How to Request Use of CALNOC Data--INSTRUCTIONS

Before you begin **take time to carefully and thoroughly read through the documents in this CALNOC Data Use Request Packet. If your timeline does not permit you to move thorough the 3-6 week CALNOC data use request and approval process plus the necessary dataset creation steps, DO NOT request use of CALNOC data. If you have questions related to completing the data use request and using CALNOC data not addressed in this packet, please contact info@calnoc.org.**

Steps in the CALNOC Data Use Request Process

1. The CALNOC Data Use and Data Services Agreement ("Agreement") outlines the terms and conditions for the use of data furnished by the CALNOC benchmarking registry. The Agreement is a legal contract between CALNOC and the Investigator requesting use of CALNOC data. This agreement must be signed by the Investigator and submitted with a completed CALNOC Data Use Request Form ("the Request Form"), contained in Addendum 1 of the Agreement.
2. The completed Agreement and Request Form must be submitted prior to CALNOC's review, data use determination and data retrieval/dataset creation estimation of costs. CALNOC cannot accept informal or incomplete requests for data use.
3. To ensure tracking of the Agreement and Request, all documents (both the Agreement and the Request Form) must be formatted by the applicant Investigator with a footer noting the Investigator's last name and the title of the study.
4. CALNOC's Scientific Enterprise Team will review completed requests to use CALNOC data within 4-6 weeks of receipt and advise the Investigator of the Team's decision. CALNOC will review the request and then approve, request additional information, or deny the request and advise the Investigator in writing.
5. Following preliminary approval of the request, CALNOC will provide a draft Data Dictionary and consult with the applicant Investigator to confirm the specifications of the data request in precise detail in order to ensure that CALNOC data extract will be appropriate for the planned research. At this time the estimation of cost for data extraction, formatting and delivery will be confirmed and the Investigator will then approve the costs and confirm payment.
6. If the Investigator is requesting and approved to use BLINDED, non-identifiable, CALNOC data, please see Section 6.0 of the Agreement for details.

7. If the Investigator is requesting and approved to use UNBLINDED, hospital-identifiable data, CALNOC will furnish the Investigator with a Hospital Authorization Form with the understanding that the Investigator will obtain written Authorization from each individual hospital for which unblinded data has been requested. ***The Investigator is responsible for contacting each hospital CNO or COO or authorized designee and obtaining permission for release of CALNOC data directly using the CALNOC Hospital Authorization Form.*** CALNOC will not accept non-standard authorization forms, letters, messages or calls of hospital approval. It is expected that the Investigator will obtain authorizations from all hospitals in the proposed data sample and submit the completed Authorization Forms, in a collated and alphabetized batch, to CALNOC accompanied by a transmittal face sheet listing each hospital that has granted permission, in alphabetical order, transmitting these to CALNOC in a single, secure communication. CALNOC will NOT create the approved dataset until all Authorizations have been received. NOTE: If Investigators request use of unblinded CALNOC data, they need to build into their study timeline the effort and response time required to obtain Authorization from each hospital in the proposed dataset.

8. Investigators with large existing data sets they would like to match with CALNOC data in which contacting CALNOC hospitals for authorization to use their data would be prohibitive may request that CALNOC create a statistically blinded matched dataset for the Investigator's use. The Investigator will be charged a fee for the additional CALNOC costs incurred in the creation of the matched data set.

9. Regardless of whether the Investigator is requesting use of blinded or unblinded CALNOC data, documentation of formal Institutional Review Board (IRB) review and approval is required prior to release of data from CALNOC to the Investigator. The Investigator is required to submit the IRB approval document(s) attached to the final approved research proposal/protocol to CALNOC.

10. Within 3 weeks of receipt of all required documents and data use fees the CALNOC Data Manager will contact the Investigator to confirm the procedure for delivery of the requested data in electronic format.

CALNOC DATA USE & DATA SERVICES AGREEMENT

THIS DATA USE AGREEMENT ("Agreement") is entered into effective this ___ day of _____, 20__, by and between the COLLABORATIVE ALLIANCE for NURSING OUTCOMES ("CALNOC"), a Public Benefit Corporation; and _____ , a _____ *insert your name here* _____("Investigator").

RECITALS

A. CALNOC is a California nonprofit public benefit corporation, and has a principal office located at 2410 Camino Ramon, Suite 360, San Ramon, CA 94583;

B. CALNOC is a benchmarking data registry which conducts collaborative outcomes assessment, reporting and research with voluntarily participating hospitals and health systems, in the course of which it collects and maintains data in a nursing quality outcomes database.

