**eMERGE Network**

# Publications and Presentations Policy & Procedures

Approval policy for research proposals &

Steering Committee and Network member structure

**Overview**

The success of the eMERGE Network (the “eMERGE Network”) will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of any eMERGE Network data, timely completion of manuscripts, and adherence to the principles of authorship. The eMERGE Network publication process is overseen by the eMERGE Network Steering Committee, the structure and membership of which is defined in this policy.

The process for review of external collaborators is set forth in this policy and require that any external collaborator involving eMERGE Network data execute an appropriate agreement with a Network Member site and work closely with the principal investigator at the site and agree in the agreement to comply with the policies of the Network.

**Publications and Presentations Policy**

**Definitions:**

* **CC**: the current coordinating center for the Network as appointed by the NHGRI and included in the applicable funding award.
* **eMERGE Network Members**: all current entities funded by NHGRI for the purposes of participating and performing certain responsibilitites in the eMERGE Network.
* **eMERGE Network affiliate member**: Member or group who has applied to and been approved by the Steering Committee for affiliate membership. Affiliate membership requires an application, scientific proposal of research, and DUA to be fully executed and is reviewed and accepted by the Steering Committee. Affiliate members can submit manuscript concept sheets and sponsor external collaborations, however do not have voting rights within the Steering Committee.
* **NHGRI**: National Human Genome Research Insititute, a division of the National Institute of Health, the funding agency for the Network.
* **Program Officer**: the manager of the eMERGE Network grant program at NHGRI.
* **Leadership group**: A group of individuals who oversees the network and is composed of the NHGRI program staff, the Steering Committee chair, the Coordinating Center (CC) contact PI and operations director.
* **Steering Committee**: is the committee responsible for admistering the eMERGE Network Publications and Presentations Policy and approval of external collaborator study proposals and is made up of the principal investigator(s) at each eMERGE Network Member.

**Goals:**

* To encourage publication submissions – particularly collaborative works involving multiple eMERGE network sites.
* To enable and provide structure for external groups to collaborate with the eMERGE Network.
* Enable the CC to maintain a complete up-to-date list of eMERGE Network presentations, approved manuscript proposals and publications, and to distribute such lists to all eMERGE Network member investigators on a regular basis.

**Principles & Functions**

* All functions will be performed by the eMERGE Steering Committee using the following principles:
  + Promote transparency and inclusiveness
  + Simplicity
* Key functions of the Steering Committee relative to publications include:
  + Manuscript and publication tracking
  + Adjudication of publication-related conflicts
  + Concept approval for eMERGE Network-wide projects
  + Manuscript approval only if policy implications or not all sites represented in authorship
  + Review and approval of all external collaborator study proposals and ensure compliance with the eMERGE network policies for approved external collaborator studies.
  + Review and approval all revisions to this Policy.

**Publications**

* **Single-site Projects**

Each Principal Investigator has the right to publish data from his/her own population without approval by the Steering Committee. For informational purposes, the title and author list should be submitted to the CC when the manuscript is in press.

* **Multi-site Projects**

Collaborations between two or more sites that are focused on topics relevant to the eMERGE 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 are considered multi-site projects and must adhere to the publication approval process outlined below. Multi-site projects should have data and resources available to be analyzed and a draft of the manuscript within approximately one year from manuscript concept sheet (MCS) submission.

**Proposal Submission and Approval**

To initiate the process that leads to a presentation at a scientific meeting or writing a paper for publication, all eMERGE Network investigators are invited to submit ideas for papers to the Steering Committee. The tentative Lead (first) Author submits a completed Manuscript Concept Sheet (see Appendix 1), which is reviewed and approved by the Steering Committeee before manuscript submission. If more than one person submits the same or similar topic, the Steering Committee may decide who will assume the project lead.

The Concept Sheet is submitted to the CC for administrative processing. The CC forwards the proposal to the Steering Committee for review. The Lead Author is responsible for promptly submitting suggested outlines of all proposed analysis projects, approved presentations and publications to the CC.

