chairs will be elected from among the members and rotate annually, staggered by 6 months.

3.4 Meetings

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

3.5 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.

3.6 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 SC Chair outlining his/her concerns.

4 NEW PROPOSALS

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

4.1 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. It is recommended that the proposal include a roster of proposed WC members for the manuscript.
    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. The latter would typically only occur for ancillary studies; in these cases, the SC will have previously approved this plan as part of the ancillary study approval process. Also for analyses not performed at the DCC, the PPC will review documentation of the qualifications of the data analyst(s) (preferably at least an MS in statistics, biostatistics, or epidemiology), and analyses will be subjected to quality review by the DCC. When the DCC is site of analysis, the DCC is responsible for producing methods, tables, and figures for abstracts or manuscripts.
2. The CureGN DCC will review the proposal for completeness and data availability at the Research Meeting following the submission to the DCC. 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 WC, 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 WC.
c. PPC determines if this is a core manuscript (not from an ancillary study) and 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.

4.2 Vote on Approval by SC

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, assign a manuscript number, and log it into the tracking system.

4.3 Timelines

- It is the expectation of the CureGN consortium that manuscript proposals should be submitted in a timely fashion, e.g. within a reasonable timeframe after data become available for core or ancillary studies.
- Abstract proposals should be submitted at least 12 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 12 weeks in advance of the scheduled presentation.

5 WRITING COMMITTEES

After approval of a new manuscript or abstract proposal, a WC is formed. [Presentations are excluded from this section, as they are typically led by individual investigators.] The SC will approve the WC Chair and members, including the participation of pathologist(s) where required. A tenet of WC selection includes equitable representation of CureGN investigators and sites whenever appropriate and feasible, and inclusion of content-area experts from across, or outside of, the CureGN network. The DCC will maintain records indicating the distribution of WC membership across the CureGN Consortium. Distribution will be reviewed annually by the SC.

5.1 Selection of Chair

- Core Manuscripts
  - The SC should consider the following principles:
    - Equitable access to leadership of WCs among members of each of the PCCs and DCC.
    - Expertise of proposed WC Chair based on prior publications and interest, as demonstrated through ancillary study proposals, etc.
    - Proposed WC Chair's commitment, initiative, and availability to moving manuscript development forward.
- Ancillary Studies
  - The PI of an Ancillary Study will typically serve as the WC Chair for Ancillary Study manuscript(s). If the PI is unable to serve as the WC Chair, the PPC may recommend a Chair to the SC.

5.2 Selection of Members

The following outlines processes for selection of WC members:

1. The WC Chair, in conjunction with the SC, works to identify potential WC members from among interested investigators.
   a. Core manuscripts: On approval of manuscript topic and WC Chair by the SC, the DCC posts notification on the secure CureGN website to facilitate identification by the CureGN PIs of any additional individuals with expertise and/or meaningful contributions to the study who are interested in inclusion on the WC.
   b. Ancillary study manuscripts: On approval of the manuscript topic by the SC, the DCC emails investigators who were part of the original ancillary study proposal to solicit interest in inclusion on the WC; additional nominations may be sought.
2. Nominations will be accepted for 2 weeks.
3. Nominations will be presented to the PPC, which will consider membership in accordance with the following principles:
   a. WCs should include at least one representative from each PCC and the DCC.
   b. The NIH Project Scientist and SC Chair will typically be offered WC membership.
   c. Generally equitable distribution of writing assignments and authorship will be sought.
   d. Authorship guidelines for target journals will be considered.
4. The composition of the WC will be recommended by the PPC and voted upon by the SC within 1 month of approval of the WC Chair, at which time the WC nominees will be notified via email.
5. WC nominees must acknowledge their acceptance of the nomination via email.

5.3 Agreement to Follow CureGN Policies

As part of the email confirmation to participate on a WC, 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.

5.4 Responsibilities

- Writing Committee Chair
  The WC Chair is responsible for all phases of manuscript or abstract preparation, including:
  - Contacting WC members to review the outline, data analysis plan, and responsibilities and assignments for each member
  - Developing the analysis plan in collaboration with the analytic team (typically at the DCC)
  - Seeking consensus from the WC on the following:
    - Analytic approach
    - Mock tables and figures
    - Graphical needs
    - Proposed timeline for each stage
  - Preparation of drafts
  - Circulation of drafts to WC members
  - Submitting interim status reports, if requested by the PPC
  - Determining order of authorship
  - 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

- Writing Committee Members
  - WC 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.

5.5 Authorship

In most cases, authors will comprise the WC members. Authorship order will be determined by the Chair, based on effort and contributions made by each member of the WC. WC membership does not guarantee authorship, which requires adherence to ICMJE standards.

5.6 Removal of Members

A WC member may be removed from the WC 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 WC Chair contacts 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 WC member no longer wishes to participate in the writing activity.

- The WC Chair then sends notification to the PPC requesting the non-contributing member's removal.
- Recommendations to remove a WC 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 WC, and involving the PPC and/or SC. Prioritization of required activities, such as DCC data analyses, will be determined by the PPC in consultation with the DCC.

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 WC receipt of the complete analyses from the DCC. This draft should be nearly complete for journal submission.
2. Review of draft will occur by the PPC and SC. The PPC and SC will each 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. The PPC will collate PPC and SC feedback in a summary document to be provided to the WC 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 WC Chair.
4. The WC will consider the feedback provided and make modifications to the draft manuscript based on his/her judgment.
5. The WC Chair will re-submit the updated draft to the PPC within 1 month of receipt of feedback; 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 WC Chair via the PPC.

6.1.2 Journal Submission

The manuscript will be formatted and submitted in adherence to journal requirements. Most manuscripts will be submitted by the DCC, and in these cases, the DCC will incur any costs associated with manuscript submission. The PPC and submitting co-authors will receive a copy of the journal cover letter and final draft of the manuscript.

The DCC 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.

6.1.3 Manuscript Revisions

If the WC proposes substantive changes in response to journal review (e.g., new analyses, new data, alterations to the study sample, or major changes to interpretation or conclusions):

- A summary of the proposed revisions must be submitted to the PPC for approval; review by PPC will primarily focus on overlap with other manuscripts in process and burden to the DCC.

- Manuscript revisions should commence only after PPC approval.
- Use of additional biological samples would be considered exceptional, and would require ASC approval.

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 WC 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 WC 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 WC 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 WC 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.

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 WC members or for disbanding or reconstituting the WC.

8.2 Deviations in Scope

For approved manuscript proposals, changes in scope will be communicated by the WC 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 WC 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 WC Chair to the PPC. WC 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 WC concludes that it will not produce a manuscript or will combine its analyses with those of another WC to generate one integrated manuscript, the WC 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 WC Chair 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
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