# NCATS Evolve to Next Gen ACT (ENACT)

## Governance

**ABSTRACT**

The Evolve to Next Gen ACT (ENACT) program, which is built upon the CTSA Consortium cohort discovery platform, ACT, will enable investigators and trainees at CTSA hubs, partners, and other designated sites to conduct EHR-based research on any disease or condition across its network of over 140 million patients.

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**Table of Contents**

**1. Terms, Definitions and Local ENACT Functions**

**ENACT Data Steward/User Liaison**: Designee(s) of an ENACT Network Site with auditing and monitoring responsibility of the local ENACT Site – including data quality and conformance to Terms of Query Access Policy. The Data Steward/User Liaison serves as the main point of contact for the site user.

**ENACT Executive Committee**: Formed by the ENACT PI leads, one lead from each Work Group (Governance, Regulatory, Technology, Dissemination & Evaluation and Data Harmonization) and a member of NCATS leadership.

**ENACT Functions:** Suggested functions for implementation, maintenance, and participation in the ENACT Network. Details are found in Appendix A. These functions are not required for participation in ENACT.

**ENACT Network Operations Procedures:** This document is designed to describe the technical structures, responsibilities and operational processes for participating ENACT sites and ENACT Network Operations. It can be found here.

**ENACT Network Site**: An institutional member of the ENACT network; one who has signed the ENACT Network Site Agreement.

**ENACT Network Site Agreement:** Agreement signed by each institutional member of the ENACT Network. Includes policies and procedures the site must follow to participate in the ENACT Network.

**ENACT Network Qualified User:** A person with authority to query the ENACT network per the ENACT Network Site Agreement and the Terms of Query Access.

> **ENACT Qualified Faculty:** A faculty appointee of an ENACT Network Site that fits the following criteria:  1) 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 2) Either primarily appointed by, contractually related to, or on the medical staff of a participating ENACT Network Site or partner institution. ENACT Qualified Faculty oversee supervised Fellows and other Qualified staff in their access of the network.

> **ENACT Qualified Staff:** A person who has been approved by an ENACT Qualified Faculty member to access the ENACT Network. All queries conducted by Qualified Staff are ultimately the responsibility of the ENACT Qualified Faculty.

**ENACT Terms of Data Use:** The terminology that defines the processes and policies surrounding potential study participant data used for the purpose of recruiting participants into the nation's highest priority clinical trials.

**ENACT Work Groups and sub-committees:** Per the NCATS supported ENACT administrative supplement notice of award, there are five Work Groups: Dissemination & Evaluation, Governance, Regulatory, Technology, and Data Harmonization. Each Work Group has a lead or co-leads authorized to create sub-committees as needed for specific tasks and for the creation of work products.  Additional Work Groups may be added to meet the needs of future Aims.

**CTSA Hub**: The institution that has been awarded an NCATS Clinical and Translational Science Award (CTSA).

**Data Concierge Honest Broker:** A local role that is responsible for providing patient identifying information that can be shared with study enrollment teams, as approved by the local IRB.

**Dissemination Lead:** Assumes overall responsibility for the rollout of ENACT to local investigators.  Details are found in Appendix A.

**EHR:** Electronic Health Record.  Also used in lieu of Electronic Medical Record (EMR).

**Hub Operations Coordinator (HOC):** Assumes overall responsibility for monitoring the ENACT test, staging, and production networks as a member of the Harvard SHRINE team.

**i2b2 Plugin:** A software module that extends the local functions of an i2b2 instance.

**Ontologist:** Collaborates with ENACT Data Harmonization Work Group and ENACT ontology development. Details are found in Appendix A.

**Originating Site:** The ENACT Network Site from which a user makes a query to the ENACT Network.

**Originating Researcher:** Researcher who performs an initial query across the ENACT Network that results in either a single or multi-site study.

**Patient Identification:** For the purposes of this document, *patient identification* refers to the _local site_ obtaining participant contact information necessary to recruit a subject to a study in accordance with their local IRB approval. This does not imply any release of patient-level data by external manual or automated means.

**PI Group:**  The four Principal Investigators listed on the NCATS grant – Steven Reis (University of Pittsburgh, Gary Firestein University of California San Diego, Robert Toto UT Southwestern Medical Center, Shyam Visweswaran, University of Pittsburgh).  The PI Group will review any policies and issues to be managed within the ENACT Executive Committee.

**Receiving Site:** An ENACT Network Site that is one of the recipients of a query made from an Originating ENACT Network Site.

**Research Data Curator:** Maps local data to ENACT ontology and ensures accuracy and compliance of data available to the ENACT Network.  Details are found in Appendix A.

**Site Lead:** Assumes overall responsibility for the site's activities in the ENACT Network.  Details are found in Appendix A.

