

## ACT Terms of Query Access

Version 5.0

06-07-2023

This Terms-of-Query-Access Agreement is designed to permit approved users access to the NCATS Evolve to Next Gen ACT (ENACT) Network federated query tool for the purpose of requesting aggregate clinical data from participating organizations who are members of the ENACT network.

Each Participating ENACT Organization individually contributes and allows access to aggregate clinical data **for clinical research and data analysis purposes only**. By selecting "I Agree" below you certify that you understand and agree to all applicable terms contained herein.

- I assert that I am a member of the <ENACT Network Site> Faculty, supervised Fellow or Qualified Staff working under a qualified faculty member, and am:
  - At or above Instructor level (Clinical and Research Fellows or doctoral students will be able to access cohort counts as approved by the Fellow's or student's designated faculty mentor) and either primarily appointed by, contractually related to, on the medical staff of, or maintain a significant relationship with <ENACT Network Site>.
- The following provision applies only to supervised Fellows and Qualified Staff:
  - I understand that I may only submit queries and obtain ENACT data directly associated with the validated Query Topic specifically delegated to me by my supervising Qualified Faculty Member.
- I understand that as a Qualified Faculty Member, supervised Fellow, or Qualified Staff, (Please refer to the ENACT Governance Document, Section 12, for responsibilities designating and overseeing Qualified Staff) I may collaborate with investigators who are not Qualified Faculty Members, supervised Fellows, or Qualified Staff in my institution under the following conditions:
  - Our collaboration must be in my area of scientific expertise.
  - I am the only individual who will be authorized to conduct actual queries.
  - I assume full responsibility for adherence by my collaborator with the ENACT Network Agreement and will obtain and retain a signed copy of this Terms-of-Access Agreement to certify my collaborator's compliance with the ENACT Network Agreement.
- I understand that collaboration and/or sharing of primary data with unauthorized personnel outside of my institution without prior approval by the <ENACT Executive Committee is prohibited.
- I understand that my ENACT Network Site has agreed to comply with the ENACT Network Site Policies under which access to deidentified aggregate clinical data is allowed and that my employing institution will hold me accountable for following these policies.
- I understand that my usage of the ENACT resource is recorded and monitored, and that this usage data may be included in publications or scientific presentations. I understand that the ENACT network will not identify me by name in publications without my permissions, but that it cannot guarantee user anonymity because query patterns may be unique.
- I further acknowledge the additional level of ethical sensitivity inherent in accessing data from institutions and patients other than my employing institution and agree to exercise exemplary ethical conduct when so doing. This includes but is not limited to the following specific issues:
  - I agree to restrict requested query topics and associated individual queries to bona fide research issues.
  - I will not formulate queries that could be used for competitive institutional or individual advantage.
  - I agree not to attempt to identify any individual or set of patients contained in the aggregate data.
- I understand that sample sizes will be obfuscated +/- 10, rounded to the nearest 5, and sizes smaller than 10 will not be returned in order to prevent inadvertent identification of the sampled patients.
- I understand that all publications (including abstracts) based on data from the ENACT Network will require prior approval from the ENACT publication committee as described in SOP 5 before submission.

- I understand that publications based on and Intellectual Property derived from clinical research and data analysis using the ENACT Network must cite the NCATS ENACT grant: “This project was supported by the National Institutes of Health through grant 1U24TR004111-01” and <appropriate CTSA Hub grant numbers from participating organizations>”.
- I understand that all appropriate institutional, state and federal policies, laws and regulations governing specially protected information will apply. In addition, I understand that there are research topics that are and will remain off limits, such as competitive market analysis.
- I understand that any violation of this agreement will subject me to disciplinary action by my institution in consultation with the appropriate office.