

gLHS Network Publication Policy

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Overview

The success of the genomics-enabled learning health system (gLHS) network will be judged largely on the number and quality of its scientific publications and presentations. The gLHS Network Publication Policy sets forth equitable, clear policies regarding the standards and expectations for use and publication of data. The purpose of the policies established in this document is to promote transparency and collaboration across the network, encourage and facilitate important analyses while providing guidelines that assure appropriate use of any gLHS network data, timely completion of manuscripts, and adherence to the principles of authorship.

This policy applies to internal, gLHS network data, specifically any publications which utilize grant funds and therefore need to be tracked centrally. The policy does not apply to publicly accessible data for which access is governed by non-network entities such as dbGaP or external controlled AnVIL access. The gLHS network publication process is overseen by the gLHS network Steering Committee, the structure and membership of which is defined in this policy.

Definitions

- **CC:** the current Coordinating Center for the network as appointed by the National Institute of Health and included in the applicable funding award.
- **Data Transfer Use Agreement (DTUA):** legally-binding contract regarding the terms for the transfer/sharing of non-public data between organizations.
- **gLHS Network Members:** all current individuals and groups funded by the National Institute of Health for the purposes of participating and performing certain responsibilities in the gLHS network.
- **gLHS Network Affiliate Member:** Individual(s) or group(s) who have applied to and been approved by the Steering Committee for Network Affiliate membership. Affiliate membership requires an application, scientific proposal of research, and DTUA to be fully executed and is reviewed and accepted by the Steering Committee. Affiliate

members can submit manuscript concept sheets, however, do not have voting rights within the Steering Committee.

- **NIH:** National Institute of Health, the funding agency for the Network, which includes the **NHGRI** (National Human Genome Research Institute) and **NCI** (National Cancer Institute).
- **Leadership Group:** A group of individuals who oversees the network and is composed of the NHGRI and NCI program staff, the Steering Committee chair, the Coordinating Center (CC) contact PI and operations director.
- **Steering Committee:** The committee responsible for administering the gLHS network Publications Policy and approval of external collaborator study proposals. The Steering Committee is made up of the principal investigator(s) at each gLHS network member site, including the CC, and the NHGRI and NCI program officers.
- **MCS:** Manuscript Concept Sheet, which outlines the proposed publication and is submitted to the Steering Committee for review and approval.

Goals

The goals of the gLHS publication policy involve the facilitation of network productivity, ensuring fairness in the publication process, and adherence to data sharing policies.

- To encourage publications, particularly collaborative science involving multiple gLHS network sites.
- To ensure appropriate use of gLHS data and compliance with data access and sharing requirements.
- To ensure appropriate recognition for authors and gLHS network sites.
- To enable tracking of gLHS network publications by the CC and highlight productivity both internally and externally.
- To avoid project overlap.
- To enable and provide guidance for collaboration with external investigators.

Principles & Functions

All functions will be performed by the gLHS Network Steering Committee with the goal to promote transparency and inclusiveness across the network.

- The roles of the Steering Committee, Lead and Senior Author, and Site PIs include:
 - **Steering Committee:** review, adjudicate, and approve manuscript concepts.
 - **Lead & Senior authors:** submission of manuscript concept sheet (MCS), communication with the CC and other sites, and transparency throughout the publication process.
 - **Site PIs:** reviewing all MCS, ensuring appropriate site author sign up, and ensuring that publications from their site adhere to the network policies.
- Key functions of the Steering Committee concerning publications include:
 - Tracking manuscripts and publications
 - Adjudication of conflicts related to publication
 - Concept approval for multi-site / network-wide projects
 - Manuscript approval, contingent upon adherence to gLHS, Institutional, and NIH publication policies
 - Review and approval of all proposals from external collaborators, ensuring compliance with the gLHS network policies for approved external collaborator studies.
 - Review and approval of all revisions to this Publication Policy.

- Individuals utilizing the network data must abide by the data transfer and use agreement signed by the site. Data use agreements must be in place before any data transfer takes place.

Publications

Single-site publications

The gLHS network aims to promote collaboration between sites via multi-site and network-wide publications, with the understanding that there may be a need for single-site publications. Sites planning to publish single-site manuscripts should be transparent with the network to ensure that site specific publications do not replace larger network projects or undermine the potential for a network-wide paper for a similar topic.