**Site Operations Coordinator (SOC):** The primary site individual responsible for technical operations.  This individual works closely with the Data Steward to troubleshoot and resolve site user issues.

**Site Researcher:** Researcher who is part of a multi-site study that shares ENACT generated information with the local data concierge / honest broker service for participant identification.

**System Administrator (application and infrastructure):** Provides support in installation, implementation, and maintenance of ENACT technology frameworks (i2b2 software, i2b2/OMOP database and SHRINE). Details are found in Appendix A.

**2. Background**

With funding from NCATS (UL1TR000005, ULTR1001847), the Accrual to Clinical Trials (ACT) federated network was created. It crafted a broad data use agreement (DUA) and stood-up local clinical data warehouses (CDWs) at 57 CTSA hubs, created an information superhighway to query the electronic health record (EHR) data for >142 million patients in the CDWs, and democratized data access for cohort discovery to all CTSA hub scientists. It established a collaboratory built on trust and sound governance.

The objective of the ACT Network was achieved, as it supported the planning and design of multisite clinical trials, including those supported by the Trial Innovation Network, and it helped the CTSA Consortium achieve its full potential as a national clinical trials network. The network enabled rapid discovery of diverse cohorts and collaborators across the country and additionally highlighted the potential value of EHR data for going beyond assessing clinical trial feasibility to actually conduct virtual trials. The ACT Network had limited analytic capacity in its previous form, so the opportunity was

addressed through Evolve to Next-Gen ACT (ENACT).

**3. Evolve to Next-Gen ACT (ENACT) Proposal**

ENACT will develop and implement new informatics tools for EHR research, serve as a platform for tool development by informaticians and statisticians across the Consortium, improve the quality of the existing structured data, incorporate data extracted from clinical text using natural language processing (NLP), and enable both federated and centralized statistical and machine learning-based analyses. It will leverage existing strengths of the CTSA structure, including the Biostatistics, Epidemiology, and Research Design (BERD), Informatics, and Translational Workforce Development Cores at each hub to ensure the full uptake and efficient utilization of ENACT, which in turn will increase the impact on translational research and health.

The purpose of this document is to outline the governance principles and procedures to be used by ENACT in its administrative functions.

ENACT has four Specific Aims and five years between 2022 – 2026 to accomplish its goals:
- *Aim 1* will create a user-friendly collaborative research and computing environment with cutting edge analytical methods.
- *Aim 2* will create a platform and provide statistical and machine learning capacity that translational scientists and their teams can apply to EHR data.
- *Aim 3* will leverage informatics tools and EHR data to enable clinicians to generate evidence that can be applied to improve patient care.
- *Aim 4* will design for dissemination and sustainability to foster a learning informatics system.

An evaluation process to monitor the progress, successful completion as well as sustainability of ENACT is in place and will be ongoing.

**4. Governance Document**

This document is designed to enable future amendments in order to include additional stakeholders, sponsors, and other items described herein. Each ENACT Network Site will collaborate with other institutions within the ENACT Network to develop the informatics tools and regulatory infrastructure that are required to leverage the EHR across CTSA sites nationwide. Each site will lend its expertise in the utilization of their EHR, informatics infrastructure and regulatory expertise to navigate their institutional policies and procedures to launch the ENACT Network and conduct cohort exploration studies serving the NIH Institutes and Centers and Industry sponsored research.

**5. Governance Principles**

Governance includes the processes we define and use to make key decisions on how ENACT will operate, accomplish strategic goals, and optimally deploy resources. The purpose of governance is to support ENACT as it works to achieve its goals and aims. Organizationally, and particularly in Academic Health Center settings, there is often a strong desire for comprehensive and highly formal governance, but this can also undermine organizational agility. ENACT governance attempts to strike a balance between ensuring an equitable decision-making process that facilitates consensus seeking while minimizing unnecessary bureaucracy. Our governing principles are as follows:
- Strive for a balanced governance that encourages open discussion and transparency
- Implement a structured, thoughtful and comprehensive governance while minimizing bureaucracy
- Ensure appropriate representation that encourages consensus-seeking

## 6. Governance Scope

Governance is an essential component of decision-making in a consortium and enabling progress towards goals and objectives.  Important aspects of governance include:
- WHAT types of decisions are covered by the governance entity or entities
- WHO will be involved
- HOW will decisions be made
- WHEN and WHERE decisions will be made
- FINANCIAL CLARITY regarding allocations, authority and accountability

The scope of ENACT requires each *site* to collaborate with other institutions within the CTSA consortium and their partners to develop the informatics tools and regulatory infrastructure required to leverage the EHR across *CTSA hubs and partners* nationwide. Each *site* will lend its expertise in the utilization of their EHR, informatics infrastructure and regulatory expertise to navigate their institutional policies and procedures to launch the ENACT Network and conduct cohort exploration studies and research serving the NIH Institutes, Centers and the member institutions. By participating, the member Institutions of ENACT concede oversight and management of the ENACT program to the ENACT Executive Committee.