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

**Authorship**

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. A major criterion for this 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). ICMJE recommends that authorship be based on the following four criteria:

* 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 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.

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.

PIs will ensure that all members at their site who have contributed to the proposed effort outlined in the Manuscript Concept Sheet will be proposed to the lead author for authorship. Once the concept sheet has been approved by the Steering Committee it is then the responsibility of all co-authors to communicate directly with the lead author.

**Preparation and Submission of Papers**

The following steps are followed in the preparation of eMERGE Network 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 CC informed of the manuscript’s progress.
* Circulates manuscript at least twice for review by full writing group; once in the early stages of drafting the manuscript and again when the manuscript is near completion. Or if the author prefers, the first circulation can be a proposed study design/analysis plan for review and comment. Upon the first manuscript circulation (or analysis plan), the writing group will have no less than one week and no more than two weeks to comment. Upon the second, near completion, circulation to the writing group, the group will have no more than one week (longer upon request) for review and comment.
* Ensures that potential authors review and comment on draft manuscripts; failure to do so should be seen as a withdrawal from authorship. Notifies non-respondents and their PIs that they will be removed from authorship list prior to submission.
* Submits 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.
* Circulates a copy of the submitted manuscript to the writing group.

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

For data submitted to meta-analyses or other large consortia projects, the Lead Author (lead contributor) for the eMERGE Network is responsible for ensuring that authorship is provided appropriately to participating sites and that the manuscript is circulated to site authors as indicated above for eMERGE Network manuscripts.

**Manuscript Review**

The purpose of manuscript review is to evaluate the scientific merit, the clarity of the writing and the consistency with other eMERGE Network findings.

Full manuscript review is only required if:

* Each site is not represented by a co-author
* The manuscript involves the presentation or discussion of broad policy guidelines

If there is a NHGRI co-author, final versions of the manuscript must be submitted to the Project Officer for review and approval.

A copy of the manuscript is submitted to the CC for circulation to the Steering Committee and Program officer for review. The Steering Committee discusses the review and manuscript during conference call or by e-mail within two weeks. If no comments are received within this time period, the manuscript is considered approved.

**Abstract Submission for Meetings**

Abstracts and presentations do not require Steering Committee approval. However, they must comply with the policies and procedures set forth for single and multi-site projects.

* **Single-site Abstracts and Presentations**

Each site has the right to publish 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 (see page 1), it must be circulated to the appropriate sites for approval and request for authorship. If the abstract is associated with an existing MCS project, it must be reviewed by the author list associated with that approved project. All MCS authors should be notified of an abstract submission.

Presentations should be sent to the CC so that they may be posted to the eMERGE Network web site. All abstract citations should be sent to the CC so that the eMERGE Network bibliography can be updated accordingly

If there is a NHGRI co-author, final versions of the abstract or presentation must be submitted to the Project Officer for review and approval.

**External Collaborations**

The eMERGE Network is receptive to external collaborators that request to collaborate with the eMERGE Network and publish on scientifically relevant research topics. External collaborators are individuals that request to utilize eMERGE Network data, but are not Affiliate members and do not request to become Affiliate members. The publication and manuscript concept sheet (Appendix 2) policy follows the above guidelines with the addition of the following requirements:

* The external collaborator requires an eMERGE Network member (site) to sponsor the introduction of the MCS to the Steering Committee.
* The eMERGE Network member sponsor (site) is responsible for executing the appropriate agreement with the external collaborator (e.g. research agreement; data transfer agreement) for performance of the study as applicable and assuring appropriate terms for data transfer, and compliance with eMERGE Network policies.
* eMERGE Network member sites and Affiliate members can sponsor an external manuscript concept sheet.
* A description of funding for the proposed research is required during submission of the external MCS.

**Industry Collaborations**

The eMERGE Network is composed of eMERGE Network members and sites with specific expertise that is valuable for a multitude of projects that are increasing of interest to industry sponsors. The CC will act as the facilitator to connect the eMERGE Network members with industry opportunities where the industry collaborator wants access to the sites and their expertise, however, does not want or need to utilize Network data or work products.

