PARTICIPANT ORGANIZATION AGREEMENT
COVER SHEET

The Participant Organization Agreement (POA) is a document that outlines the guidance for participation in The National Pediatric Readiness Quality Initiative (NPRQI). Each participating hospital/organization/ED must have a signed and executed POA on file to participate in NPRQI. To streamline the POA process, the following information will assist hospital's in routing the POA for signature and submitting the POA to NPRQI.

POA Process:

1. Download Participant Organization Agreement during the registration process.
    a. Note: **A survey link and access code will be provided** if you decide to end the survey early to return to the registration process to upload the signed POA.
    b. To use this feature, select "Save and Return Later" to receive the survey link and return code.
2. Identify the authorized POA signatory at your organization. The authorized signatory will vary by organization. For hospitals and networks this may be the Chief Nursing Officer, Director of Nursing, Director of Quality Improvement, the CEO or CFO. For EMSC State Partnership Managers this may be the EMSC Manager, organization Director, CEO, or CFO.
    a. Name and Title
    b. Email
    c. Phone
3. **Route the POA for signature as soon as possible.** This process will vary by each organization and could take 1-2 weeks or possibly 3 months to complete.
4. Ensure the organization's legal name is typed/inserted (not handwritten) into the agreement in the following places:
    a. 1st page, first paragraph (line 3), where it says "insert participant organization name here"
    b. 1st page, under Background item A. where it says "insert participant organization name"
    c. Signature page, under participant organization, organization name
5. Do not hand write additional information or cross out text on the POA.
6. POA must be signed by an authorized signatory and dated. Both electronic or "wet signatures" are acceptable.
7. Once an authorized signature has been obtained, the organization will upload the POA into the NPRQI registration system.
    a. See information in item #1 for uploading POA.
8. NPRQI will review the POA for accuracy and completeness.
9. If POA is accurate and complete, NPRQI will proceed with routing the signed POA for final execution with The University of Texas. This process may take up to 14 business days.
10. Once the POA is executed a finalized copy will be emailed to your organization's primary contact(s).

Participant Organization Agreement
National Pediatric Readiness Quality Initiative

This Participant Organization Agreement ("Agreement"), effective as of the date of the last signature, is entered into by and between The University of Texas at Austin on behalf of its Dell Medical School ("University") and **[**_____], a pediatric medical care entity (each a "Party" and collectively the "Parties"). The Terms and Conditions for Data Use attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). Any Capitalized terms used in this Participant organization agreement without definition shall have the means given to them in the Terms and Conditions for Data Use.

I. Background:

A. **[**_____**]** (PO) has agreed to participate in the National Pediatric Readiness Quality Initiative (NPRQI), an initiative conducted under the University (hereafter referenced as NPRQI Program). The NPRQI program provides a platform for acute care hospital emergency departments to engage in quality improvement efforts based on evidence-based, standardized quality metrics that reflect optimal delivery of pediatric emergency care for children.

B. NPRQI is the implementation arm of the National Pediatric Readiness Project. The goal of NPRQI is to support emergency departments (EDs) to ensure high quality emergency care for children in their communities.

C. NPRQI Program has contracted with the Center for Patient Safety (CPS), a federally-listed Patient Safety Organization (PSO), and is conducting this project under the umbrella of the PSO. The information submitted to the project and the identifiable work product it generates, as well as the deliberations that take place, are protected by federal privilege and confidentiality under the Patient Safety and Quality Improvement Act (PSQIA). See NPRQI Welcome Packet for overview: www.nprqi.org .

D. The NPRQI Program is a Quality Improvement effort organized and operated under the Dell Medical School at The University of Texas at Austin (University). University is a public research university of the State of Texas.

E. NPRQI Program will receive certain confidential data that may be classified as Protected Health Information (PHI) that is protected under the Health Insurance Portability and Accountability Act (HIPAA) and the HIPAA Regulations, Health Information Technology for Economic and Clinical Health Act (HITECH Act) and state law, including the Medical Records Privacy Act (MRPA), and is permitted to manage such information only in accordance with HIPAA and the HIPAA Regulations, HITECH Act, and MRPA. The Parties agree that this data is being transmitted for quality improvement efforts in support of the Patient Safety

Organization under the Patient Safety and Quality Improvement Act and for research based on de-identified data but desire to comply with the aforementioned laws and regulations to the maximum extent required.

F. Participant Organization (PO) will submit patient data and understands that the value of the program lies in the collection of sufficient data from the participants. Data collection will facilitate local quality improvement efforts and provide benchmarking capabilities to help decrease pediatric morbidity and mortality.

