

Data Use Agreement

For use by and among Members of the Electronic Medical Records and Genomics Research Network (eMERGE)

TERMS AND DEFINITIONS: The Electronic Medical Records and Genomics (eMERGE) Network (<https://www.mc.vanderbilt.edu/victr/dcc/projects/acc/index.php/About>) is a National Institutes of Health (NIH)-organized and -funded consortium of medical research institutions (“eMERGE Network”). The primary goal of the eMERGE Network is to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research. Member institutions participating in the consortium study the relationship between genetic variations and clinically relevant human traits, using the technique of genome-wide association (GWAS) analysis. Such studies involve testing hundreds of thousands of genetic variants called single nucleotide polymorphisms throughout the genome in people with and without a condition of interest. A fundamental question that eMERGE seeks to answer is whether electronic medical record (EMR) systems can serve as resources for such complex genomic analysis of disease susceptibility and therapeutic outcomes, across diverse patient populations. In addition, the consortium includes a focus on social and ethical issues such as privacy, confidentiality, and interactions with the broader community. Detailed information on the eMERGE network can be found at the eMERGE website (www.gwas.org).

eMERGE Network members (“eMERGE Network Members” or “Members”) include: sites funded through the primary eMERGE Network grant mechanism, the Network’s coordinating center, the National Center for Biotechnology Information (NCBI), NIH; and the National Human Genome Research Institute (NHGRI), NIH, and other sites with whom the Members have agreed to partner with in accordance with the eMERGE Network Criteria for Participation and which have signed this Data Use Agreement.

Researchers with a wide range of expertise in genomics, statistics, ethics, informatics, and clinical medicine employed by an eMERGE Network Member participate in the eMERGE network, including: Principal Investigators of the eMERGE clinical sites, the Coordinating Center, the Genotyping Facilities, and Program Officials from the National Center for Biotechnology Information and the National Human Genome Research Institute.

Data Sharing Guiding Principles: All data sharing will adhere to 1) the terms of consent agreed to by research participants; 2) applicable laws and regulations, and; 3) the principle that individual sites within the network have final authority regarding whether their site’s data will be used or shared, on a per-project basis. These principles are intended to maximize sharing of GWAS data generated by the eMERGE Members among and between other Members as well as with the wider scientific community, and to do this without compromising data security or the confidentiality of information about individuals whose data and/or samples are used for research.

Data Sharing Responsibilities: Principal Investigators of each eMERGE clinical site may designate data to accomplish activities defined in research studies sanctioned by the eMERGE Network according to eMERGE Network policies (eMERGE Data) to be shared as follows: (1) distribution through dbGaP; (2) distribution within the eMERGE Network; and/or (3) distribution to the eMERGE Coordinating Center. The eMERGE Data to be shared within eMERGE will be provided only to eMERGE Network Members that have signed this Agreement. All eMERGE Network Members and the eMERGE Coordinating Center may aggregate eMERGE Data from all Member sites and, with documented approval prior to each submission from the contributing site(s), submit said eMERGE Data to dbGaP and/or other databases administered by the National Institutes of Health. Each eMERGE Network Member may share its own data with external collaborators without approval of the other Members. If eMERGE data received from any Member is shared externally by another Member, prior approval from the Member providing the eMERGE Data must be obtained and documented. Members sharing eMERGE Data externally must also ensure that each external eMERGE Data recipient agrees to the same restrictions and conditions applicable to Members and Member Representatives regarding the use and disclosure of the eMERGE Data as outlined in this Agreement or as may be required by law. eMERGE Data may be shared by Members with their partner organizations (e.g., organizations that provide direct services such as genotyping on Member-provided samples, site-initiated subcontracted services and/or other services required for eMERGE sanctioned studies), provided that said partner organizations are held to an equivalent standard of confidentiality

that applies to Network Members

(https://www.mc.vanderbilt.edu/victr/dcc/projects/acc/index.php/Member_Resources).

Statement of Confidentiality: By signing this Agreement, the authorized official representing an eMERGE Network Member, certifies that s/he and the Principal Investigators, fellows, students, and research staff (collectively, "Network Member Representatives") working on eMERGE-related projects are aware of the confidential nature of data on research participants maintained by the Member and of the necessity for maintaining that confidentiality.

The eMERGE Network Member agrees not to attempt to personally identify any eMERGE participant based on eMERGE Data and agree not to attempt to contact any eMERGE participant of a site other than their own. The Member agrees not to transfer or disclose any confidential data or any information about individual eMERGE participants, except as permitted by this Agreement or as required by law, either during or after the conclusion of the affiliation with eMERGE. The Member agrees to provide adequate security for the eMERGE Data, including but not limited to safeguards intended to prevent unauthorized use or disclosure of such information. In addition each Member agrees to report in writing to the other Members any use or disclosure of any portion of the data of which it becomes aware that is not permitted by this Agreement including disclosures that are required by law.

The eMERGE Network Member agrees to ensure that its Network Member Representatives do not use, disclose or transfer any eMERGE Data to anyone who is not an eMERGE Network Member except as permitted by this Agreement or as required by law. Further, the Member agrees to return all eMERGE Data to the eMERGE Coordinating Center or delete/destroy all electronic eMERGE Data upon termination of its affiliation with the eMERGE Network and to notify the eMERGE Coordinating Center when it has done so.

Limitations of Data Use: The eMERGE Network Member agrees to ensure that Network Member Representatives will only use eMERGE Data in a manner that is consistent with any limitations that have been specified for individual studies by the disclosing Member and agreed to by the Steering Committee and shall ensure compliance with all applicable state and federal laws and regulations governing the use of such data including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), if applicable, including any and all future amendments.

The eMERGE Network Member agrees to comply with all established policies of eMERGE governing the acquisition, analysis, reporting, publication, use and distribution of eMERGE Data.

This Agreement supersedes and replaces all prior agreements made between eMERGE Network Members regarding the sharing and confidentiality of eMERGE Data.

Agreed to by:

eMERGE Institution Authorized Official name and title (print): _____

Signature: _____ Date: _____

Read & Understood by:

Network Member Representative name & title (print): _____

Signature: _____ Date: _____

Member Representative's Institution:
