

## TCRN STANDARD OPERATING PROCEDURE

**TITLE: Auditing of TCRN Users and Searches**

**NUMBER: SOP-2      Version: 11**

**PREPARED BY:**

**JoEllen Weaver, University of Pennsylvania Tissue Bank**

**APPROVED BY:**

**TCRN Executive Committee**

**DATE WRITTEN:**

**March 9, 2015**

**ISSUE DATE:**

**March 10, 2015**

### **1.0 PURPOSE:**

The TIES Cancer Research Network (TCRN) provides access to large cohorts of data and samples. As part of the responsibilities of good governance, periodic audits of TCRN users will be conducted.

### **2.0 REVISION HISTORY:**

Date	Rev. No.	Modification
6/23/14	1	Original document drafted by JoEllen Weaver
7/1/14	2	Reformatted by Rebecca Crowley Jacobson
7/3/14	3	Revisions to text by JoEllen Weaver
9/7/14	4	Revisions to text by Rebecca Crowley Jacobson
9/16/14	5	Revisions to text by Rebecca Crowley Jacobson to include comments from Subcommittee made at 9/8/14 meeting
9/17/14	6	Revisions to text by JoEllen Weaver and minor cleanups by RCJ
10/5/14	7	Revisions to text by Rebecca Crowley Jacobson to incorporate comments from Subcommittee made at 9/22/14 meeting
2/24/15	8	Modifications by Julia Corrigan and Liz Legowski to reflect updated Network Agreement
3/5/15	9	Modifications for clarity by Rebecca Crowley Jacobson
3/5/15	10	Modifications by Julia Corrigan
3/9/15	11	Minor modifications by Liz Legowski

### **3.0 PERSONS AFFECTED:**

The **TIES Administrator** and **TCRN Quality Assurance Personnel** at member institutions participating in TCRN.

### **4.0 POLICY:**

It is the policy of the TCRN that each TCRN member institution will conduct periodic audits of users. Audits will include (1) a determination that the current users of the system at a given member institution are valid users of the TCRN, (2) a determination that searches of external institutions conducted by valid users are within the scope of their approved use of the system, and (3) a determination of how TCRN is being used and the degree to which it provides value.

## 5.0 DEFINITIONS:

**TIES** – TIES (Text Information Extraction System) 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.

**TCRN User** – A TCRN user is a TIES user who has one or more TCRN studies allowing use of de-identified data from another TCRN institution (in addition to their own). Users must be faculty, or trainees or staff under the direction of faculty at a TCRN institution.

**Valid User** – A user who has legitimate access to TIES given local policies, and who has been deemed an Authorized User by one or more TCRN member sites.

**Approved Use** – Describes range of activities approved by a given organization for a TCRN user as described in the TCRN Network Agreement, IRB protocol (if applicable), and Materials Transfer Agreement (if applicable).

**TCRN Study** – A TCRN study is a study within TIES with access to de-identified data from another TCRN institution (in addition to the user's own institution). Searching in TCRN requires that the user specify which study they are conducting their search under.

## 6.0 RESPONSIBILITIES:

The **TIES Administrator** will conduct audits of users within their own institution every 6 months to determine that all TCRN users are **valid users** of the system.

The **local data steward** will serve as the TCRN Quality Assurance Manager and will conduct query audits against their TIES node (from internal and external users) every 12 months to determine that usage of TIES is within the scope of **approved use** of the system.

The **TIES Administrator** will obtain information from approved users regarding the usage of TCRN.

## 7.0 PROCEDURES:

1. The **TIES Administrator** or their proxy at each member institution will conduct an **audit of all user accounts associated with investigators from their own institutions every 6 months** in order to ensure that all TCRN users at their institution are valid users. Users will only be considered valid if:
  - A. The investigator or their designee is still an employee of the institution with a current valid network ID for their institution.
  - B. Related IRB approvals (if applicable) remain valid.
  - C. Related MTA approvals (if applicable) remain valid.

