ClinGen Publication Policy

April 2019

The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of any ClinGen Consortium data, timely completion of manuscripts, and adherence to the principles of authorship.

PUBLICATION POLICY OVERVIEW

Goals

- To encourage publication submissions – particularly collaborative works involving the ClinGen Consortium.
- To enable external groups to collaborate with the ClinGen Consortium.
- To maintain a complete up-to-date list of ClinGen presentations, approved manuscript proposals and publications, and to distribute such lists to all ClinGen investigators on a regular basis.
- To comply with the NIH's Public Access Policy for all ClinGen related publications.

Publications

- **Single-site manuscripts**
  - Principal Investigators (PIs) have the right to publish his/her own specific data/work products without approval by the Steering Committee.
- **Consortium manuscripts**
  - Manuscripts that make extensive use of ClinGen data/work products, describe ClinGen procedures/protocols, or have broad policy implications must adhere to the publication approval process described in more detail on page 2.

Role of the ClinGen Steering Committee (SC)

- All publication functions will be performed by the ClinGen Steering Committee using the following principles:
  - Promote transparency and inclusiveness
  - Simplicity
- Key functions of the Steering Committee relative to publications include:
  - Concept approval for consortium-wide projects (e.g., WG generated manuscripts)
  - Manuscript approval if the publication has broad implications for the ClinGen program
  - Manuscript and publication tracking (with the NHGRI)
  - Adjudication of publication-related conflicts

PUBLICATION PROCESS

- **Submitting Abstracts to Scientific Meetings**
  - Abstracts do not require approval before submission. However, if there is a NHGRI or NCBI co-author, final versions of the abstract must be submitted to the Project Officer for review and approval.

- Citations of all approved abstracts should be sent to the NHGRI so that the ClinGen bibliography can be updated accordingly.

- **Submission and approval of manuscript proposals**
  - All ClinGen investigators are invited to submit manuscript proposals to the Steering Committee.
  - The lead (first) author submits a completed Manuscript Concept Sheet (*see Appendix 1*) to the NHGRI. The NHGRI forwards the Concept Sheet to the Steering Committee for review and approval before manuscript development. If more than one person submits the same or similar topic, the Steering Committee may decide who will assume the project lead.

- **Preparation and journal submission of manuscripts**
  - The Lead Author of a writing group:
    - Contacts the Steering Committee if a change in Lead Author or Senior Author is necessary (for instance due to workload) and informs them of the request to transfer the lead to another individual.
    - Keeps the Steering Committee and the NHGRI informed of the manuscript's progress.
    - Submits the final version of a manuscript for review/approval (only if deemed necessary) to the Steering Committee before journal submission.

- **Manuscript Review**
  - The purpose of manuscript review is to evaluate the clarity of the writing and the consistency with other ClinGen findings. Full manuscript review is only required if:
    - Each site is not represented by a co-author
    - The manuscript has broad implications for policy implementation or the project as a whole.
  - A copy of the manuscript is submitted to the NHGRI for circulation to the Steering Committee. The Steering Committee has two weeks to review the manuscript either by conference call or by email. After a decision has been made, NHGRI will notify the lead author. If concerns are noted during the SC's review, NHGRI will share these concerns with the lead author. If no comments were given by the SC within two weeks, the manuscript will be considered approved.
    - In some circumstances, NHGRI may refer the concept sheet to relevant WGs for approval rather than the SC.

- **Acknowledgements**
  - All relevant papers should include a statement citing the NIH grant support for the work, listing the appropriate grant numbers and acknowledging the ClinGen consortium (*see Appendix 2*).
  - All requests for color figure reprints of final publications are directed to the lead author.

- **Access, Tracking & Reporting**
  - **All manuscripts developed by or in association with ClinGen must be deposited in PubMed Central[1].** For more information on this process, please visit the NIH's website on their Public Access Policy[2].
  - **Single-site Publications**: For informational purposes, the citation should be added to the ClinGen website and noted in progress reports.