Publications using data or concepts from only one site are considered single-site publications. Single-site publications require submission of a manuscript concept sheet (MCS), which will be circulated to the network for awareness but will not require a formal approval process like a multi-site MCS. During the one-week MCS review period, if investigators believe that the manuscript would benefit from being a multi-site publication rather than a single-site publication, investigators are encouraged to reach out directly to the site to discuss. The CC should be notified in order to pause the MCS while under discussion. If it is determined that the MCS should be a multi-site publication, the MCS will be re-circulated and follow the process for a multi-site publication.

Authors of single-site publications are responsible for ensuring the appropriate recognition of the gLHS Network in the publication. Single-site publications should have data and resources available to be analyzed and a draft of the manuscript within approximately one year from MCS submission. If a publication is not generated in this period, the CC will reach out to the lead author to confirm the plans to publish and discuss removal or revision of the MCS as needed.

Additional information about the single-site MCS process can be found in the [“Proposal submission and approval timeline”](#) section.

Multi-site publications

Multi-site publications are defined as collaborations between two or more gLHS Network Member sites that are focused on topics relevant to the gLHS Network, involve data from more than one site, make extensive use of Network-generated meta-data or procedures/protocols or involve policy/guidelines applicable to more than one site.

For all multi-site publications, a manuscript concept sheet (MCS) is required for each project (paper) that is proposed. Multi-site publications should have data and resources available to be analyzed and a draft of the manuscript within approximately one year from MCS submission. If a publication is not generated in this period, the CC will reach out to the lead author to confirm the plans to publish and discuss removal or revision of the MCS as needed.

Additional information about the multi-site MCS process can be found in the [“Proposal submission and approval timeline”](#) section.

Network Marker Papers and Primary Results Papers

Network marker papers and primary results papers are particular cases of multi-site publications which describe findings and lessons learned from the gLHS network as a whole. These publications require extra care to ensure that all gLHS stakeholders have the opportunity to

contribute to and review the manuscript and ensure that all individuals are in agreement with the publication.

- All marker papers and primary results papers should include co-authors from each gLHS network site, the CC, and NIH.
- It is the responsibility of the co-authors from each site to review the manuscript in full on behalf of the site and raise any concerns prior to publication.

Proposal submission and approval timeline

All gLHS network investigators are invited to submit ideas for papers to the Steering Committee via a MCS. Access and utilization of network data is restricted to active members of a current site or affiliate members. The MCS is considered a commitment to carry out the work described. As such, the MCS for a project should not be submitted until the project concept is fully formed and ready for development, but should be submitted prior to substantial work on the project to allow for network feedback and addition of authors as necessary. One MCS is required to be submitted for each proposed publication.

The tentative Lead (first) Author is required to submit a completed MCS for review and approval by the Steering Committee prior to manuscript drafting and submission. In the event that multiple individuals propose the same or similar topics, the Steering Committee can assess and designate the project lead. The lead author should submit the MCS to the CC for administrative processing. Following processing, the CC will forward the proposal to the Steering Committee for a one week review period. The lead author is responsible for promptly addressing questions, and submitting proposed changes to the request and analysis during review.

During the review period of a multi-site MCS, Steering Committee members have the option to acknowledge with approval or voice any concerns. At the conclusion of the one week review, if there are no unresolved concerns or any objections to the manuscript, the multi-site MCS is marked as approved. If a site does not respond to a proposal, the absence of objection will serve as approval.

During the review period of a single-site MCS, Steering Committee members will not be asked to formally approve the MCS, however, Steering Committee members should raise any concerns about the MCS with the Lead and Senior Authors. If the conflict cannot be resolved directly, the process for [adjudication of conflicts](#) will be enacted.

- The network encourages that the PIs share and discuss the MCS with their team prior to approval.
- During the review process, the CC will relay any questions or concerns that are raised to the tentative Lead Author for resolution.
- Sites may request that their data not be included in the manuscript.
- The MCS will not be approved until all outstanding questions and concerns have been resolved.

A multi-site project cannot proceed without Steering Committee approval of the MCS. Following approval, publication should occur within approximately one year, or revision of the MCS is required. Publication progress will be centrally tracked by the CC.

If during the course of the manuscript development a second project (manuscript) develops, the lead authors of the new concept must submit an additional MCS for approval.

For Special Issue Journals the project lead organizer will submit a MCS for the entire Issue, listing proposed articles and lead authors along with abbreviated MCS for each article. Abbreviated MCS will contain at a minimum Title, Lead Author, Project Outline and Desired Data. Once the main MCS and all abbreviated MCS have been submitted, the CC will forward the proposal as a Special Issue Journal packet to the Steering Committee for review.

