JABSOM Department of Medicine
Guidelines for Use of Global TriNetX
The Queen's Medical Center, Hawaii Pacific Health and UH JABSOM

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1. Purpose
These guidelines establish standards for the ethical, compliant, and scientifically rigorous use of TriNetX by faculty affiliated with The Queen's Medical Center (QMC), Hawaii Pacific Health (HPH) and UH JABSOM. The goal is to support high-quality research, clinical innovation, and education using real-world data while ensuring patient privacy and regulatory compliance.

2. Scope
This policy applies to:

- Faculty, clinicians, and investigators at QMC and HPH
- UH JABSOM faculty, trainees, and affiliated researchers including HRP residents, Medical Students and Allied Health Personnel
- Staff and collaborators granted access through institutional credentials

3. Access
All residents and allied health personnel are required to have a faculty mentor. Residents can not access Trinetx without a faculty member overseeing their project.

4. Mandatory Training Requirements
4.1 Initial Training (Required Prior to Access)
All users must complete the following before obtaining TriNetX access:

- Review of TriNetX platform capabilities, limitations, and appropriate use
    - TriNetX Summer Bootcamp 2025, Six sessions:
    - Week 1 (6/23) – Navigating TriNetX and Developing a Project https://www.youtube.com/watch?v=-vm1KD0siUo
    - Week 2 (6/30) – Defining and Exploring Cohorts https://www.youtube.com/watch?v=z-6qlr4rTQ0
    - Week 3 (7/7) – Comparing Cohorts and Propensity Score Matching https://www.youtube.com/watch?v=RGsaBMuWv1g
    - Week 4 (7/14) – Conducting Outcomes Analyses https://www.youtube.com/watch?v=_po1Bf6q0dk
    - Week 5 (7/21) – Cox Proportional Hazards Models and Treatment Pathways Tools https://www.youtube.com/watch?v=AZLlERalAoQ
    - Week 6 (7/28) – Posters, Manuscripts, and Writing Tools https://www.youtube.com/watch?v=VudCYfY4ry0

  Completion of **CITI Human Subjects Research training and HIPAA**
    - Biomedical and biological responsible conduct of research
    - Conflict of interest
    - Non-exempt Biomedical Researchers and Key Personnel
    - Non-exempt Biomedical Researchers and Key Personnel IPS
    - HIPAA Privacy

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4.3 Documentation and Enforcement

- Training completion must be verified prior to account activation - look at form
- Departments or designated TriNetX administrators will maintain records
- Failure to maintain CITI training will result in suspension of access

5. Acceptable Use
TriNetX may be used for:

- Feasibility queries for grants and clinical trials
- Retrospective observational research
    - Established databases available at Trinetx (https://trinetx.com/solutions/real-world-datasets/)
- Hypothesis generation and pilot data analyses
- Quality improvement (QI) initiatives
- Educational activities under faculty supervision

The TriNetX platform includes a set of built-in analytics tools designed for rapid, IRB-exempt feasibility analyses. These are valuable for initial cohort exploration but are intentionally limited in scope:

- Cohort discovery and patient counts
- Basic Kaplan-Meier survival curves
- Simple cohort comparison (Compare Cohorts)
- Basic propensity score matching
- Treatment pathway visualization
- Incidence and prevalence estimates

6. Prohibited Use
Users are strictly prohibited from:

- Attempting to identify or re-identify individual patients
- Exporting or sharing data in violation of TriNetX or institutional policies
- Sharing login credentials or unauthorized account access
- Using TriNetX data for unapproved commercial or external purposes
- Misrepresentation or misuse of data findings
- Manipulating study parameters — including time windows, inclusion/exclusion criteria, or outcome definitions — after observing results for the purpose of achieving statistical significance (p-hacking). All key analytic decisions must be pre-specified in a Statistical Analysis Plan (SAP) prior to running queries.
- Combining TriNetX data with third-party software, tools, or AI/LLM applications without prior written authorization from TriNetX and the institutional data governance office
- No downloading

7. Data Privacy and Security Compliance
All users must comply with:

- HIPAA regulations
- Policies of QMC, HPH, and UH JABSOM
- Applicable Data Use Agreements governing TriNetX