C Investigator is conducting a research project (the "Project") pursuant to an Institutional Review Board approval by [insert the name of the approving Institutional Review Board here] (the "IRB Approval"), a true and complete copy of which has been furnished to CALNOC, and has submitted to CALNOC a written request for access to selected CALNOC data for the Project (the "CALNOC Data Use Request"); and

D. CALNOC has approved Investigator's Data Use Request, on the terms set forth below.

NOW, THEREFORE, in consideration of the mutual promises and covenants herein, CALNOC and the Investigator agree as follows:

1. **Access to Blinded Data**. CALNOC will furnish blinded data described on the written CALNOC Data Use Request, Addendum 1 (the "CALNOC Data"), provided that (1) the data is not the focus of active CALNOC analyses or publications; (2) the data does not disclose (and cannot be used with other available information to determine) the identity of the hospital or health system that provided it, or of any individual to whom it relates; and (3) the data is readily available and can be extracted and shared without undue difficulty or expense.

2. **Use and Disclosure of Data**.

a. Investigator may use CALNOC Data only for the Project as described in the Data Use Request and the IRB Approval as furnished to CALNOC. Investigator shall not use CALNOC Data in any manner or for any purpose not approved by CALNOC.

b. Except for publications reporting the results of the Project and as contemplated by the Data Use Request or otherwise approved by CALNOC, Investigator shall not disclose or publish any CALNOC data to any person, other than (i) to employees of Investigator assisting with the Project, (ii) to contractors of Investigator assisting with the Project who are approved in each instance by CALNOC, and who have signed a written agreement, for the benefit of CALNOC, to be bound by this Agreement; or (iii) as required by law, provided that Investigator shall notify CALNOC immediately in writing if it is required by law to disclose CALNOC Data, and shall cooperate with CALNOC in protecting such data.

c. Without limiting the foregoing restrictions, Investigator shall not use, reuse or disclose CALNOC data for any purpose other than those set forth above, whether or not for commercial gain.

3. **Access to Data**. Investigator shall not have, or attempt to have, formally or informally, access to any CALNOC data other than the data to which CALNOC has authorized access, or to have access to any data in any manner or at any time otherwise than as authorized by CALNOC.

4. **Safeguarding Data**. Investigator shall use appropriate safeguards to prevent use or disclosure of CALNOC Data otherwise than as permitted by this agreement, including administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality and integrity of the data. Without limiting the foregoing, Investigator shall maintain policies, procedures and practices that ensure physical, technical and personnel security, as well as data management systems protections, including data access and remote user security. Upon request, Investigator shall furnish CALNOC with copies of its information privacy and security policies and procedures, and shall permit CALNOC to inspect its facilities where CALNOC Data is maintained on reasonable notice and during normal business hours.

5. **Incident Reporting**. Investigator shall report to CALNOC any use or disclosure of CALNOC Data not provided for by this agreement, and any security incident affecting CALNOC data, of which Investigator becomes aware, and shall provide CALNOC with such further information concerning the use, disclosure or incident as CALNOC may request.

6. **Identification of Data**.

a. Unless CALNOC expressly grants Investigator access to data that is identifiable as contributed by a particular hospital ("Unblinded Data"), Investigator shall not seek to identify the source of CALNOC Data, and shall not contact any hospital contributing data. Under no circumstances shall Investigator seek to identify or contact any individual to whom data relates.

b. CALNOC is a Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA). CALNOC collects nursing quality-related data including the month and quarter of individual subject's outcomes and subject's ages. As a result, CALNOC is considered a Limited Data Set according to HIPAA regulation, with direct or indirect identifiers removed from the health information. Covered Entity is providing the Investigator with a Limited Data Set of Protected Health Information ("PHI") as defined in 45 CFR sec. 164.514(e)(2). This Agreement sets forth the terms and conditions under which Covered Entity will disclose the Limited Data Set to Investigator. Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, as amended, the HIPAA provisions shall control.

c. Except as otherwise specified herein, the Investigator may make all uses and disclosures of the Limited Data Set necessary to conduct the research described herein:

(1) In addition to the Investigator, the following individuals, or classes of individuals, are permitted to use or receive the Limited Data Set for purposes of the named research project.

(2) Investigator agrees that it, and any employees, agents and subcontractors to whom it discloses the PHI, will not use or further disclose the PHI other than as permitted by this Agreement or as otherwise required by law or regulation.

