August 28, 2024

Policy and Guidelines for Collaborative Research using the Vermont Oxford Network Databases

Goal

The policy and guidelines described below are intended to govern access to the data in the Vermont Oxford Network (VON) databases for research.

Background

The mission of Vermont Oxford Network, a non-profit voluntary membership organization, is to improve the quality, safety, and value of care for newborn infants and their families. In support of this mission, VON collects data from member institutions on the characteristics of neonatal intensive care unit (NICU) patients, their treatments, and outcomes. VON maintains databases for very low birth weight infants, all NICU infants, Global Quality Improvement Neonatal database for members in resource limited settings, and neuro-developmental follow-up of extremely low birth weight infants. Additionally, VON maintains a database from an annual survey of members. Data in support of VON trials and studies may also be collected.

The purpose of these databases is to support quality improvement by providing members with confidential reports that document their performance over time and support comparisons with aggregated results from VON as a whole and/or with specific subgroups of hospitals with characteristics like their own. Each individual hospital's data and reports are strictly confidential and may be accessed only by named individuals authorized by the member hospital. The VON Policy on Data Use outlines the parameters for use of center specific and VON data by member hospitals. That policy is available at: http://www.vtoxford.org/datause.

The policies in this document refer to access to data for research use, defined in the Common Rule as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" ((45CFR46.102(d)).

Policy Guidelines

1. The purpose of the VON databases is to describe clinical outcomes and trends over time and to support improvements in the quality, safety, and value of neonatal care to support quality improvement. Research using the VON databases should contribute to quality improvement and support VON's missing.

2. The confidentiality of individual patients and of data corresponding to individual hospitals will be protected.

3. The analysis, publication, and dissemination of results from the VON databases to the scientific community, the public, or other interested parties is conducted at the sole

discretion of the VON Chief Scientific Officer, contingent on the premise that the identity of individual patients and of the data corresponding to individual member hospitals are protected.

4. VON supports collaborative research in which qualified investigators work with VON staff to design and conduct research using the VON databases. Appropriate analysis and interpretation of the databases requires detailed knowledge of the data items, definitions, and eligibility criteria. Therefore, all research using the VON databases will include appropriate VON staff as formal members of the research team. It is critical that these individuals be involved beginning in the design phase of the research.

5. Investigators who are not staff members or employees of VON may propose research projects using the VON databases for public presentation, dissemination, or publication under the following conditions:

a. The proposed research is consistent with and is expected to advance the VON's mission.
b. The proposed research is of significant scientific merit, addresses a hypothesis of importance, and has clearly stated specific aims.
c. The proposed research is feasible, has a high likelihood of successful completion, and uses methods and statistical techniques that are appropriate to the aims.
d. The investigators are fully qualified with the necessary clinical, scientific, and statistical knowledge, skills, and experience.
e. The research team includes VON staff in appropriate roles as determined by the Chief Scientific Officer. These individuals must be involved beginning in the design phase of the research proposal.
f. The proposal addresses the source of funding for necessary resources and for time and effort of VON staff. Priority will be given to proposals with identified external funding or potential external funding. Unfunded studies will be unlikely to be approved.
g. The proposal must describe in detail which data items from the VON databases will be used, which years of data will be included, which records will be included, and how the raw data items will be used to create variables for analysis.
h. The proposal must include an analytic plan with statistical methodology and appropriate methods for measuring and adjusting for potentially confounding variables.
i. The plans for publication, presentation, and dissemination of results must be described.
j. The proposal must include a timeline for analysis, manuscript preparation, publication, presentation, and dissemination.
k. The proposal is reviewed by the Institutional Review Boards (IRBs) at the institutions of all investigators and by the IRB at the University of Vermont, the IRB for VON.
l. Authorship assignment will follow the steps outlined on pages 4 and 5 of this document.

6. Given the complexity of the databases and the importance of maintaining confidentiality of individual patients and of data corresponding to individual hospitals. It is highly unlikely that an investigator will receive a copy of VON data for analysis. However, if VON does agree to provide data for analysis, the following additional conditions also apply.

a. Infants and hospitals will only be identified by codes, and hospital characteristics or case mix information which could reasonably be expected to allow the identification of an individual hospital will be removed.
b. The investigators must ensure that the data will be maintained in a secure location, that access will be limited to individuals identified and approved in the original proposal, and that the data will be returned to VON or destroyed at the conclusion of the research, or immediately upon request of VON.
c. The data requested are present in the VON Data Repositories.
d. The investigator approved to receive the data signs VON Repository Use Agreement.