## 7. Governance Structure

The governance structure developed for ENACT includes required reporting to NCATS through the ENACT Executive Committee, an entity providing executive oversight for the project. It is outlined in Figure 1, below.
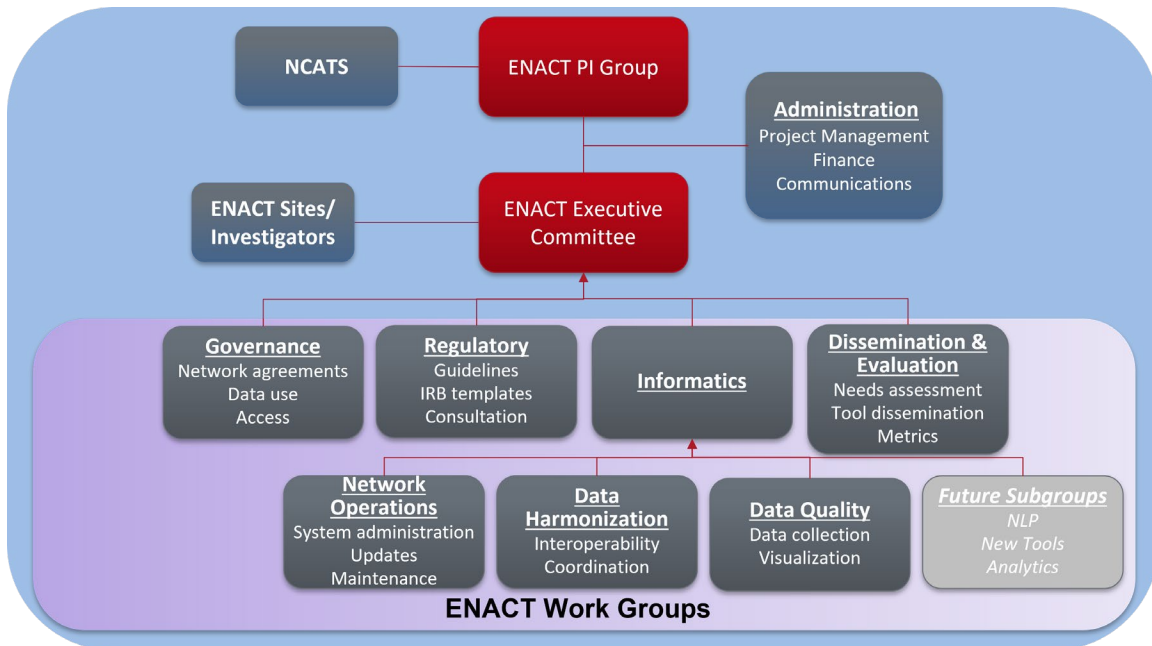


**Figure 1. ENACT Project Governance.**
ENACT Governance Elements include:
1. PI Group
2. ENACT Executive Committee
3. ENACT Work Groups and subgroups

PI Group:  Formed by the ENACT PI leads, this group is ultimately responsible for the overall performance and strategy for ENACT. As such, the PI group has the authority to adjudicate decisions and issues.

6

ENACT Executive Committee: Formed by the ENACT PI leads, Work Groups leads (Governance, Regulatory, Informatics, Dissemination & Evaluation and Data Harmonization) and a member of NCATS leadership. The goal of this committee is to make most or all decisions by consensus and/or voting for ENACT. It decides on the priorities and deliverables for each ENACT Work Group. An NCATS ENACT principal investigator will be appointed to serve as the committee chairman.

ENACT Work Groups and Subgroups: Per the ENACT contract, there are five Work Groups: Governance, Regulatory, Informatics, Dissemination & Evaluation and Data Harmonization. Each Work Group has a lead or co-leads that serve(s) on the ENACT Executive Committee and may create sub-committees as needed for specific tasks and for the creation of work products. Each Work Group reports to the Executive Committee and each Work Group has an appointed PI liaison as an ex officio (non-voting) member. The Executive Committee can sunset Work Groups and create new Work Groups to support the project as ENACT evolves. Work Group membership varies and is defined by the Work Group Leads. Membership is either open to anyone who is interested in participating, or membership is extended to individuals voted upon from across the ENACT community. Membership is evaluated annually and is likely to change.