The CC will work with the industry collaborator to complete the ‘Industry Collaboration Opportunity’ form (Appendix 3). The Industry Collaboration Opportunity form will be submitted for review by the eMERGE Network Leadership Team. Once approved, the CC will circulate the Industry Collaborator Opportunity form to the Steering Committee.

After circulation of the Industry Collaboration Opportunity form, the sites are responsible for contacting the industry collaborator if they are interested in participating. Contracts and data use agreements will be negotiated between individual sites and the collaborator. Network data will not be shared centrally as part of these industry collaborations.

**Publication Administrative Items: Acknowledgement Statements, Reprints, Publication Costs**

All eMERGE Network-wide papers should include a statement citing the NHGRI/NIGMS grant support for the work, listing the appropriate grant numbers (Appendix 4), and acknowledge the eMERGE Network.

All requests for reprints of final and eMERGE Network-wide papers are directed to the eMERGE Network site associated with the corresponding author of the paper. The costs of slides for specific presentations, publication of specific manuscripts and reprints are the responsibility of the Lead Author.

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

**Publication Tracking & Reporting**

* **Single-site Publications**

As outlined in section II, during the manuscript planning stages, authors should submit the title and author list to the CC. When the manuscript is in press, a final copy of the manuscript should be submitted to the CC for informational purposes.

* **Multi-site Publications**

The CC will provide access to a listing of publications via the Network website. This report lists the Lead Author and Senior Author, 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 eMERGE Network manuscript number.
* Abstract Presentation List - full citation and eMERGE Network manuscript number, date, and meeting.

**APPENDIX 1: Internal Manuscript Concept Sheet**

|  |  |  |
| --- | --- | --- |
| **eMERGE Network: Manuscript Concept Sheet** | | |
| **Reference Number**  *(to be assigned by CC)* |  | |
| **Submission Date** |  | |
| **Project Title** |  | |
| **Tentative Lead Investigator** *(first author)* |  | |
| **Tentative Lead Investigator Email *(first author)*** |  | |
| **Tentative Senior Author**  *(last author)* |  | |
| **All Other Authors** |  | |
| **Sites Participating** |  | |
| **Background / Significance** |  | |
| **Outline of Project** |  | |
| **Desired Data - Common Variables\***  *(Available from the CC)* | ☐Demographics  ☐ICD9/10 codes  ☐CPT codes  ☐Phecodes  ☐BMI | ☐Common Variable Labs  ☐Common Variable Meds  ☐ Geocoding 2015 ACS variables  ☐Other: Case/Control status |
| **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)* | |
| **Desired Genetic Data** | ☐eMERGE I-III Merged set (HRC imputed, GWAS)  ☐eMERGE PGx/PGRNseq data set  ☐eMERGEseq data set (Phase III)  ☐eMERGE Whole Genome sequencing data set  ☐eMERGE Exome chip data set  ☐eMERGE Whole Exome sequencing data set  ☐Other (not listed above): | |
| **Does project pertain to an existing eMERGE Phenotype?** | ☐Yes, if so please list  ☐No | |
| **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.)* |  | |

***\*\**** *This section should include the timeline for completion of project, including: approval, project duration, first and second draft of the paper and submission.*