(3) Investigator agrees to use appropriate safeguards to protect the PHI from misuse or inappropriate disclosure and to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement or as otherwise required by law or regulation.

(4) Investigator agrees to report to Covered Entity any use or disclosure of the Limited Data Set not provided for by this Agreement, of which he or she becomes aware. Recipient will take reasonable steps to limit any such further use or disclosure.

(5) Investigator agrees to ensure that any agent, including a subcontractor, to whom he or she provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement with respect to such information.

(6) Investigator shall not attempt to identify the individuals to whom the PHI pertains, or attempt to contact such individuals.

d. CALNOC will not grant Investigator access to Unblinded Data without the express approval of the hospital that contributed the data, after completion of CALNOC's and the hospital's evaluation of Investigator's request for such data, and subject to such conditions as the hospital may impose.

(1) After CALNOC approval of the Investigator's proposed data use, CALNOC will provide to the Investigator a Hospital Authorization Form for the Investigator to obtain written permission from each individual hospital where identified data has been requested.

(2) <u>The Investigator is responsible for independently and directly contacting each hospital to obtain written permission using the CALNOC Hospital Authorization Form. Written permission must be in the form of the signed Hospital Authorization Form.</u>

(3) The Investigator will collect and batch all completed Hospital Authorization Forms to CALNOC accompanied by a transmittal face sheet listing each hospital, in alphabetical order, that has granted permission, and collating the written agreements in alphabetical order, and providing these to CALNOC in a single communication.

(4) After the inventory of Hospital Authorization Forms and supporting documents has been received, CALNOC will initiate electronic retrieval of the data from the registry and confirm the procedure for data delivery.

7. **<u>Policies and Procedures</u>**. CALNOC, while the Investigator's study is in progress, may find it necessary to adopt policies and procedures relating to the use and security of CALNOC Data.

Investigator shall comply with all such policies and procedures that are furnished to it in writing (which may be electronic).

8. **Costs and Fees**. In consideration of the provision of data for the Project, Investigator shall pay CALNOC a fee which will be determined based on the scope of work and amount of data requested as identified in the CALNOC Data Use Request (Addendum 1). Fees will reimburse CALNOC for the costs of consultation, creating and delivering the data and customary hourly rate for CALNOC staff involved in the Investigator's Project. Data will not be released prior to receipt of required fees.

9. **Reports**. Investigator shall provide CALNOC an semi-annual interim progress report and with a final report of the findings, conclusions and outcomes of its study, and any abstracts, publications, reports, posters or presentations presenting the results of studies using CALNOC Data. All such publications, reports and presentations shall provide attribution to CALNOC for its database and services, and state that data were "obtained through data sharing from the Collaborative Alliance of Nursing Outcomes, a not-for-profit quality benchmarking registry." Manuscripts must not violate the confidential provisions set forth in this Agreement.

10. **NO WARRANTIES; LIMITATION ON REMEDIES**. CALNOC MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO CALNOC DATA, INCLUDING ITS ACCURACY, INTEGRITY OR VALIDITY. IN NO EVENT SHALL CALNOC OR ANY CONTRIBUTOR OF DATA TO THE DATABASE BE LIABLE TO INVESTIGATOR ON ACCOUNT OF ANY INACCURACY, ERROR, INVALIDITY ON INCOMPLETENESS OF THE DATA, AND CALNOC'S TOTAL LIABILITY FOR ANY BREACH OF THIS AGREEMENT OR NEGLIGENCE SHALL IN NO EVENT EXCEED THE AMOUNT OF USER FEES (IF ANY) RECEIVED FROM INVESTIGATOR FOR THE PROJECT.

11. **Term and Termination**. This agreement shall remain in effect until the termination of the Project, or until it this Agreement otherwise terminated, whichever occurs first. Either party may terminate this agreement without cause on thirty (30) days' notice to the other party, or immediately in the event of a material breach. Upon termination of this Agreement, Investigator shall return or destroy all CALNOC Data that it maintains in any form and retain no copies of such data or, if the parties agree that return or destruction is not feasible, Investigator shall extend the protections of this agreement to such information for as long as Investigator retains it, and limit further use and disclosure of the information to those purposes that make the return or destruction of the information infeasible.

12. **Injunctive Relief**. The parties agree that monetary damages are inadequate for any violation or threatened violation by Investigator of this Agreement, and that in the event of such a violation or threat, CALNOC shall be entitled to injunctive relief in addition to any other remedies available in equity or at law.