II. Data Security and Confidentiality

A. NPRQI Program has contracted with Clario (formerly known as BioClinica) to host all confidential data, performance dashboard, and de-identified aggregate performance dashboards of Participant Organizations.
B. Clario's Trial Application Platform (TAP) is a 21 CFR Part 11 and European Union General Data Protection Regulation (GDPR) compliant, cloud-based clinical trial support system utilizing industry-standard encryption technology, and employing Standard Operating Procedures governing the handling of trial-related data (e.g., PHI and Patient Safety Work Product (PSWP)) through the full program lifecycle.
C. Data is encrypted pursuant to current standards from the National Institute of Standards and Technology (256-Bit encryption) while in transit (when files are uploaded or downloaded) over HTTPS. Data is encrypted at rest (in Amazon Web Services RDS databases) utilizing 256-Bit encryption as well. (NIST: https://csrc.nist.gov/publications/detail/sp/800-175b/rev-1/final).
D. User authentication is managed through Active Directory Federation Services (ADFS), Virtual Private Tunnels between servers, and leverages Single Sign-On (SSO) and Active Directory (AD) services.
E. TAP's architecture is designed to ensure that only authorized users may trigger operations (e.g., create, edit, delete records, etc.) within the system. TAP's security posture includes full system monitoring to detect potential user and system anomalies, with business continuity and disaster recovery capabilities that span a geographically dispersed cloud network to minimize the risk of catastrophic failure.

III. Patient Safety Organization Requirements:

The PO must meet the following requirements to satisfy requirements for the PSO:

A. Participant staff members working with the project data will sign confidentiality agreements that will be kept on file by PO and view a 10-minute educational video that explains the PSQIA's practical impact on their work in the project. The link to the educational video will be provided when the PO completes NPRQI registration.
B. Each participating hospital will adopt measures to protect the confidentiality of the data gathered and submitted to the project, described in the educational video.
C. The PO's engagement with the NPRQI Program will have no effect on the

participants' relationships with other PSOs.

D. CPS will be available to support participants on PSO-related questions through the FAQ section of the website or direct consultation.
E. Pursuant to the PSQIA, NPRQI Program will only disclose aggregated, de-identified participant data and only the PO will have access to its own identifiable data.

IV. Participant Organizations:

A. PO will submit data and understands that the value of the program lies in the collection of sufficient data from the participants.
B. The platform will be accessed through a password-protected portal, with unique identifiers that control access levels for select PO staff, and only those select individuals will have access to the PO's identifiable data.
C. The PO will designate a contact person to interact with NPRQI Program on activities related to this agreement. If the designated contact person changes at the site of the PO, the PO will notify NPRQI Program and CPS of the change via email at: NPRQI@austin.utexas.edu
D. PO will identify to NPRQI Program any network parent organization with which it will be affiliated on the data system such that the other organization may have access to the identifiable data of the Participating Organization (Affiliated Organizations as defined by the PSQIA).
E. PO agrees that participation in the NPRQI Program will be recognized in publicly available NPRQI Program documents and the NPRQI Program website.
F. PO agrees their participation will be disclosed as a PO in the NPRQI Program to the Health Resources and Services Administration - Emergency Medical Services for Children (EMSC) State Partnership Program.
G. PO understands that by signing the Agreement the PO will be recognized as described above as a participant in the National Pediatric Readiness Quality Initiative.

V. Funding:

A. The National Pediatric Readiness Quality Initiative is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $1.2M with 0% percentage financed with non-governmental sources. The contents do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government.
B. There are no fees for POs participating in this initiative.

VI. Requests for Protected Information

A. If a PO, NPRQI Program, or CPS receives a request for Patient Safety Work Product protected by the PSQIAA, it will notify the other Parties and will assert all

relevant privileges under HIPAA and the PSQIA. The Parties will communicate with each other regarding any decision to disclose potentially protected information.

B. The PO will have primary responsibility for defending the privilege and confidentiality protections in cases where it or its affiliated providers are a party and/or are the subject of an investigation. In other cases, the Parties will confer as to the appropriate responsibility. NPRQI Program and CPS will make resources and expertise available (through technical assistance from NPRQI, NPRQI

website, CPS website, Welcome Packet, and intervention guidebooks) to support the PO's efforts under this paragraph.

VII. Ownership, Work Product, and Research

A. The PO owns all identifiable PSWP and other identifiable information it submits to NPRQI.
B. The University of Texas at Austin owns all aggregate and non-identifiable information it has developed subject to the PSQIA requirements of CPS as a PSO.
C. The University of Texas at Austin may use and make available collected de-identified data for research purposes.

VIII. Term and Termination.

A. Term. The term of this Agreement shall commence as of the date of last signature and shall continue for so long as this project is ongoing.

B. Termination by University. University may terminate this agreement at any time by notifying the Provider and returning or destroying the data set provided by the PO. Termination of the agreement shall also result in termination of PO from the NPRQI program.