Key Requirements

- Use only de-identified, aggregate data within TriNetX
- Do not attempt re-identification under any circumstances
- Store exported outputs (if permitted) only on secure, approved systems
- Immediately report any suspected data breach or misuse

8. IRB and Regulatory Oversight

- All users must follow the policies of the University of Hawai‘i Institutional Review Board and/or HPH and Queen’s IRB as applicable
- Investigators are responsible for determining whether their work constitutes:
    - Human subjects research
    - Exempt research
    - Quality improvement
- IRB approval or exemption must be obtained prior to initiating research activities, when required
- Documentation of IRB determination must be maintained and available upon request

9. Data Validation and Scientific Responsibility

Trinetx users are responsible for:

- Understanding limitations of real-world data (e.g., coding variability, missing data) https://apps.cctr.vcu.edu/blog/!/6/what-is-in-trinetx-for-vcu
- Applying appropriate epidemiologic and statistical methods- https://www.urmc.rochester.edu/clinical-translational-science-institute/services-and-support/trinetx
- Avoiding overinterpretation of associative findings

Publication Standards - see Addendum 2 https://trinetx.com/publication/trinetx-publication-guidelines/

- Clearly describe TriNetX methodology
- Disclose limitations of the dataset
- Ensure transparency and reproducibility

10. Violations May Result In:

- Immediate suspension or revocation of access
- Notification of department leadership

11. Governance and Support

- TriNetX access and governance will be coordinated through:
    - Queen’s Research Office
    - HPH BRIC
    - UH JABSOM Hawaii Network
- Users are encouraged to:
    - Engage biostatisticians or data scientists when appropriate
    - Consult TriNetX administrators for technical support
    - Report concerns promptly

12. Presentation at Conferences and Publications in Journals

- All presentations and publications that utilize TriNetX data must be presented first at the University of Hawaii Department of Medicine (DOM) Internal Medicine Research Interest Group (IMRIG) meeting
- Investigators should contact the DOM Residency Program staff at uhimrp@hawaii.edu to schedule an IMRIG session. These meetings provide an opportunity to discuss project concepts, review data analysis plans, and receive feedback and support prior to presentation or publication

Addendum 1.

Additional videos to consider watching regarding Trinetx

- TriNetX Live Training (Dr. James Potter): A comprehensive session covering the interface, study creation, and query building. https://www.youtube.com/watch?v=PJIyepErP6M
- Trinetx instructional videos https://sites.google.com/ucr.edu/scholarly-activities-portal/trinetx-resources/2025-bootcamp-recordings/trinetx-instructional-videos-2024
- Pitfalls on analyzing big data (EHR) https://ascpt.onlinelibrary.wiley.com/doi/full/10.1111/cts.70093
- Trinetx 101 dataset https://www.umaryland.edu/media/umb/ictr/general-media/Datasets-101-General-Overview-Slides-Oct.-2025.pdf

Addendum 2.

How to cite work done using Trinetx

Please go to Trinetx.com for suggestions on how to reference work using Trinetx.

https://trinetx.com/publication/trinetx-publication-guidelines/

Citing TriNetX

TriNetX, LLC should be mentioned in the methods section. A suggested adequate general description would read:

"The data used in this study was collected on [INSERT DATE OF ANALYSIS OR DATE OF DATA DOWNLOAD] from the TriNetX [INSERT NETWORK NAME] Network, which provided access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from approximately [##] million patients from [##] healthcare organizations."

For publication ethical considerations. A suggested adequate general description would read:

"This retrospective study is exempt from informed consent. The data reviewed is a secondary analysis of existing data, does not involve intervention or interaction with human subjects, and is de-identified per the de-identification standard defined in Section §164.514(a) of the HIPAA Privacy Rule. The process by which the data is de-identified is attested to through a formal determination by a qualified expert as defined in Section §164.514(b)(1) of the HIPAA Privacy Rule. This formal determination by a qualified expert refreshed on December 2020."

Please note that although TriNetX recommends the above-mentioned language for publication, it may be revised as applicable.