13. **General Provisions**.

a. **Notices**. Any notice or other communication hereunder must be given in writing to the address set forth below and either (a) delivered in person; (b) sent by telefax provided that any notice so given is also mailed as provided in subsection (d) herein; (c) delivered by Federal Express® or similar commercial delivery service; or (d) mailed by certified mail, postage prepaid, return receipt requested, to the party to which such notice or communication is to be given at the address set forth below. Each such notice or other communication shall be effective (i) if given by telecommunication, when transmitted; (ii) if

given by mail, three (3) days after such communication is deposited in the mail and addressed as aforesaid; (iii) if given by Federal Express® or similar commercial delivery service, three (3) business days after such communication is deposited with such service and addressed as aforesaid; and (iv) if given by any other means, when actually delivered at such address:

If to CALNOC:

Tony Sung
Chief Executive Officer
2410 Camino Ramon, Ste 360
San Ramon, CA 94583
Phone No.: (888) 586-1994
Email: tony.sung@calnoc.org

If to Investigator:

_____
_____
_____
_____
_____

With a copy to: _____

b. **Entire Agreement; Changes In Agreement**. This Agreement constitutes the entire agreement of the parties relating to the subject matter hereof. Any changes to the terms of this Agreement in any way shall be valid only if the change is made in writing and signed by the parties.

c. **Assignment**. The parties may not assign or transfer any of their rights or responsibilities under this Agreement without the prior written consent of the other parties. Notwithstanding the foregoing, CALNOC may assign this Agreement to any entity that assumes responsibility for the Database.

d. **Compliance with Law**. The parties agree to comply with all applicable federal, state and local laws, regulations, ordinances and orders with respect to the performance of the Project and this Agreement.

e. **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of California. Venue shall be Sacramento, California.

f. **Counterparts**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument.

IN WITNESS WHEREOF, authorized representative or officers of the parties hereto have executed this Agreement effective as of the date above stated:

COLLABORATIVE ALLIANCE FOR NURSING OUTCOMES "CALNOC"

By: _____(Signature) Date_____

Tony Sung
Chief Operating Officer
2410 Camino Ramon Ste 360,
San Ramon, CA 94583
Phone No.: (888) 586-1994
Email: tony.sung@calnoc.org

"INVESTIGATOR"_____

By: _____(Signature) Date_____

Print Name Here_____

Address_____

Title: _____

CALNOC
Advancing global patient care excellence.

Addendum 1---CALNOC Data Access Request

Proposed Project	
Applicant Principal Investigator	Name Address Phone Email Brief CV—Please attach an abbreviated CV highlighting experience and qualifications related to the proposed study.
Co Investigators	Name Brief CV—Please attach an abbreviated CV highlighting experience and qualifications related to the proposed study.
Study Title	
Student Letters	For a study proposed by a student, attach **a letter of support from the primary academic advisor** confirming their commitment to supervising the research and mentoring the applicant investigator.
Project Overview	Project Abstract—Please provide a 500 word narrative abstract summarizing the study aims, primary research question(s), design, methods, measures, procedures and analytic plan
Time Line	Please provide a timeline for the conduct and analysis of the study noting critical milestones.
IRB Approval	Attach IRB approval documentation and the final version of the study protocol approved by the IRB. If IRB review is in progress, please attached documentation confirming this received from the IRB.
Dissemination Plans	Summarize target activities for disseminating the results of the study during the first 18 months after its completion.

Data Request Specifications		
Time Frame for Data Pull	From _____ Month, _____ Year to _____ Month, _____ Year.	
Service Lines	☐ Medical ☐ Surgical ☐ Step Down ☐ Critical Care ☐ Observation	☐ Pediatrics ☐ Rehabilitation ☐ Distinct Part Skilled Nursing ☐ Emergency Department (2012 forward) ☐ Maternal Child (2012 forward)
Measure Sets	☐ Skill Mix ☐ Staffing ☐ RN Education & Experience ☐ PICC BSI	☐ Pressure Ulcers ☐ Falls ☐ Restraints ☐ Medication Administration Accuracy
Data Identification	☐ Blinded De-Identified Data (Hospitals are not identified)	☐ Unblinded Data (Hospitals or Hospital Systems are Identifiable) ☐ I understand that the Investigator will be required to obtain written consent from each hospital prior to release of data.