- **Governance** – responsible for network agreements, data use, governance documentation and network access guidance
- **Regulatory** – provides regulatory guidelines, IRB templates and consultation as necessary
- **Informatics** – supports system administration, technology upgrades/updates and system maintenance, informatics community building, new tool feasibility assessments and implementation planning, data quality, and strategic technical planning
- **Data Harmonization** – oversees data harmonization, the ENACT ontology, interoperability, and coordination
- **Dissemination & Evaluation** – responsible for developing training materials and dissemination guidelines for network rollout to investigators; also includes evaluation efforts that will assess the efficacy of training, communications, and the overall functioning of the ENACT network

Project Management: There is external project management contracted for the ENACT Project to:
- Provide a single point of contact for information, while managing and facilitating all communication, documentation, and reporting across the ENACT program.
- Deploy a consistent set of tools and processes to assist the individual site implementations.
- Encourage collaboration, best practices and information sharing across the sites.

## 8. Voting

The ENACT Executive Committee votes on items brought forward by the Work Groups, network operations, and member institutions on an as needed basis. The committee is composed of the following individuals: four principal investigators of the ENACT program, Work Group leads, co-leads and additional Work Group designees and an NCATS member appointed by NCATS leadership. Note: Up to two representatives from each Work Group can participate on the executive committee if there are Work Group co-leads, but each Work Group has only one vote. Voting members must either cast a vote or name a delegate to cast a vote. The required quorum is participation by at least five voting members, of different work groups, and including at least two ENACT PIs, in any item brought to a vote. To be passed, decisions/resolutions require a simple majority. A voting member may vote in absentia (e.g. email) as needed.

## 9. Communications

Guidelines are provided for external communications to stakeholders and internal communication – between sites, Work Groups, sub-committees and Executive Committee, and external communication to stakeholders.
- **Use of the ENACT name** – The ENACT name, NCATS Evolve to Next Gen ACT (Accrual to Clinical

Trials) may be used by NCATS and all participating ENACT Network Sites. In addition, others may use the ENACT name with written prior approval by the ENACT Executive Committee. In all communications on behalf of the project and network, refer to the project as NCATS Evolve to Next Gen ACT, using the ENACT abbreviation after it has been spelled out initially.

- **External Communications**
  - NCATS
    - Communications with NCATS are facilitated by the NCATS appointed member of the ENACT Executive Committee.
    - Communications with NCATS are both informal and formal. These communications will also be shared with the ENACT Network Sites in order to foster understanding, trust, and confidence.
    - Status updates to NCATS are provided on a quarterly basis.
    - Meetings with NCATS leaders, to discuss project progress, may include invited speakers from the project and from sites, as recommended by NCATS and the ENACT Executive Committee. Presentations will be shared with the entire ENACT team.
    - Feedback and questions that arise from presentations to NCATS should be recorded by a designated scribe at the meetings. These notes should be made available to the entire ENACT team via email and archived in a secure area of the ENACT SharePoint site (see below).
  - Potential Sites - Project status and information regarding participation in the network should be provided to potential sites by the ENACT Executive Committee, as prepared by its Work Groups. Material should be made available online, as well as document format (PDF) for emailing as attachment. The following are principles governing communications with potential sites:
    - Transparent communications are critical, especially regarding the requirement to contribute data, the site onboarding process, and expectations for being part of the network.
    - Inquiries from potential sites must be managed by the Executive Committee.
  - The Public - ENACT maintains a document management site and a national website, clearly identified as NCATS Evolve to Next Gen ACT. A regular newsletter is also distributed to the ENACT community and others who express interest in receiving it. The communication channels provide the following forms, documents and checklists:
    - Governance documents
    - Requirements for participating in ENACT
    - Policies and procedures for queries
    - Standard Operating Procedures for ENACT
    - Metrics (data quality, usage, other metrics as captured and appropriate)
    - Progress Reports
    - End user training materials and general network guidance
    - ENACT work products such as the ontology
    - Media - All inquiries from the media should be referred to NCATS communications specialists
- **Internal Communications**
  - Principles
    - The work of parts of the team (Work Group, Committee) must be visible to the entire team through the national website or designated document repository tool.
    - Promote transparency and open communications. That is, the work of each team member must be visible to the entire team.
    - Promote continuity. There will be a transition from Work Group centric activity to site centric activity. As the network is defined, we will move from predominantly Work Group communications towards network-focused communications regarding site status and the needs of the network as a whole.

- Characteristics
  - Dissemination of decisions, status updates
  - Key project information such as schedules, budget, risks, modifications
  - Transparency of meeting schedules
  - Freedom for ad hoc meetings/calls as Work Groups require
  - Site-specific numbers of records, years covered, date of last refresh, etc.
- **Contact List** - The ENACT internal shared site must contain an up-to-date contact list of all active ENACT team members and site contacts. A designated ENACT team member should maintain this information.
  - Contact information for each person should include:
    - Name
    - Institution/Site
    - Email address
    - Phone
    - Committee/Work Group(s) and role (e.g., Governance Work Group, Communications sub-committee lead), if appropriate
- **Standard communication language for participants**: ENACT sites will agree to use (or base their own communications) on standard language that can be used with participants regarding such issues as disclosure, transparency, security, protection of data, no sale of data to industry, etc.