**APPENDIX 2: External Manuscript Concept Sheet**

|  |  |  |
| --- | --- | --- |
| **eMERGE Network: External Collaborator Manuscript Concept Sheet** | | |
| **Reference Number**  *(to be assigned by CC)* |  | |
| **Submission Date** |  | |
| **Project Title** |  | |
| **Tentative Lead Investigator** *(first author)* |  | |
| **Tentative Lead Investigator Email** *(first author)* |  | |
| **Tentative Senior Author**  *(last author)* |  | |
| **eMERGE Site Sponsor & Contact** |  | |
| **All Other Authors** |  | |
| **Sites Participating** |  | |
| **Background / Significance** |  | |
| **Outline of Project** |  | |
| **Desired Data - Common Variables\***  *(Available from the CC)* | ☐Demographics  ☐ICD9/10 codes  ☐CPT codes  ☐Phecodes  ☐BMI | ☐Common Variable Labs  ☐Common Variable Meds  ☐ Geocoding 2015 ACS variables  ☐Other: Case/Control status |
| **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)* | |
| **Desired Genetic Data** | ☐eMERGE I-III Merged set (HRC imputed, GWAS)  ☐eMERGE PGx/PGRNseq data set  ☐eMERGEseq data set (Phase III)  ☐eMERGE Whole Genome sequencing data set  ☐eMERGE Exome chip data set  ☐eMERGE Whole Exome sequencing data set  ☐Other (not listed above): | |
| **Does project pertain to an existing eMERGE Phenotype?** | ☐Yes, if so please list  ☐No | |
| **Planned Statistical Analyses** |  | |
| **Ethical Considerations** |  | |
| **Available Funding or Resources** |  | |
| **Target Journal** |  | |
| **Milestones**  *(This section should include the key dates for completion of project, including approval, project duration, draft completion, and submission.)* |  | |

**\*Common Variables available across all datasets:**

* Demographics: sex, year of birth, decade of birth, race, ethnicity
* Codes: (repeated values & age at event): ICD, CPT, Phecodes
* BMI: (repeated value & age at event) height, weight, BMI
* Labs: (lab name, repeated lab value & age at event) Serum total cholesterol, LDL, HDL, Triglycerides, Glucose fasting/non-fasting/unknown, & White Blood Cell count
* Medications: (medication name, repeated, & age at event) Cerivastatin sodium, Rosuvastatin, Simvastatin, Fluvastatin, Pravastatin, Lovastatin, Atorvastatin, & Pitavastatin
* Other: Case/Control status on Phase I and Phase II phenotype: only on GWAS dataset participants

**APPENDIX 3:**

|  |  |  |
| --- | --- | --- |
| **Industry Collaboration Opportunity** *for* **eMERGE Network** | | |
| **Reference Number**  *(to be assigned by CC)* |  | |
| **Submission Date** |  | |
| **Project Title** |  | |
| **Contact** |  | |
| **Tentative Lead Investigator** *(first author)* |  | |
| **Tentative Lead Investigator Email** *(first author)* |  | |
| **Tentative Senior Author**  *(last author)* |  | |
| **All Other Authors** |  | |
| **Sites Participating** |  | |
| **sBackground / Significance** |  | |
| **Outline of Project** |  | |
| **Desired Data** | ☐ Demographics  ☐ ICD 9/10  ☐ CPT Codes  ☐ Phecodes  ☐ BMI | ☐ Geocoding 2015 ACS variables  ☐ Other |
| **Other Desired Data *(Available from participating sites)*** |  | |
| **Does project pertain to an existing eMERGE Phenotype?** | ☐ Yes, if so please list  ☐ No | |
| **Planned Statistical Analyses** |  | |
| **Available Funding or Resources** |  | |
| **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 4: Acknowledgement Text**

**eMERGE Network (Phase IV)**

This phase of the eMERGE Network was initiated and funded by the NHGRI through the following grants: U01HG011172 (Cincinnati Children’s Hospital Medical Center); U01HG011175 (Children’s Hospital of Philadelphia); U01HG008680 (Columbia University); U01HG011176 (Icahn School of Medicine at Mount Sinai); U01HG008685 (Mass General Brigham); U01HG006379 (Mayo Clinic); U01HG011169 (Northwestern University); U01HG011167 (University of Alabama at Birmingham); U01HG008657 (University of Washington); U01HG011181 (Vanderbilt University Medical Center); U01HG011166 (Vanderbilt University Medical Center serving as the Coordinating Center)

**eMERGE Network (Phase III)**

This phase of the eMERGE Network was initiated and funded by the NHGRI through the following grants: U01HG008657 (Group Health Cooperative/University of Washington); U01HG008685 (Brigham and Women’s Hospital); U01HG008672 (Vanderbilt University Medical Center); U01HG008666 (Cincinnati Children’s Hospital Medical Center); U01HG006379 (Mayo Clinic); U01HG008679 (Geisinger Clinic); U01HG008680 (Columbia University Health Sciences); U01HG008684 (Children’s Hospital of Philadelphia); U01HG008673 (Northwestern University); U01HG008701 (Vanderbilt University Medical Center serving as the Coordinating Center); U01HG008676 (Partners Healthcare/Broad Institute); U01HG008664 (Baylor College of Medicine); and U54MD007593 (Meharry Medical College).