[1] https://www.ncbi.nlm.nih.gov/pmc/
[2] https://publicaccess.nih.gov/submit_process.htm

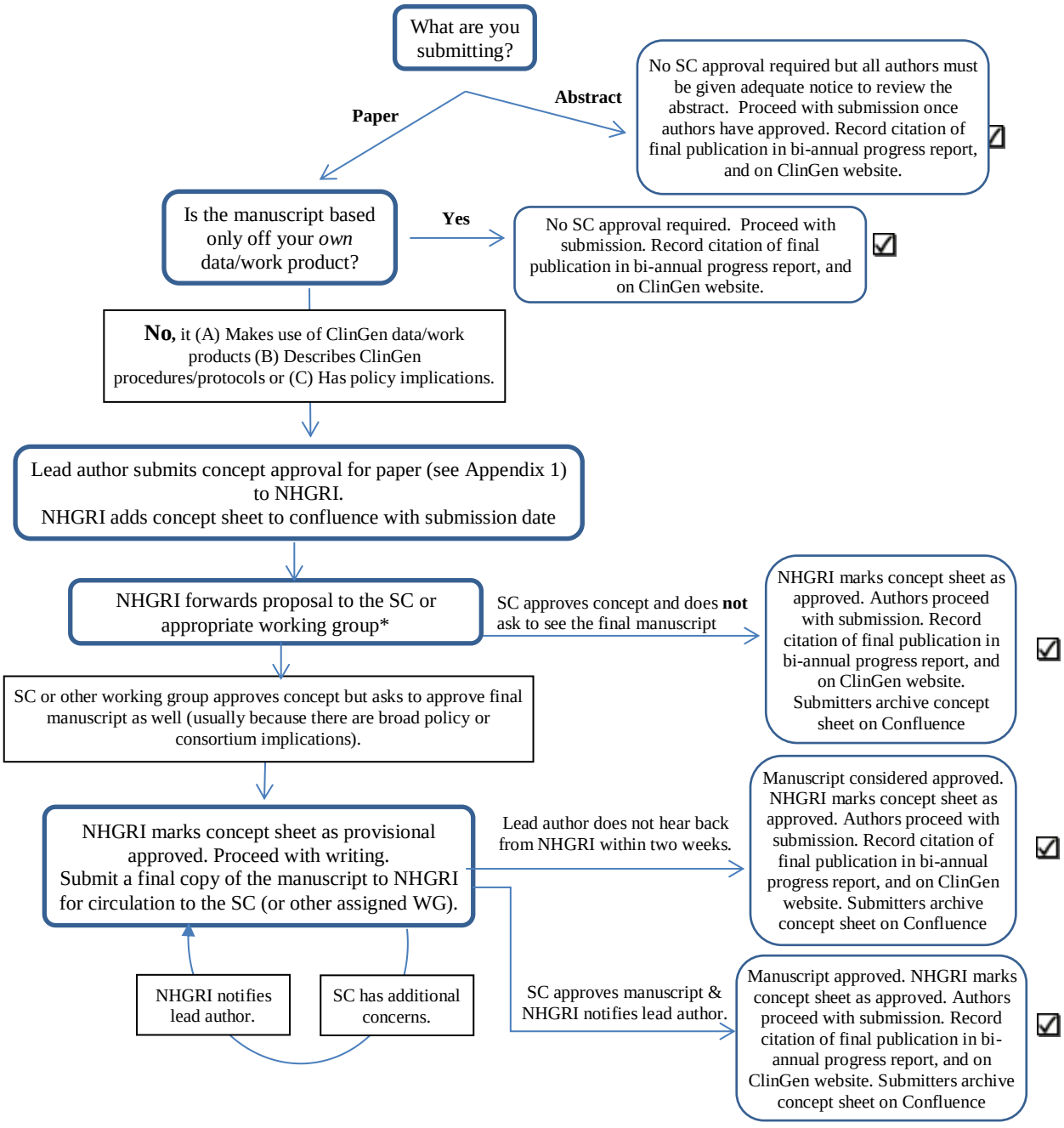
- **Consortium Publications:** Please see the publication process summary workflow on the following pages. The citation should be added to the ClinGen website and noted in progress reports.