## 10. ENACT Network Site Responsibilities

The decision to participate in a study is left to the ENACT Network Site authority. There is no obligation for a site to participate in a study proposed by another ENACT Network Site.

It is not the responsibility of the Data Steward or the Site Operations Coordinator to identify a site PI for a proposed study.

Additional ENACT Network Site Responsibilities are found in the ACT Network Operations Procedures document.

All institutions desiring to participate in the ENACT Network must agree to the following:

- ENACT Network Sites hold active NCATS-funded CTSAs, are partner health systems of an NCATS-funded CTSA, are Institutional Development Award (IdEA) sites, or a Research Center in Minority Institutions (RCMI).

- New ENACT Network Sites will join on their own schedules. Criteria used to demonstrate readiness to onboard to the production network include:

  - Support and commitment from institutional leadership to support the goals of the ENACT project,
  - Installation of i2b2 and SHRINE software,
  - Performance of regular data updates from the site EHR to the site data repository,
  - Dedicated informatics staff to support software and informatics systems and upgrades,
  - A patient population that will contribute to diversity across the network

- The ENACT Network Site CTSA PI will nominate a faculty representative to lead the ENACT project locally, who will serve as the ENACT Site Lead and have the authority and resources to appoint faculty and staff to participate in working groups and serve on committees. These representatives will possess appropriate experience, authority and knowledge to assist in establishing best practices.

- ENACT Network sites will conduct example queries as needed to demonstrate the functionality of the ENACT Network and will provide aggregate counts of patients meeting designated criteria.

- ENACT Network Sites will only provide a summary data count in response to a query. Opportunities for limited data sets and deidentified data in a secure enclave-like environment will be defined later in the ENACT project with the appropriate governance and regulatory guidance in place.

- Once an ENACT Network Site's institutional leadership has provided approval of the ENACT Network Site Agreement, ENACT Network Sites will be permitted to join the production network hub.

- ENACT Network Sites agree to participate in a governance structure that will work collaboratively to develop and adopt policies and procedures for data harmonization, query access, data privacy, communications and dissemination of results, attribution, and management of Conflicts of Interest.

- ENACT Network Sites will secure appropriate institutional approval for the sharing of clinical data for research purposes, including approval (if granted) to publish patient counts identified as originating from their institution.

- Insuring Integrity of Data Use:

  - All data queries will be archived and can be included, by request, in reports to the ENACT Network Executive Committee.

  - The Local Data Steward will periodically audit individual data queries for compliance with the original intent of the query.

  - The ENACT Executive Committee will resolve requests and issues not covered by existing policies and will develop a policy for penalties (and possible exclusion from ENACT) that will be applied for violations of these policies.

  - Participating sites will be expected to provide data to sites that comprise the network.

  - This policy will be reviewed by the NCATS ENACT Executive Committee regularly and updated as needed based on feedback from the investigator communities and the leadership of each organization involved. Any updates or changes will require an amendment(s) to the agreement.

- Citations

  - Publications in which data source partners (hospitals) are to be identified by name will be reviewed for use of name only by each identified hospital or health system prior to submission of a manuscript. At no time will specific participating data source partners be named unless explicitly approved by the data partner. Such approval must be requested and received in writing between the requestor and the Senior Vice President of Research, the Chief Information Officer, or their respective designee. Any entity (e.g., hospital) that does not agree to be identified by name as a data source will be instead identified as a "CTSA-affiliated hospital."

  - Publications based on research using the ENACT Network should cite the NCATS ENACT grant and appropriate CTSA Hub grant numbers from participating organizations. It is the responsibility of the ENACT Network Site to provide reminders to ENACT Network Users and to monitor to ensure appropriate citing of the grant.

  - Any Intellectual Property derived from use of the ENACT Network must cite the NCATS ENACT grant.

  - Publication details are found under Standard Operating Procedure 5.

- Site Technical Service Level Agreements

- Network uptime will be maintained by participating sites in the following manner (additional information may be found in the ENACT Network Operations Procedures document).

  - The Hub Operations Coordinator (HOC) will run routine tests of the network that will check for operational issues. Results of each test will be shared with system administrators and Site Operations Coordinators (SOCs). In the future, network Uptime/Downtime status may be posted on the website.

  - Each site will designate a member of their staff as the Site Operations Coordinator (SOC) who is responsible for local technical operations.

