

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 databases for research.

Background

The mission of Vermont Oxford Network, a non-profit voluntary membership organization, is to improve the quality and safety of medical care for newborn infants and their families. In support of this mission, Vermont Oxford Network maintains data for member institutions on the characteristics of neonatal intensive care unit (NICU) patients, their treatment and outcomes. In addition to the core database for Very Low Birth Weight Infants, the Network also maintains databases for all NICU infants, and for neuro-developmental follow-up of Extremely Low Birth Weight infants. Members have the option of submitting data to these additional databases as well as other detailed databases including those developed for use in Network trials and studies that may be offered from time to time. The Network also maintains a Global Quality Improvement Neonatal database for Members in resource limited settings. Additionally, the Network maintains a database containing information about the characteristics of member hospitals gathered in an annual survey of members.

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 the Network as a whole and/or with specific subgroups of hospitals with characteristics similar to 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 Vermont Oxford Network Policy on Data Use outlines the parameters for use of center-specific and Network 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.

Policy Guidelines

1. The purpose of the Vermont Oxford Network databases is to support quality improvement, both in terms of describing relevant clinical outcomes and trends over time and supporting improvements in the quality, safety, and value of neonatal care. Research using the Vermont Oxford Network databases should contribute to quality improvement and support the mission of the Network.
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 Vermont Oxford Network databases to the scientific community, the public, or other interested parties is conducted at the sole discretion of the Board of Directors, contingent upon the premise that the identity of individual patients and of the data corresponding to individual member hospitals are protected.
4. Vermont Oxford Network supports collaborative research in which qualified investigators work with staff and employees of Vermont Oxford Network to design and conduct research using the Network databases. Appropriate analysis and interpretation of the databases requires detailed knowledge of the data items, definitions, and eligibility criteria. Therefore, all research using the Vermont Oxford Network databases will include appropriate staff and employees of the Network as formal members of the research team. Furthermore, it is critical that these individuals be involved beginning in the design phase of the research.
5. The use of the Vermont Oxford Network databases for research and grant proposals will be limited to qualified investigators at sites that are current members of Vermont Oxford Network participating in the databases. Exceptions to this policy may be granted by the Chief Executive and Scientific Officer in exceptional circumstances (see section 10).
6. Investigators who are not staff members or employees of Vermont Oxford Network may be granted access to the Vermont Oxford Network databases for use in research, public presentation, dissemination, or publication under the following conditions:
 - a. The proposed research is consistent with and is expected to advance the mission of Vermont Oxford Network.
 - 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 staff or employees of Vermont Oxford Network in appropriate roles as determined by the Board of Directors of Vermont

Oxford Network. 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 Vermont Oxford Network staff and employees. 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 Network databases will be used, which years of data will be included, which patient 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. If datasets are provided to investigators in the course of the research or during preparation of the proposal, these datasets must not allow the identification of individual patients or the identification of individual hospitals. 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.

l. If datasets are provided to investigators, these investigators must insure 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 Vermont Oxford Network or destroyed at the conclusion of the research, or immediately upon request of Vermont Oxford Network.

m. 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 Vermont Oxford Network.

n. The proposed research must be free of commercial bias or conflict of interest.

o. If the data include items collected as part of a Network trial or other formal study, the use of the data must conform to all agreements and approvals regarding the original trial or study.

p. The proposal must have been 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 Vermont Oxford Network.

q. The proposal must have been submitted, reviewed, and approved according to the process described in item 9 below.

r. Since Network resources are limited, priority will be given to prospective research addressing a clear and important hypothesis. Retrospective analysis of the databases for descriptive research will be given low priority.

s. The data requested are present in the Vermont Oxford Network Data Repositories.

t. The investigator approved to receive the data must sign the Vermont Oxford Network Repository Use Agreement.

7. All presentations, abstracts, manuscripts and publications in any medium, print or electronic, resulting from the analysis of the Vermont Oxford Network databases shall acknowledge the role of the Network and its members. The text for the acknowledgement must be approved in writing by Vermont Oxford Network prior to submission for publication or presentation. *All co-authors must use the name of the Vermont Oxford Network member hospital as their authorship affiliations in all publications.*

8. Vermont Oxford Network 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.

9. Investigators requesting access to data from the Vermont Oxford Network databases for research must submit a letter of intent in which any affiliations, funding, honoraria, consulting fees, salary, 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 Board of Directors in evaluating all proposals.

10. All inquiries related to research from investigators who are not members of the staff or employees of Vermont Oxford Network will be reviewed and evaluated by Vermont Oxford Network in the following three stage process:

a. A letter of intent describing the justification, consistency with Network mission, scientific hypothesis, specific aims, methods, personnel, resources, funding plans, confidentiality, and potential conflicts of interest is submitted to Vermont Oxford Network for consideration along with brief bios of the investigators. Vermont Oxford Network 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 Network resources and the effort of Network personnel, only projects of the highest priority will be considered.

Although investigators from non-member centers may submit letters of intent, the expectation is that proposals will only be considered from investigators at member centers participating in the databases unless in the opinion of Chief Executive and Scientific Officer the investigators demonstrate unique qualifications not available at member sites.

b. If a determination is made to proceed with the development of a full proposal, appropriate employees or staff of Vermont Oxford Network and any necessary consultants will be identified by Vermont Oxford Network to work with the investigators to prepare a detailed proposal.

c. The Chief Executive and Scientific Officer, CESO, of Vermont Oxford Network will decide whether to approve the proposal. The CESO or Board of

Directors 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 Vermont Oxford Network.

11. If the research is approved, the data required for the research will be provided under the terms of use for the Vermont Oxford Network Data Repository as described in the Vermont Oxford Network Repository Use Agreement.

12. In the event that Vermont Oxford Network 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 Board of Directors, or the Chief Executive and Scientific Officer as its designee, 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.

13. This policy will be reviewed at regular intervals by the Database Advisory Committee and Board of Directors of Vermont Oxford Network.

Reviewed and approved by the Board of Directors June 28, 2019.