

TCRN STANDARD OPERATING PROCEDURE

TITLE: Joining of New Member Institutions

NUMBER: SOP-8 Version: 4

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APPROVED BY:

Executive Committee

DATE WRITTEN:

July 30, 2015

ISSUE DATE: Sept 30, 2015

1.0 PURPOSE:

The TIES Cancer Research Network (TCRN) provides access to large cohorts of data and samples to researchers at member institutions. This policy outlines the criteria that candidate member institutions must meet to be eligible for participation in the TCRN, and the application process that applicants from the institutions must follow.

2.0 REVISION HISTORY:

Date	Rev. No.	Modification
7/30/15	1	Drafted by Julia Corrigan
8/12/15	2	Rebecca Crowley Jacobson
8/17/15	3	Rebecca Crowley Jacobson and Julia Corrigan
9/30/15	4	Additional Edits for clarity by Julia Corrigan
9/28/15	4	Approved by the Policy and Process Subcommittee
9/30/15	4	Approved by the Executive Committee

3.0 PERSONS AFFECTED:

The applicant(s) representing the candidate institution, the TCRN Executive Committee, and the TCRN Policies and Processes Subcommittee are affected by this policy.

4.0 POLICY:

It is the policy of the TCRN that institutions that wish to join the TCRN meet specific criteria. These criteria determine that the candidate institution has the resources, preparation, and security infrastructure to contribute to the TCRN and ensure regulatory compliance. Applicants must follow the application and interview process described in this policy in order to demonstrate they meet these criteria.

These criteria are minimum requirements only. The TCRN Executive Committee may use its discretion in making final decisions.

5.0 DEFINITIONS:

TIES – The Text Information Extraction System (TIES) is a computer-based system that establishes a repository of natural language processing (NLP) coded, de-identified pathology reports for the purpose of identifying cohorts and cases associated with formalin fixed paraffin embedded materials, frozen tissues, or other research resources.

TCRN – The TIES Cancer Research Network (TCRN) represents all member institutions that have signed the TCRN Network Agreement, with the intent of supporting collaboration (data, tissue, or data and tissue) across institutions that have deployed the TIES system.

Applicant – The applicant is the individual at a non-member institution who initiates the process for joining their institution to the TCRN and who represents that institution throughout the application process.

Candidate Institution – The candidate institution is the non-member institution that is being considered for membership in the TCRN.

TCRN Network Agreement – The Network Agreement is the document that is the regulatory foundation of the TCRN. Representatives from each site agree to sign and follow the terms put forth in the Network Agreement.

Standard Operating Procedures – Standard Operating Procedures (SOPs) are policies developed by TCRN representatives that all TCRN member institutions must follow.

TIES Regulatory Administrator – The Regulatory Administrator approves studies, drafts regulations, and communicates with other TCRN institutions through the TCRN Policies and Procedures Subcommittee.

TIES IT Administrator – The IT Administrator verifies eligibility of local users and creates user accounts and studies.

TCRN Approval Committee – Each member site has a TCRN Approval Committee. The Approval Committees determine how external users gain access to the local institution's data and tissue.

TCRN Executive Committee – The TCRN Executive Committee is comprised of the TCRN principle investigator (PI), member site principle investigators, and a representative from the TCRN Policies and Processes Subcommittee. It is responsible for approving Standard Operating Procedures (SOPs), promoting use of the TCRN, and approving the addition of new TCRN members.

TCRN Policies and Processes Subcommittee – The TCRN Policies and Processes Subcommittee is comprised of representatives from each member institution who are

responsible for providing data and tissue access to local investigators. It is responsible for drafting policies, procedures, and recommendations for the Executive Committee, and serves as a forum for communication between member sites.

6.0 RESPONSIBILITIES:

The **applicant** must follow the process outlined below in order to apply for membership in the TCRN. They must also represent the **candidate institution** accurately.

The **TCRN Policies and Processes Subcommittee** must follow the process outlined below to provide feedback to and aid the applicant during the application process.

The **TCRN Executive Committee** must follow the processes outlined below and issue the final decision on the joining of the candidate institution to the TCRN.