  - The Data Steward will be the main point of contact for local users (users at that institution/site) regarding possible operational and technical access issues. The Data Steward will work with the SOC to troubleshoot and resolve these issues.

  - Scheduled site technology downtime will occur during the weekly downtime window of Tuesday nights (between 4pm EST and Wednesday 7am EST). There may be times when additional downtime is required across the network. These times will be communicated out across the ENACT technology distribution list and posted on the ENACT website.

  - Locally scheduled downtimes will be communicated by the SOC to all other network SOCs and the HOC at least 24 hours prior to the event. It is required that sites abide by the network downtime window timeframe. Emergency or unplanned downtimes will also be communicated by the SOC to all other network SOCs and the HOC utilizing the ENACT technology distribution list as the SOC learns of the issue.

  - Each site's SOC will be responsive to other site SOCs and the HOC regarding possible operational issues at their site.

  - If an operational error is identified at a site, the SOC will coordinate resolution of that error and the process of bringing their site back online. The SOC will notify all SOCs and the HOC, again utilizing the ENACT technology distribution list, that the issue is recognized and is being addressed.

- Network participation will be based on adhering to these uptime agreements and the following site maintenance criteria. Additional information may be found in the ENACT Network Operations Procedures document.

  - Each site is expected to refresh their data at least monthly, although more frequently is preferred.

  - Software and ontology updates – each ENACT Network Site will perform annual updates/upgrades to the i2b2 and SHRINE software and the ENACT ontology as guided by the ENACT Network Operations group and approved by the ENACT Executive Committee.

  - Utilization reporting – each ENACT Network Site will provide reporting to the ENACT Executive Committee on numbers of users and queries on a regular basis, as requested. This process is coordinated among site Data Stewards, the ENACT Evaluation team, and the national project manager.

  - Feedback from users – each ENACT Network Site will agree to survey their users for feedback as determined by the Executive Committee and ENACT Dissemination and Evaluation team.

**11. ENACT Network Site Policies**

- All institutions desiring to participate in the ENACT Network must agree to and officially sign an ENACT Network Site Agreement that incorporates the following principles of participation: ENACT Network Sites will secure IRB review and approval for their i2b2/OMOP and SHRINE participation in the ENACT network.

- The ENACT Network Sites will implement the Terms of Query Access and Standard Operating Procedures that will permit approved users access to the SHRINE federated query tool for the purpose of requesting aggregate clinical data from participating ENACT organizations.

- Insuring Integrity of Data Use:

  - All Qualified Faculty, supervised Fellows, Qualified Staff working under a qualified faculty member and their collaborating investigators must complete and sign the ENACT Terms of Query Access before making a data request; this module will contain the following elements:

    - Acknowledgement of principles regarding ethical considerations in using shared clinical data;
    - Statement prohibiting any attempt to identify any individual patient;
    - Appropriate language regarding protection of intellectual property;
    - Publication policy (regarding citation of CTSA Hub grants, use of participating ENACT Network Site names, etc.);
    - Statement of penalty for violating agreement as designated by local institution.

- Extension of network access beyond connected site – each ENACT Network Site is permitted to extend access to end users beyond the site provided that the following items are true:

  - Institutions in question must be a partner of an ENACT CTSA hub currently participating in the network.
  - The ENACT CTSA hub is ultimately responsible for controlling end user access and abiding by ENACT policies set forth in this document, including but not limited to the ENACT Terms of Query Access.
  - A local data agreement must be in place between the partner institution and the institution with connection to the ENACT Network.
  - If the partner institution has data that can be contributed to the ENACT Network, then the partner institution may stand up its own ENACT instance and connect directly to the network as an affiliate institution.

- Utilization Reporting – each ENACT Network Site will provide reporting to the ENACT Executive Committee on numbers of users and queries on a regular basis, as requested, facilitated by the ENACT Evaluation team, local Data Steward, and national project manager.

- Feedback from users – each ENACT Network Site will agree to survey their users for feedback as facilitated by the ENACT Evaluation team and determined by the Executive Committee and ENACT Evaluation team.

**12. Terms of Query Access**

The Terms of Query Access is designed to permit approved users access to the NCATS Evolve to Next Gen ACT Network SHRINE federated query tool for the purpose of requesting and receiving cohort counts from participating ENACT Network Sites. Each Organization individually contributes and allows access to aggregate clinical data for research purposes only with an intention to accrue for clinical trials or for feasibility of clinical trials. This section provides a framework intended to ensure that research collaborations among the NCATS ENACT Network investigators are realized in an ethical, respectful and transformative fashion.

Access to Data

- Access to data is limited to ENACT Qualified Faculty, supervised Fellows or Qualified Staff working under a qualified faculty member. ENACT Qualified Faculty, herein defined as faculty appointees at the participating ENACT Network Sites who are

  o 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

  o Either primarily appointed by, contractually related to, or on the medical staff of, or maintain a significant relationship with a participating ENACT Network Site or partner institution.