***eMERGE Network (Phase II – addition of pediatric sites) Acknowledgement Text***

The eMERGE Network was initiated and funded by NHGRI through the following grants: U01HG006828 (Cincinnati Children’s Hospital Medical Center/Boston Children’s Hospital); U01HG006830 (Children’s Hospital of Philadelphia); U01HG006389 (Essentia Institute of Rural Health, Marshfield Clinic Research Foundation and Pennsylvania State University); U01HG006382 (Geisinger Clinic); U01HG006375 (Group Health Cooperative/University of Washington); U01HG006379 (Mayo Clinic); U01HG006380 (Icahn School of Medicine at Mount Sinai); U01HG006388 (Northwestern University); U01HG006378 (Vanderbilt University Medical Center); and U01HG006385 (Vanderbilt University Medical Center serving as the Coordinating Center).

\*\*If the project includes data from:

the eMERGE imputed merged Phase I and Phase II dataset, please also add U01HG004438 (CIDR) and U01HG004424 (the Broad Institute) serving as Genotyping Centers.

The PGRNSeq dataset (eMERGE PGx), please also add U01HG004438 (CIDR) serving as a Sequencing Center.

***eMERGE Network (Phase II – CERC Survey Project) Acknowledgement Text***

The CERC Survey project within the eMERGE Network was initiated and funded by NHGRI with additional funding by the NIH Office of the Director through the following grants: U01HG006828 (Cincinnati Children’s Hospital Medical Center/Boston Children’s Hospital); U01HG006830 (Children’s Hospital of Philadelphia); UOIHG006389 (Essentia Institute of Rural Health, Marshfield Clinic Research Foundation and Pennsylvania State University); U01HG006382 (Geisinger Clinic); U01HG006375 (Group Health Cooperative/University of Washington); 3U01HG006379 (Mayo Clinic); U01HG006380 (Icahn School of Medicine at Mount Sinai); 3U01-HG006388 (Northwestern University); U01HG006378 (Vanderbilt University Medical Center); and 3U01HG0006385 (Vanderbilt University Medical Center serving as the Coordinating Center).

***eMERGE Network (Phase II – Year 1) Acknowledgement Text***

*The eMERGE Network was initiated and funded by NHGRI through the following grants: U01HG006389 (Essentia Institute of Rural Health, Marshfield Clinic Research Foundation and Pennsylvania State University); U01HG006382 (Geisinger Clinic); U01HG006375 (Group Health Cooperative/University of Washington); U01HG006379 (Mayo Clinic); U01HG006380 (Icahn School of Medicine at Mount Sinai); U01HG006388 (Northwestern University); U01HG006378 (Vanderbilt University Medical Center); and U01HG006385 (Vanderbilt University Medical Center serving as the Coordinating Center);* U01HG004438 (CIDR) and U01HG004424 (the Broad Institute) serving as Genotyping Centers.

***eMERGE Network (Phase I) Acknowledgement Text***

*The eMERGE Network was initiated and funded by NHGRI, in conjunction with additional funding from NIGMS through the following grants: U01-HG-004610 (Group Health Cooperative/University of Washington); U01-HG-004608 (Marshfield Clinic Research Foundation and Vanderbilt University Medical Center); U01-HG-04599 (Mayo Clinic); U01HG004609 (Northwestern University); U01-HG-04603 (Vanderbilt University Medical Center, also serving as the Administrative Coordinating Center);* U01HG004438 (CIDR) and U01HG004424 (the Broad Institute) serving as Genotyping Centers.

*Last update: August 5, 2020*