- **Data Sharing**
  - All authors should ensure that their analysis is consistent with all conditions of the *Points to consider for sharing variant level information with ClinVar*[3], NIH Genomic Data Sharing Policy[4], Institutional Review Board (IRB)-approved protocols, informed consent forms signed by Research Participants, HIPAA, and Title XIII of the American Recovery and Reinvestment Act of 2009.
  - All ClinGen-supported working groups must agree to dissemination of their curation results via the ClinGen website or ClinVar immediately upon completion of expert review of each variant, gene, genomic region, or topic. Individual curation results cannot be held for publication. Data will be exported in either real time (GCI, ACI, etc) or on a regular basis (VCI to ClinVar). It is the responsibility of the author to confirm that, upon publication, the data he/she analyzed is available through ClinVar and/or ClinGen.
  - It is the expectation that whenever possible, manuscripts will be pre-published on bioRxiv. If the authors do not anticipate submitting their manuscript to bioRxiv they must provide a written justification in their concept sheet.

- **Terms of Use**
  - Curated content (e.g. gene-disease validity, dosage sensitivity and clinical actionability) distributed on the ClinGen website is released openly for the benefit of the wider community. You can freely capture the data and we encourage the use and publication of results generated from these data. All curated content published by ClinGen is available free of restriction under the CC0 1.0 Universal (CC0 1.0) Public Domain Dedication. However, ClinGen requests that you give attribution to ClinGen whenever possible and appropriate.

[3] https://www.clinicalgenome.org/events-news/publications/points-to-consider-for-sharing-variantlevel-information-from-clinical-genetic-testing-with-clinvar/
[4] NIH Genomic Data Sharing Policy: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html.

PUBLICATION PROCESS SUMMARY



NOTES

***Working groups that may be asked to consider concept sheets in lieu of the SC include: Clinical Domain Working Group Oversight Committee, Sequence Variant Interpretation WG, and Gene Curation WG. Other WGs may be utilized as well depending on the content of the concept sheet.**

Appendix 1

Manuscript Concept Sheet

Purpose: All ClinGen investigators are invited to submit ideas for papers. First, the tentative Lead Author submits this Manuscript Concept Sheet to the NHGRI. The NHGRI will then forward the Concept Sheet to the Steering Committee (SC) for review and approval before manuscript submission. If more than one person submits the same or similar topic, the SC may decide who will assume the project lead.

Submission Date	
Project Title	
Tentative Lead Investigator (1st author)	
Tentative Senior Author (last author)	
All other authors	
Sites Involved	
Background / Significance	
Outline of Project	
Desired Variables (essential for analysis)	
Planned Statistical Analyses	
Ethical considerations	
Target Journal	
BioRxiv (Please indicate plans to post pre-print or justification for not posting pre-print)	
Milestones (Include the timeline for completion of project, including approval project duration, first and second draft of the paper and submission)	

Appendix 2
ClinGen NHGRI Acknowledgement

Papers spanning ClinGen broadly:
ClinGen is primarily funded by the National Human Genome Research Institute (NHGRI), through the following three grants: U41HG006834, U41HG009649, U41HG009650. ClinGen also receives support for content curation from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), through the following three grants: U24HD093483, U24HD093486, U24HD093487. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Papers specific to certain grants:
This publication was supported by the National Human Genome Research Institute of the National Institutes of Health through the following grants and contracts: *add specific grant numbers*. The content is solely the responsibility of the author and does not necessarily represent the official views of the National Institutes of Health.

- If an NCBI co-author is included, the publication needs the statement, *'This research was supported in part by the Intramural Research Program of the National Library of Medicine, National Institutes of Health.'*
- **All abstracts and papers with a NHGRI or NCBI co-author** must be submitted in their final version to the Project Officer for review and approval.