- Faculty from outside of the ENACT Network who wish to access data for research purposes must collaborate with a discipline appropriate Qualified Faculty member from one or more of the participating ENACT Network Sites.

- Qualified Staff who wish to have access to the network must be approved by ENACT Qualified Faculty.

- ENACT Qualified Faculty are responsible for all queries conducted by their approved qualified staff.

- Sample sizes will be obfuscated +/- 10 and rounded to the nearest 5, and sizes smaller than 10 will not be returned in order to prevent inadvertent identification of the sampled patients. This is an inherent feature of the SHRINE software.

- All appropriate institutional, state and federal policies, laws and regulations governing specially protected information will apply and will be enforced by the site where necessary.

**13. Standard Operating Procedures for ENACT and ENACT Sites**

There are multiple Standard Operating Procedures (SOPs) developed for the ENACT Network. Detailed information defining each SOP can be found in the ENACT Standard Operating Procedures V7.0 document.

**14. Conclusion**

The contents of this document will continuously be reviewed and updated as appropriate to encompass the changes and growth of the ENACT Network. Oversight and revisions are the responsibility of the ENACT Governance Work Group with final sign off by the ENACT Executive Committee.
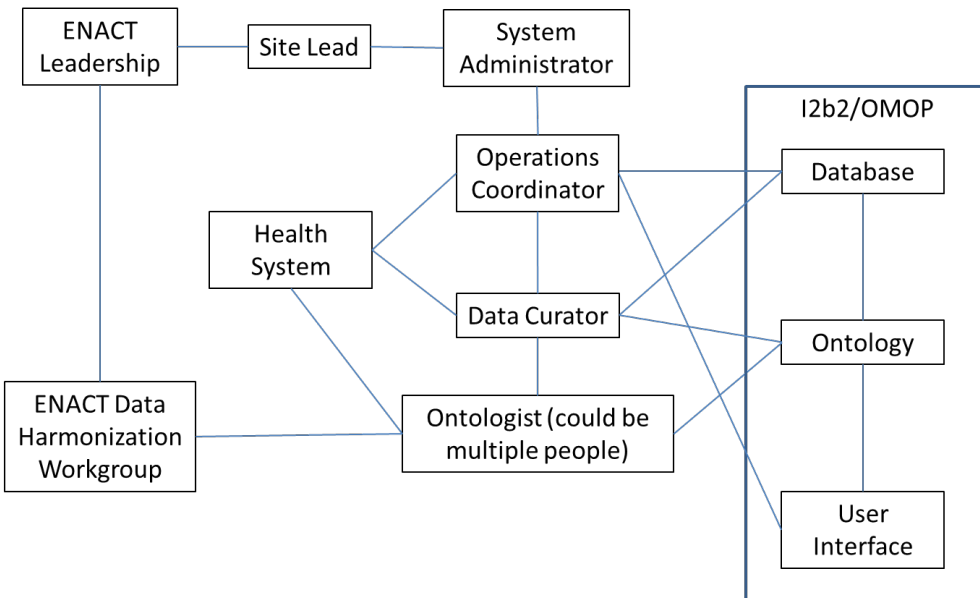
## APPENDIX A

