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Policy and Guidelines for Collaborative Research with the Vermont Oxford Network Database

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 the Vermont Oxford Network, a not-for-profit-501(c)3 membership organization, is to improve the quality and safety of medical care for newborn infants and their families. In support of this mission, the Vermont Oxford Network maintains a database for member institutions containing data on the characteristics of NICU patients, their treatment and outcomes. In addition to the core database for Very Low Birth Weight Infants, in which all members participate, the Network also maintains databases for all NICU infants, for infants with neonatal encephalopathy, and for neuro-developmental follow up of Extremely Low Birth Weight Infants and those with encephalopathy. 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. In addition 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 with specific subgroups of hospitals with characteristics similar to their own. Reports are accessible to authorized individuals at member institutions in print, CD ROM, and over the Internet through the Network's Nightingale Internet Reporting tool.

The Vermont Oxford Network does not accept protected health care information. All data submitted to the Network are de-identified. No personal patient identifiers are included in the database. Infants are identified by a numeric code assigned by the hospital. Each individual hospital's data are treated as strictly confidential and may only be accessed by those individuals authorized by the member hospital to access the data and reports.

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Policy guidelines

1. The purpose of the Vermont Oxford Network databases is to support quality improvement.
2. Analysis and reporting of outcomes and trends in the Vermont Oxford Network database contributes to quality improvement and supports the mission of the Network.
3. The confidentiality of individual patients and of data corresponding to individual hospitals will be protected.
4. Each member hospital receives a complete file of their individual hospital's infant level dataset each year. The purpose of this dataset is to allow members to perform more detailed analysis and exploration of their own hospital's performance for the purpose of quality improvement.
5. The data from an individual member hospital will only be provided to individuals or organizations authorized by that hospital to receive such data.
6. The analysis, publication, and dissemination of results from the Vermont Oxford Network database to the scientific community, the public or to other parties will be conducted at the sole discretion of the Network and its Directors provided that the identity of individual patients and of the data corresponding to individual member hospitals are strictly protected.
7. The Vermont Oxford Network supports collaborative research in which qualified investigators work with staff and employees of the Vermont Oxford Network to design and conduct research using the Network database. Since appropriate analysis and interpretation of the database requires detailed knowledge of the data items, definitions, and eligibility criteria, all research which uses the Vermont Oxford Network database 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.
8. Outside investigators who are not staff members or employees of the 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 the mission of the Vermont Oxford Network and is expected to advance that 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 has a high likelihood of successful completion and uses methods and statistical techniques that are appropriate to the aims.

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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 the Vermont Oxford Network in appropriate roles as determined by the Directors of the 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 outside 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 outside 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 the 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 the Vermont Oxford Network.

n. The proposal 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 and, if necessary, approved by the Institutional Review Boards, IRBs, at the institutions of all outside investigators and by the IRB at the University of Vermont (the IRB for the Vermont Oxford Network).

q. The proposal must have been submitted, reviewed, and approved according to the process described in item 11 below.

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

9. 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 the Vermont Oxford Network prior to submission for publication or presentation. The 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.

10. Investigators requesting access to data from the Vermont Oxford Network database 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 Directors in evaluating all proposals.

11. All inquiries related to research from investigators who are not members of the staff or employees of the Vermont Oxford Network will be reviewed and evaluated by the 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 the Vermont Oxford Network for consideration along with brief bios of the investigators. The Directors of the 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.

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

c. The full proposal will be reviewed by the Vermont Oxford Network Database Advisory Committee and a recommendation made to the Directors. The Directors of the Vermont Oxford Network 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 the Directors of the Vermont Oxford Network.

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12. This policy will be reviewed at regular intervals, not to exceed three years, by the Database Advisory Committee and Directors of the Vermont Oxford Network.