7.0 CRITERIA FOR JOINING THE TCRN

Basic Criteria: The institutions that are candidates for membership in the TCRN must meet the basic criteria listed below, which fall into three categories: **security, resources, and preparation.**

1. *Security*

- A. Candidate institutions must meet the minimum security standards set forth in Exhibit B of the Network Agreement:
 1. All TIES servers must be secured in a manner as approved by institutional information Security Officers, that includes at least:
 - a. Servers must be located behind a local firewall and in a secure data center.
 - b. Physical access to TIES servers must be limited to approved systems administrators.
 - c. Logical access to TIES must use the standard of least privilege required.
 - d. Critical security patches for both OS and applications must be applied within 45 days.
 - e. Services that are not required for the use of the application must be disabled.
 - f. Servers should be solely dedicated to their role/function as it relates to TIES.
 - g. Servers should be segmented on the network by role/function.
 - h. Server and application logging must be enabled, said logs protected from alteration.
 - i. Use an operating system software that is in a currently supported state.
 - j. Servers should undergo at least annual vulnerability scans.
 2. All data hosted in the TIES research data store will be de-identified to the HIPAA safe harbor standard, and will meet the requirements for validation outlined in the **TCRN Validation of De-identification Quality SOP.**
 3. TCRN users originating from the candidate institution must be vetted by the candidate institution to verify employment and authorized status.
 - a. Institution-specific user login credentials shall never leave an individual site.

4. All workstations connecting to a TIES server must:
 - a. Use operating system software that is in a currently supported state.
 - b. Be running a mainstream and up-to-date version of Anti-Virus/Malware.
5. In the event of a security incident, real or perceived, institutions must follow the **TCRN Incident Reporting Standard Operating Procedure**.

2. Resources

- A. Applicants must provide evidence that their candidate institutions possess sufficient resources for membership in the TCRN, including the following:
 1. Sufficient medical records:
 - a. Must have at least five years of electronic pathology reports available.
 - b. Must have at least 100,000 electronic pathology reports potentially available at the time that their node becomes available to the network.
 2. Access to tissue samples:
 - a. Must document the types of biomaterials that may be available to collaborators through the TCRN. This does not require any guarantees of availability.
 - b. Must have a system of obtaining and providing tissue and data to external researchers.
 - c. Must demonstrate prior experience with biospecimen sharing across institutions in some capacity.

3. Preparation

- A. Applicants must provide evidence that their candidate institutions are sufficiently prepared for membership in the TCRN, including the following:
 1. Deployment:
 - a. Must have had TIES deployed at the institution for a minimum of 2 months.
 - b. Must have a TIES deployment IRB protocol that will cover use of TIES at the institution, which must include a determination that use of TIES and TCRN are considered “no human subjects” research.
 2. Preparation of resources:
 - a. Must have at least 50,000 pathology reports loaded into TIES.
 - b. Must have at least 25,000 of the loaded pathology reports de-identified and coded.
 3. Policies:
 - a. Must have determined individuals who will fill necessary roles in the TCRN:
 - i. Regulatory Administrator
 - ii. IT Administrator
 - iii. Quality Assurance Manager
 - iv. TCRN Approval Committee
 - b. Must be familiar with and agree to comply with the Network Agreement and the TCRN Standard Operating Procedures. Signing of the Network Agreement by your institutional official is a requirement for joining the network.

8.0 PROCESS OF JOINING THE TCRN

Application Process: The applicant representing a candidate institution that meets the basic criteria must follow the process outlined below in order to apply for membership in the TCRN. The decision to admit the candidate institution to the TCRN will be made by the TCRN Executive Committee.

All links and forms needed for the application process are available at <http://ties.dbmi.pitt.edu/>