**ENACT Functions (*suggested, not required for participation in ENACT*)**

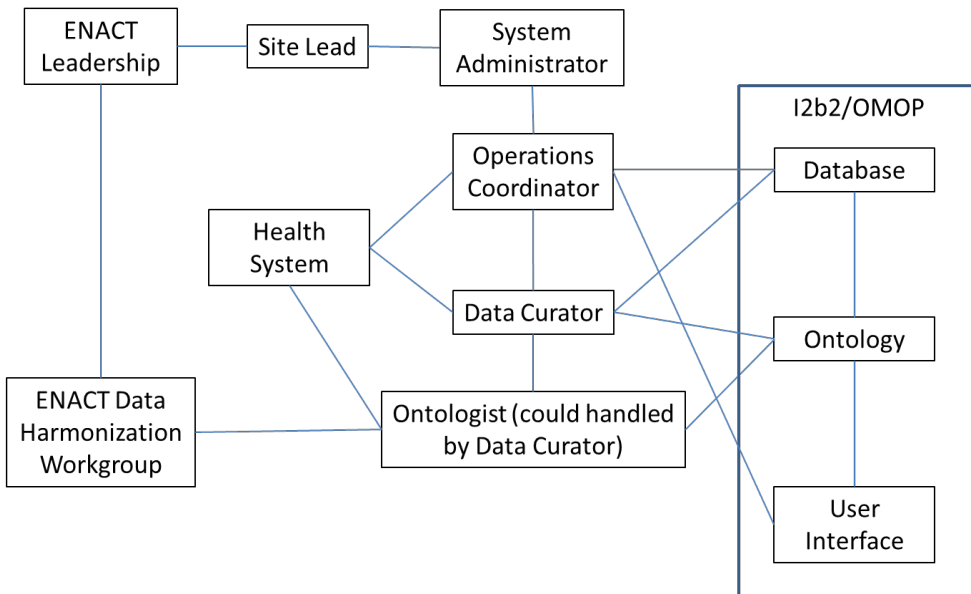| Function | Responsibilities | Recommended Qualifications | Interaction Points | Duration of Role |
|---|---|---|---|---|
| **Site Lead** | Overall responsibility for site's activities in the ENACT network. | Institutional approval to be PI of subcontract. | ENACT Leadership. Oversees other roles. | Throughout project. |
| **System Administrator (application and infrastructure)** | **Application**<br>-Installation, implementation, maintenance of SHRINE and i2b2/OMOP systems<br>-Ability to provide deep level troubleshooting when needed<br>-Communicate with project sponsors, leadership, other local technical resources, end users on an as needed basis<br>**Infrastructure**<br>-Well rounded knowledge of servers, operating systems<br>-Familiarity with local (institutional) network operations, local IT policy, and experience with top-tier infrastructure and front-line service support | **Basic Qualifications**<br>-BA / BS in Computer Science / Engineering or related field<br>-Have at least 3+ years of system / network administration<br>**Additional Qualifications**<br>-Knowledge of Linux / Unix systems<br>-Scripting (bash, python, etc.)<br>-Database Administration (SQL, Postgres, Oracle, etc.)<br>-Networking skills (firewalls, proxies, certificate / encryption methods, port configuration)<br>-Web services (Apache Tomcat, Axis, WildFly, JDK) | -Works closely with SOC, other local technology contacts | -Focused effort in the early stages of joining the ENACT Network to implement i2b2 software, SHRINE<br>-Continued role in regular health and maintenance once on ENACT production network |
| **Site Operations Coordinator (SOC)** | -Institution's main, day-to-day, point of contact for network operations, administration<br>-Report status of routine network activities (software upgrades, data refresh activities)<br>-Assist in compiling audit information for Data Steward<br>-Assist in creating and deactivating users in accordance with local and network policy<br>-Serve as point of contact for local end users | -Familiarity with project management concepts<br>-Experience with Atlassian JIRA<br>-Attention to detail<br>-Good communication skills | -Works closely with System Administrator, Data Steward, Research Data Curator | -Necessary for duration of ENACT network participation |
| **Research Data Curator** | -Ensuring accuracy and compliance of research data available to the ENACT network<br>-Perform data mappings as needed<br>-Provide feedback on local data availability to assist in development of the ENACT ontology<br>-Respond / troubleshoot data anomalies discovered on the network | -Prior experience with i2b2/OMOP, SHRINE, ontologies, ETL and data mapping<br>-Have at least 2+ years of database administration<br>-Knowledge of scripting methods (SQL, Python, etc.)<br>-Familiarity with local EHR and research data handling processes<br>-Familiarity with scientific research topics highly valuable | -Works closely with SOC | -Necessary for duration of ENACT network participation |

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| **Data Steward (User Liaison)** | -Serve as contact for users (researchers) with questions or problems using the network<br>-Monitors research network behavior per the Terms of Query Access<br>-Ensures appropriate use of the network<br>-Serves as point of contact for other institution Data Stewards, as necessary | -Experience with biomedical research topics<br>-Bachelor's or Master's degree in a related field is desired<br>-Good communication skills<br>-Attention to detail | -Works closely with the System Administrator and/or Site Operations Coordinator | -Onboarded prior to local dissemination of ENACT to end users<br>-Regular role throughout participation in ENACT network |
| **Dissemination Lead** | -Conducts ENACT related communication and outreach activities to local CTSA investigators | -Good communication skills<br>-Ability to facilitate rollout of ENACT to local end users | -ENACT Dissemination & Evaluation Work Group | -Immediately following the technical implementation of ENACT, if not before, and continue through participation in the network |
| **Ontologist (if available)** | -Mapping local terminologies to standards<br>-Collaboration on ENACT ontology development and participation in the ENACT Data Harmonization Work Group | -Understanding of ontology principles<br>-Patient care and/or health systems domain knowledge | -Research Data Coordinator<br>-ENACT Data Harmonization Workgroup | -Immediate and for duration of project<br>-This is an optional role; mapping tasks could be carried initially as a team effort (with extra resources) and then handled by research data curator in maintenance mode |

**ENACT Functions Interaction Points**

**Onboarding**

**Maintenance**



**System Use**