Authorship

It is important to ensure that authors and gLHS network sites are properly recognized, particularly in multi-site network publications. During the MCS review period, PIs will be responsible for ensuring that all members at their site who have made significant contributions to the proposed efforts outlined in the MCS are proposed to the lead author for authorship consideration. After the MCS has received approval by the Steering Committee, it becomes the collective responsibility of all co-authors to communicate directly with the lead author. Any additional author additions should be directed to the lead author of the manuscript after the MCS approval period has elapsed.

The Lead Author or Senior Author of each project writing group, with the concurrence of other members of the group, determines the order of authorship. To encourage collaboration across the network, it is encouraged that the Lead Author and Senior Author are from different gLHS Network Member sites.

A major criterion for authorship determination is the effort and contribution made by the members of the writing group in preparation of the manuscript. Criteria for authorship will follow the recommendations of the International Committee of Medical Journal Editors (<http://www.icmje.org>).

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing 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 individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript. The number of authors should not necessarily be limited but should be determined by actual contribution to the manuscript.

An acknowledgement section in the paper can give authorship credit to those in the network that may have had a smaller, but important, contribution to the paper. Contributors who do not meet all four criteria should be acknowledged.

Disagreement regarding the order of authors, which cannot be resolved by the Lead or Senior Author of the project writing group, will be resolved by the Steering Committee.

Preparation and Submission of Papers

The preparation of the gLHS multi-site or network manuscripts includes the process outlined below, with the lead author of the writing group being responsible for:

- Contacting the Coordinating Center if a change in Lead Author or Senior Author becomes necessary and requests to transfer the lead to another individual.

- Ensuring that authorship is provided appropriately to participating investigators, workgroups, and sites.
- Keeping the Steering Committee and the CC informed of the manuscript progress.
- Utilizing data only for which the MCS has been approved.
- Circulating the manuscript at least twice for review by the full writing group; once in the early stages of drafting the manuscript and again when the manuscript is near completion. Alternatively, the first circulation can be a proposed study design/analysis plan for review and comment. The writing group will have no less than one week to comment upon the first manuscript circulation. Upon the second circulation, near completion, the writing group will have no more than one week (longer upon request) for review and comment.
- Ensuring that potential authors review and provide feedback on draft manuscripts; failure to do so should be seen as a withdrawal from authorship. The lead author should notify non-respondent authors and their PIs that they will be removed from the authorship list prior to submission.
- Submitting the final version of a manuscript for review/approval (if necessary) by the Steering Committee and Program Officer before the paper is submitted to a journal for publication.
- Circulating a copy of the submitted manuscript to the writing group.

The CC role in manuscript preparation is to assist with tracking and coordination of projects, including consultative support for analyses as appropriate.

Sensitive and stigmatizing language

All investigators are encouraged to review their manuscripts prior to publication to ensure that they are referring to individuals and populations appropriately and with respect. The following resources are useful in conducting this review. Investigators should take special care with analysis of results and conclusions that may have variation in interpretation by certain groups.

- American Psychological Association:
<https://www.apa.org/about/apa/equity-diversity-inclusion/language-guidelines>
- Center for Disease Control and prevention:
https://www.cdc.gov/healthcommunication/Preferred_Terms.html
- National Academies of Science, Engineering, and Medicine:
<https://www.nationalacademies.org/our-work/use-of-race-ethnicity-and-ancestry-as-population-descriptors-in-genomics-research>

Abstract Submission for Meetings

Submission of abstracts, posters, and seminars to various meetings and conferences can be very time dependent. Because of this, abstracts do not require approval by the gLHS Steering Committee but must comply with the policies and procedures set forth for single and multi-site projects. Submitted and accepted abstracts should be communicated to the CC for centralized tracking.

When an abstract is ready to be written as a manuscript, it will need to go through the MCS process and receive approval by the gLHS Steering Committee. Network members should be aware that presentation of an abstract at a conference does not guarantee lead authorship in a future publication.

Institutional seminars, posters, and presentations do not need to be circulated to the network prior to presentation.

Single-site Abstracts and Presentations

Each site has the right to submit abstracts containing data from its own site participants without approval by the Steering Committee. For informational purposes, the title and author list for the abstract should be submitted to the CC.

