**Vermont Oxford Network iNICQ**

[To the Institutional Review Board / or appropriate authority to conduct quality improvement projects and audits at your institution]

To those concerned:

We are writing regarding our participation in a new quality improvement series, iNICQ: All Care is Brain Care, sponsored by Vermont Oxford Network. This internet-based multicenter quality improvement collaborative is focused on preventing brain injury, protecting normal brain maturation and development, and promoting positive experiences and relationships between care teams, infants, and families. The series will run from 2023 to 2026.

In 2023, we will participate in webinars led by Vermont Oxford Network faculty, experts in neonatal care, quality improvement and implementation science. The faculty will guide and motivate teams as they work through a structured curriculum designed to improve the effectiveness, efficiency, safety, quality, and value of care. A toolkit that details the supporting evidence, provides a driver diagram, potentially better practices, and change ideas that centers may consider will be provided.

In conjunction with the educational program, we plan to conduct one quality improvement audit in 2023. The audit includes an assessment of specific policies and guidelines regarding brain care in our unit. The specific data elements for the audit are included in these materials. The audit does not involve any specific intervention, nor does it involve direct physical contact with any family member or patient. No aspect of infant care will be directly affected by the auditing process and no individually identifiable data, or protected health care information will be collected.

A comprehensive report of our center’s performance compared to the aggregate results of all VON centers (de-identified by site) will be shared with us and discussed in web seminars. In the future the results may be submitted for publication in peer-reviewed literature. In each step of these efforts, no specific data regarding the center will be identifiable. In addition to the VON Day Audits, our local team may elect to perform serial quality improvement audits to measure improvements in care over time.

The iNICQ Collaborative and the VON Day Audit have been reviewed by The University of Vermont Institutional Review Board utilizing a self-determination tool. It has been identified that this work does not require IRB review because it does not meet the definition of a “research” activity under the regulatory definition according to 45 CFR 46.102(d). However, that determination is solely about the role of Vermont Oxford Network in sponsoring the iNICQ Collaboratives and the VON Day Audit. The approval from The University of Vermont Committee on Human Research does not cover any activities conducted by institutions or staff participating in VON Day Audits or iNICQ Collaboratives.

We have been advised that each site participating in VON Day Audits and/or the iNICQ Collaborative should obtain any and all necessary human subjects reviews and approvals from their own institutional review boards or appropriate local governing bodies before participating.

Our center is interested in participating in these quality improvement opportunities. This letter is our request to our local IRB to determine if any reviews or approvals are needed prior to our center’s participation in these projects.

Thank you for consideration of this project. Please feel free to contact me with any questions.

Sincerely,

(Local Investigator)

See attachments below

**Attachments:**

VON Day Audit Questions

The University of Vermont Committee on Human Subjects determination letter

iNICQ flyer