1. All potential applicants must contact Rebecca Jacobson at rebeccaj@pitt.edu to express their interest in joining the TCRN. This discussion will serve as an opportunity for the applicant to learn more about the TCRN. The applicant will then need to request a TIES Production Node License at <http://ties.dbmi.pitt.edu/request-a-license>. After this, the applicant will be invited to complete the Application to Join the TIES Cancer Research Network (see Appendix).
2. TIES Personnel will submit the completed Application to Join the TIES Cancer Research Network to the TCRN Policies and Procedures Subcommittee.
 - a. Applicants are strongly encouraged to provide documentation that supports the application.
3. The TCRN Policies and Procedures Subcommittee will review the application and determine whether the candidate institution meets the basic criteria outlined above. If it believes that the application is incomplete or needs improvement, the committee will help the applicant prepare the document.
4. The TCRN Executive Committee will review the application and determine whether the candidate institution meets the criteria for joining the TCRN.
 - a. The TCRN Executive Committee will meet with the applicant if they believe that the institution needs guidance in meeting the above requirements.
5. The applicant must make a presentation to all TCRN committee members. This presentation should address the following topics:
 - a. Why the institution wants to join the TCRN
 - b. The types and number of potential users from the candidate institution
 - c. The biomaterial resources that are available to internal and external researchers, and experience in previous biospecimen sharing
 - d. The unique attributes of the institution that will contribute to the TCRN
 - e. The plan for de-identifying electronic pathology reports
 - f. The plan for sharing biomaterials and data external to TIES with TCRN member institutions
 - g. The strategy for disseminating TIES and the TCRN locally
 - h. The plan for engaging and training potential users at the institution.
6. The TCRN Executive Committee will issue its decision whether to allow the candidate institution to join the TCRN.
 - a. Candidate institutions that are not accepted into the TCRN will be notified with reasons the requests were denied. Applicants are encouraged to apply again when they have addressed these concerns.

9.0 APPENDICES:

Application to join the TIES Cancer Research Network (TCRN)

Institution _____

Adopter of TCRN _____

Title _____

School/Department _____

Email _____ Phone _____

Preparation

Do you have an installation of TIES at your institution? Yes No

How long have you been using TIES at your institution? _____

Have you started to de-identify your medical record information? Yes No

What percentage of data have you de-identified? _____%

Are there investigators at your institution who are interested in using TCRN for a pilot research project?
 Yes No

Have you assigned personnel for the following TIES/TCRN duties? List their names if applicable.

Regulatory Administrator Yes _____ No

IT Administrator Yes _____ No

Quality Assurance Manager Yes _____ No

TCRN Approval Committee members Yes _____ No

Are any of the following trained? Please list the percentage:

Investigators Yes _____% No

Quality Assurance Personnel Yes _____% No

Administrators Yes _____% No

Do you have the resources to train individuals in the following ways?

Workshops Yes No

Demonstrations Yes No

Trainings Yes No

Other _____

Resources

List the approximate amount of electronic pathology reports you have access to at your institution:

Do you have access to any additional resources?

Cancer Registry Yes No

Biobank Yes No

Honest brokers Yes No

Other _____

What types of tissue/materials do you have available? List their approximate quantities:

FFPE Yes _____ No

Frozen Tissue Yes _____ No

TMA Yes _____ No

Other _____

Tissue is stored: on site off site both on and off site

Who controls access to materials? _____

What is the approximate number of potential investigators or users at your institution?

What types of additional patient data are accessible?

Security

You must meet the minimum security standards outlined in **Exhibit B** of the **Network Agreement**:

- Servers must be located behind a local firewall and in a secure data center.
- Physical access to TIES servers must be limited to approved systems administrators.
- Logical access to TIES must use the standard of least privilege required.
- Critical security patches for both OS and applications must be applied within 45 days.
- Services that are not required for the use of the application must be disabled.
- Servers should be solely dedicated to their role/function as it relates to TIES.
- Servers should be segmented on the network by role/function.
- Server and application logging must be enabled, said logs protected from alteration.
- Use an operating system software that is in a currently supported state.
- Servers should undergo at least annual vulnerability scans.

What is your plan for de-identifying data to TCRN standards? (See **Validation of De-Identification Quality Standard Operating Procedure**)

Does your institution have any research collaborations with the existing TCRN members? If yes, briefly describe.

Georgia Regents University Roswell Park Cancer Institute Penn Pitt

Please describe any unique characteristics that your institution can contribute to the TCRN.

According to the terms of the TCRN Network Agreement, all applicants to the TCRN must do the following:

Sign the Network Agreement;

Sign the Instrument of Adherence;

Comply with all Standard Operating Procedures;

Meet all minimum security standards enumerated in Exhibit B of the Network Agreement;

Provide a copy of the IRB approval letter for participation in the TCRN or the determination of “no human subjects” research; and

De-identify medical record information in accordance with the Validation of De-Identification Quality Standard Operating Procedure.

REFERENCES:

None