Multi-site Abstracts and Presentations

If the abstract meets any of the [multi-site project criteria](#) defined in this policy, it must be circulated to the appropriate sites, workgroups, and co-authors for approval and request for authorship prior to submission. If the abstract is associated with an existing MCS project, the abstract must be reviewed by the author list associated with that approved project. All MCS authors should be notified of an abstract submission.

Presentations and abstract citations should be sent to the CC so that the gLHS Network bibliography can be updated accordingly.

If the author list includes any NIH co-authors, final versions of the abstract or presentation must be submitted to the Program Officer(s) for review and approval.

Adjudication of conflicts

Adjudication of conflicts, including authorship disagreements and content overlap, will be handled by tiered levels of resolution:

- Any disputes should first be addressed with the lead and senior author, to determine if the issue can be resolved directly.
 - The CC should be informed of any conflicts at this stage. A hold will be put on the MCS at this stage until the conflict is resolved. Actions will be taken to resolve the conflict in a timely manner, so that progress on the publication can continue as soon as possible. If further adjudication is needed, the CC will bring the issue to gLHS Leadership group for review.
- If the issue cannot be resolved by gLHS Leadership, the full gLHS Network Steering Committee will be asked to review and provide input.

MCS that are pending conflict resolution will not be approved by the CC until all parties have come to a final resolution.

Amended MCS (with tracked changes) can be circulated to resolve issues during the SC review period.

Publication Tracking & Reporting

The CC will provide the network with access to a listing of all publications. This report lists the lead and senior authors, working title and journal submission title, date of receipt and approval by the Steering Committee and proposal status.

The following reports will be distributed at each Steering Committee meeting:

- Manuscript Status List - number, title, lead author, date received, status, date submitted, and date approved.
- Manuscript Publication List - full citation and gLHS network manuscript number.
- Abstract Presentation Summary - metrics (number of posters and talks) about presentations at scientific conferences

Publication Administrative Items: Acknowledgement Statements, Reprints, Publication Costs

All gLHS network-wide papers should include a statement citing the NHGRI/NCI grant support for the work, listing the appropriate grant numbers and acknowledgement of the gLHS network (Appendix 2).

All publication and figure charges, requests for reprints of final and gLHS network-wide papers, are the responsibility of the corresponding author's gLHS network site. The costs of slides for specific presentations, publication of specific manuscripts, and reprints are the responsibility of the corresponding author.

After manuscripts have been published, requests for non-individual level network wide summary statistics can be released by the authors of the publication.

APPENDIX 1: Manuscript Concept Sheet

gLHS Network: Manuscript Concept Sheet	
Reference Number <i>(to be assigned by CC)</i>	
Submission Date	
Project Title	
Tentative Lead Investigator <i>(first author)</i>	
Tentative Lead Investigator Email <i>(first author)</i>	
Tentative Senior Author <i>(last author)</i>	
All Other Authors	
Sites Participating	
Background / Significance	
Outline of Project	
Sensitive/Stigmatizing data requested	<i>Does this MCS request data that could be considered sensitive or stigmatizing?</i> <input type="checkbox"/> Yes, PIs encouraged to review <input type="checkbox"/> No sensitive or stigmatizing concepts

gLHS Network data* (Available from the CC)	<input type="checkbox"/> Demographics <input type="checkbox"/> ICD9/10 codes (limited) <input type="checkbox"/> CPT codes (limited)	<input type="checkbox"/> Labs (limited) <input type="checkbox"/> Medications (limited) <input type="checkbox"/> Referral data (limited)
Other Desired Data (Available from participating sites)	Please specifically list out any data elements that participating sites would collect or extract from clinical or other sources for this project (i.e. not common variables above)	
Planned Statistical Analyses		
Ethical Considerations		
Target Journal		
Milestones (This section should include the key dates for completion of project, including approval, project duration, draft completion, and submission.)		

APPENDIX 2: Acknowledgement Text

The genomics-enabled learning health system (gLHS) Network was initiated and funded by the NHGRI and NCI through the following grants: 1U01HG013796-01 (Geisinger), U01HG013770 (Indiana University), 1U01HG013745-01 (Northwestern University), 1U01HG013784-01 (University of Utah), 1U01HG013776-01 (Vanderbilt University Medical Center), 1U01HG013781-01 (Veterans Affairs), 1U01HG013771 (Vanderbilt University Medical Center serving as the Coordinating Center).