C. Termination by PO. PO may terminate this Agreement at any time by providing thirty (30) days prior written notice to University.

D. Disposition of Data Set. Upon the first to occur of 1) Termination of this Agreement or 2) completion of the Purpose of this Agreement, NPRQI Program shall return the data set to PO or certify destruction of any portion of the data set not returned.

IX. Miscellaneous.

A. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section VIII.

B. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding HIPAA, HIPAA Regulations, the PSQIA, and PSQIA Regulations.

C. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

D. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing, or enforcing any of the provisions of this Agreement.

E. Other Provisions. No amendment to the Agreement will be effective unless in writing and signed by the Parties. Neither the Agreement nor the rights and obligations of the Parties hereunder may be sold, assigned or otherwise transferred. If any provision of the Agreement is held to be unenforceable, all other provisions will continue in full force and effect. The Agreement supersedes any and all prior understandings or previous agreements between the Parties, oral or written, relating to the subject matter herein and constitutes the sole and complete agreement between the Parties related to the subject matter hereof. Any delay by a Party to enforce any right under the Agreement shall not act as a waiver of that right, nor as a waiver of the Party's ability to later assert that right relative to any particular factual situation. The Parties acknowledge that nothing in the Agreement shall constitute a waiver of sovereign immunity by Parties that are state agencies.

THE UNIVERSITY OF TEXAS

SIGNATURE

PRINTED NAME

TITLE

DATE SIGNED

PARTICIPANT ORGANIZATION

SIGNATURE OF AUTHORIZING OFFICIAL

PRINTED NAME

TITLE

ORGANIZATION

DATE SIGNED

Attachments:

Exhibit A: Data Use

Exhibit A

TERMS AND CONDITIONS **FOR DATA USE**

These Terms and Conditions ("Terms and Conditions") for Data Use are attached to and incorporated into the referenced Participation Agreement. All Section number references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

Background

Participant Organization ("Provider") owns rights in a data set and considers it desirable to make its data set available to The University of Texas at Austin ("Recipient") in support of the National Pediatric Readiness Quality Initiative, a quality improvement project based on evidence-based, standardized quality metrics and focused on optimal delivery of pediatric emergency care for children.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. Responsibilities of Recipient. Recipient agrees any disclosure of data set is made in the strictest confidence and to:

   Use or disclose the data set only as permitted by the Participation Agreement, this Agreement, as required by law, or otherwise authorized in writing by Provider;

   Safeguard the data set according to commercially reasonable administrative, physical and technical standards (e.g., National Institute of Standards and Technology, Center for Internet Security, Gramm-Leach Bliley Act) to prevent use or disclosure of the data set other than as permitted by this Agreement or required by law, including all reasonable efforts to ensure the protection, confidentiality, and security of any data set in its possession, such efforts to be no less than the degree of care employed by Recipient to preserve and safeguard its own confidential information, but in no event less than a reasonable degree of care;

   Continually monitor its operations and take any action necessary to assure the data set is safeguarded in accordance with the terms of this Agreement;

   To provide written notice to Provider of any use or disclosure of the data set of which it becomes aware that is not permitted by this Agreement or required by law, within ten (10) business day after discovery of misuse or disclosure. Recipient will promptly provide all information requested by Provider regarding the impermissible use or disclosure;

   Require any of its subcontractors or agents that receive or have access to the data set to agree to the same restrictions and conditions on the use and/or disclosure of the data set that apply to Recipient under this Agreement;

Not use the information in the data set to contact the individuals who are data subjects; and

Follow the terms of this Agreement *in addition to* any official policies and standards of University, or their functional equivalent. University policies and standards include[1], but are not limited to, the Information Resources Use and Security Policy[2], the Acceptable Use Policy[3], the Minimum-Security Standards for Systems[4], the Minimum-Security Standards for Application Development and Administration[5], the Data Classification Standard[6], the Data Encryption Guidelines[7], the Minimum-Security Standards for Data Stewardship[8], and Protecting Sensitive Research Data[9].

5. Permitted Uses and Disclosures of the Data Set.

a) Recipient may use and disclose the data set only in support of the National Pediatric Quality Readiness Initiative.

[End of Terms and Conditions]

[1] https://it.utexas.edu/policies
[2] https://security.utexas.edu/policies/irusp
[3] https://security.utexas.edu/policies/aup
[4] https://security.utexas.edu/content/min-security-standards
[5] https://security.utexas.edu/content/min-security-standards
[6] https://security.utexas.edu/policies/data_classification
[7] https://security.utexas.edu/policies/encryption
[8] https://security.utexas.edu/content/min-security-standards
[9] https://security.utexas.edu/policies/sensitive_research