**Steps to be taken based on these findings:**

- i. Any user who does not meet requirement (A) will be de-credentialed immediately by the local TIES Administrator.
  - ii. Any user who does not meet requirements (B) or (C) will be prevented from running new and previously saved queries on that specific TCRN study until they are in compliance.
2. The **TCRN Quality Assurance Manager** or their proxy will conduct an **audit of all user queries against their TIES node (internal and external users) every 12 months** in order to:
  - A. Identify cases where the search was incongruous with the topic of research as described in the research description. For example, a search for cases of hepatocellular carcinoma under a study describing use of TIES for identification of patients with dysplastic nevi would be considered incongruous.
  - B. Identify queries that suggest that the user was attempting to re-identify the data. Queries that suggest an attempt to re-identify include use of free text fields for names, dates, occupations, etc. Miscreants will be referred to the Institutional Privacy Officer for further adjudication.

The audit will occur at the end of the funding year. Auditor will maintain a record of all findings, including reasons for not pursuing a particular anomaly.

**Steps to be taken based on these findings:**

- i. For TCRN users who have conducted searches that are not within the scope of the topic described in the research description, the TCRN Quality Assurance (QA) Manager will contact the TCRN user (if a local user) or TIES Administrator associated with the user (if an external user) and request amendment to their current TCRN study, addition of a new TCRN study, or instructions to search under the relevant TCRN study. If the TCRN user does not comply, the TCRN QA manager will terminate access to the TCRN study and follow the procedure described in the Incident Handling Policy.
- ii. For TCRN users who have conducted searches where there is evidence that they have attempted to re-identify cases, the TCRN QA manager will disable access on all TCRN studies and follow the procedure described in the **Incident Handling** Standard Operating Procedure.

Continued access to studies restricted to their own institutional TIES node will be a local regulatory decision.

**Note 1:** This auditing policy is not intended to apply to local review of IRB or MTA as needed to supply data or tissue.

**Note 2:** It is the intent of this policy to provide the auditor with some discretion to identify concerning cases that may not be enumerated above. In these cases, the auditor is encouraged to discuss concerns directly with their local regulatory and compliance staff and with the TCRN Executive Committee.

3. The **TIES Administrator** at each member institution (or their proxy) will contact all TCRN users via email during the yearly search audit for the purposes of updating statistics on TCRN usage. Users will be asked to provide information regarding resulting publications, presentations, pilot data, grant

submissions, and negative analysis results (see Appendix A). During this process, the TIES Administrator should:

- A. Confirm that users have properly acknowledged use of the TIES system and TCRN in their manuscripts.
- B. Validate that the samples were used appropriately and as indicated on the user's initial proposal.

**Steps to be taken based on these findings:**

- i. Local TIES administrator tracks usage and acknowledgement of TCRN and TIES resources.
- ii. Local TIES administrator contributes list of all usage for TCRN progress reports annually.

**8.0 APPENDICES:**

- A. Example Email Update Request for Users

**Review Notes:**

**Annual Review**

\_\_\_\_\_ **Comments**

\_\_\_\_\_ **Benefit Validation**

\_\_\_\_\_ **Challenges/Issues**

**REFERENCES:**

None

**Appendix A Example Email for Usage Survey**

Dear Sir/Madam,

As part of our annual audit, please report your usage of TIES Cancer Research Network (TCRN). This update of usage is essential to document the utility of TCRN. We greatly appreciate your prompt reply to this email.

For the study titled "<The full title of the distribution protocol>," you are registered as a "<role>." Has this study been completed?  Yes  No

If so, have you published, presented, applied for grant funding, completed pilot data, or otherwise utilized the resulting analysis?  Yes  No

Please provide the citation of any publications and presentations. For grant applications, please provide a description of the grant. For pilot data, please describe the future use of this pilot study.

---

---

---

---

If you have not yet completed this study, please provide an estimate of the completion date and a description of your intended release of results.

Estimated completion date \_\_\_\_\_

Description of intended release of results:

---

---

Based on your "Researcher" account permissions <username>, have you published, presented, applied for grant funding, completed pilot data, or otherwise utilized the resulting analysis?

Yes  No

Please provide the citation of any publications and presentations. For grant applications, please provide a description of the grant. For pilot data, please describe the future use of this pilot study.

---

---

Please attach a current copy of your C.V.

If possible, please highlight any listing on your C.V. that relates to your TIES/TCRN access.

To access the TIES application directly you may use the following link:

<http://ties.upmc.com>

Please contact the TIES Administration Team at 215-870-5667 if you have any questions or concerns.

Thanks

Penn TIES Administration Team