7. For all research using VON data, researchers must adhere to the following:

a. The proposed research must be free of commercial bias or conflict of interest.
b. The uses of the data will be limited to those described in the original research proposal. Any additional uses or modifications of the proposal will require the written permission of VON.
c. All presentations, abstracts, manuscripts and publications in any medium, print or electronic, resulting from the analysis of VON data shall acknowledge the role of VON and its members. The text for the acknowledgement must be approved in writing by VON prior to submission for publication or presentation.
d. VON shall have the right to review all presentations, abstracts, manuscripts, and publications in any media prior to submission for publication, dissemination, or posting on the Internet to assess that all of the above requirements have been fulfilled.
e. If the data includes items collected as part of a VON trial or other formal study, the use of the data must conform to all agreements and approvals regarding the original trial or study.
f. The proposal must have been submitted, reviewed, and approved according to the process described in item 9 below.

8. Investigators requesting access to data from the VON databases for research must submit a letter of intent in which any affiliations, funding, salary, fees (monies paid for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, bureaus, expert testimony, employment, or other affiliations), financial interests, or potential or actual conflicts of interest related to any companies or organizations with an interest in health care products and services including, pharmaceutical companies, device manufacturers, payers, insurers, vendors, hospitals or hospital systems are described. Potential and actual conflicts of interest will be considered by the Chief Scientific Officer in evaluating all proposals.

9. All inquiries related to research from investigators who are not VON staff will be reviewed and evaluated by VON in the following three stage process:

a. A letter of intent describing the justification, consistency with VON's mission, scientific hypothesis, specific aims, methods, personnel, resources, funding plans, confidentiality, and potential conflicts of interest is submitted to VON for consideration along with brief bios of the investigators. VON will review the materials and determine whether to move forward with the development of a full proposal. Because development of a full proposal will require VON resources and the effort of VON personnel, only projects of the highest priority will be considered. Although investigators from non-member centers may submit letters of intent, letters from investigators at VON member centers will be given preference.
b. If a determination is made to proceed with the development of a full proposal, appropriate VON staff and any necessary consultants will be identified by VON to work with the investigators to prepare a detailed proposal.
c. The Chief Scientific Officer will decide whether to approve the proposal and may at their discretion request outside review of the proposal. The final decision regarding how to proceed with the research proposal will be at the sole discretion of VON.

10. If the research is approved, the data required for the research will be conducted under the terms of use for the VON Data Repository as described in the VON Repository Use Agreement.

11. If VON receives a request from the editors of a peer-reviewed journal for access to data in order to verify or reproduce the results in a submitted manuscript, the Chief Scientific Officer will review the request. If a decision is made to grant access, the conditions of access will be specified so as to guarantee the protection of confidentiality and anonymity for patients and hospitals in the Database.

12. This policy will be reviewed at regular intervals by the VON Board of Directors.

Reviewed and approved by the VON Board of Directors on August 28, 2024.

Requirements for Authorship of VON Research Papers

Vermont Oxford Network (VON) will follow the recommendations of the International Committee of Medical Journal Editors (ICJME) when assigning authorship:

- 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.

https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Substantial contributions to the conception or design of the work will require participation in meetings or discussions with the other co-authors to identify the aims and methods for the research.

Requirements for the acquisition of data for the work may be based on developing data definitions, the design of data collection forms or tools, collection of data, or the training and support of those collecting the data.

Analysis will include development of the analytic plan, coding, or conduct of data analysis.

Interpretation of data will include participation in meetings, discussions, or email correspondence with co-authors in which the analytic results are reviewed and interpreted.

Drafting the work includes writing the paper in whole or in part including identifying relevant references.

Reviewing the work critically for important intellectual content includes participation in meetings, discussions, or email correspondence regarding the way the results and conclusions are framed and presented.

Final approval of the version to be published must be communicated by each co-author to the first author.

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 must be communicated by each co-author to the first author.

Decisions regarding eligibility, order of authorship, and identification of the corresponding author will be at the discretion of the Chief Scientific officer except in the case of papers reporting externally grant supported research where the principal investigator of the funded study will have this authority. In the event of conflicts among authors or potential authors they may appeal to the CEO of VON for final resolution.

Co-authors will agree to these terms regarding identification and order of co-authors.