**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 2019: The Ins and Outs of Neonatal Care. Improving Critical Transitions and Clinical Outcomes for Every Newborn, sponsored by the Vermont Oxford Network.

This internet-based quality collaborative is a multicenter collaborative focused on improving physical and clinical transitions of care. These transitions will include physical transitions such as admission from the delivery room, transfer from an outlying facility and within facility transitions, such as moving from the NICU to diagnostic areas (such as MRI) or operating facilities. Clinical transitions will also be evaluated, such as the initiation of antibiotics or pharmacological therapy for neonatal abstinence syndrome. Every team will also work on improving the fidelity and safety of patient hand-offs.

In 2019, we will participate in eight webinars led by the 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 and quality of care of these physical and clinical transitions.

A toolkit that details the supporting evidence, provides a driver diagram, keys potentially better practices and change ideas that centers may consider will be provided.

A subset of centers [including our center] OR [not including our center] will participate in the iNICQ Intensive, which will include three additional webinars focused on a new quality improvement methodology, experience-based co-design, provided in collaboration with the Point of Care Foundation.

In conjunction with the educational program discussed above, we plan to conduct to participate in two quality improvement audits: the iNICQ 2019 VON Day Audit: The Ins and Outs of Neonatal Care. The audit includes an assessment of specific policies and guidelines regarding both physical and clinical transitions of infants in our unit, including transport from outlying hospital facilities, delivery room care, transfer for imaging or MRI, transfer for surgical procedures, early planning of transfer home, transfer home of medically complicated newborn infants, as well as clinical transitions of antibiotic initiation, treatment for neonatal abstinence syndrome and extubation.

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 individual or patient; however, the local data collector will need to review unit logs, review patient paper charts and/or electronic medical records and approach the infant’s bedside to determine eligibility and review specific chart orders, management plans and laboratory values.

Select One option A or B. Delete the option you will not be using.

Option A: Our unit will not obtain or record identifying data on any specific infants.

Option B. In order to follow-up on any quality concerns brought out by the audit, our unit has chosen to record identifying data on specific infants for local quality improvement efforts. However, no identifying data (such as medical record number or other identifiers) will be submitted to Vermont Oxford Network.

No aspect of the infant’s care will be directly affected by the auditing process and no individually identifiable data or protected health care information will be transmitted to VON; further the website will not accept any data of this nature.

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 extensively in follow up 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 or the individuals 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 it’s supporting 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