TIES Cancer Research Network Data and Tissue Project IRB Guidelines

This document is intended for the use of research teams that are submitting an IRB protocol for a study needing de-identified data (reports) and tissue from the TIES Cancer Research Network (TCRN). The document lists the questions in the OSIRIS application and exempt form, and provides sample answers that accurately reflect the nature of the data that is available from TCRN. (OSIRIS is available at https://www.osiris.pitt.edu/osiris/).

Questions from OSIRIS are shown in **Bolded** text, and example responses are shown below them in *italics.* Selections from drop-down lists are identified with red asterisks (*). We use double angle brackets (for example << information>>) to denote project-specific information that the investigator must insert. Additional instructions are in this format.

IMPORTANT NOTES:

1. **Researchers who wish to obtain only de-identified data from TCRN (but no tissue) should follow the guidelines for projects needing de-identified data.**

2. **Answers provided are typical answers for TCRN studies and only reflect use of TCRN. Depending on the nature of your study, you may need to answer some questions differently than these guidelines suggest. For some questions, additional study-specific information needs to be included.**

OSIRIS Triage Section

T1.0 Select the type of application:
* New Research Study

T2.0 Is the proposed research study limited to the inclusion of deceased individuals?
* No

T2.1 Are any research activities being conducted at the VA Pittsburgh Healthcare System or with VA funds?
Answer Yes only if you are conducting research using VA funds. There are no VA records in TIES TCRN.

T3.0 What is the anticipated risk to the research participants?
* Minimal Risk

T3.1 Why do you feel that all aspects of this research study, including screening and follow-up, involve no more than minimal risk to the research subjects?
* There will be no human subjects. This study will use de-identified preexisting data extracted from TIES Cancer Research Network (TCRN), a database of de-identified pathology reports. At no point will the researchers have the option to view identified data.

T4.0 Does the proposed research study qualify for "exempt" IRB review status or for a "no human subject research" determination?
* Yes

E1.0 Which category applies to your proposed research study?
* Request for a determination that planned activity is not research or does not involve human subjects

E2.0 Upload the exempt category form(s)
Fill out the exempt form for TCRN protocols that is available for download at http://ties.dbmi.pitt.edu/tcrn-materials. See the end of this document for an example of the TCRN exempt form.

E3.0 I certify that any member of my research team accessing, reviewing and/or recording information from medical records have completed HIPAA Researchers Privacy Requirements (Formerly RPF Module 6) training. The HIPAA certificates must be available for review if audited but do not need to be uploaded into this OSIRIS application. NOTE: If medical record information is NOT being accessed, answer ' Yes' to this question.
* Yes

E4.0 Have you obtained the following clearances from all research staff who may interact with children?
* N/A

If Not Applicable, please explain:
* No interactions with children will occur. The study will only use data and specimens acquired through TCRN.

OSIRIS Cover Sheet Section

CS2.0 Title of Research Study

CS2.0.1
Leave this question blank. You do not need to request specific approval letter wording.

CS2.1 Research Protocol Abstract:
<<Describe background and significance as appropriate, and include text like the following, modifying it as appropriate to reflect the nature of your study>>

* *METHODS: Collection of de-identified reports and specimens will be through TIES Cancer Research Network (TCRN), a database of de-identified pathology reports from the UPMC hospitals and other network sites. Cases of <<disease, finding, or other criteria>> from <<list the TCRN sites you will be querying data from>> will be queried. <<Describe what you will do with the cases; for example, "The number of cases of each specific form of <disease> will be tallied and sorted by the demographic information (age, sex, race)." Etc>>*

CS3.0 – CS3.9

CS4.0 List of Co-investigators:
Include any co-investigators from Pitt/UPMC. Do not list collaborators from other TCRN sites.

CS5.0-CS6.3

CS11.0 Is this research study supported in whole or in part by industry? This includes the provision of products (drugs or devices).
Answer this question appropriately

Is this a multi-centered study?
* *No*

CS15.0 Indicate the sites (i.e., institutions or facilities) where research interventions or interactions will be performed and/or private information will be obtained:
Select only the site where you are located – for example, the University of Pittsburgh. Do not select all of the hospitals that are represented in the TIES database. Do not mention other TCRN sites you will be obtaining data and/or tissue from.

CS15.1 Have you verified that all members of the research team have the appropriate expertise, credentials, and if applicable, hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB protocol?
Answer this question appropriately

CS15.2 Describe the availability of resources and the adequacy of the facilities to conduct this study:
* Data and specimens will be acquired through TCRN. TCRN includes reports that have been de-identified with De-ID and can be accessed from any computer with an internet connection and the latest version of Java installed. Honest brokers must be behind their institutional firewall to access identified data in TCRN. The TCRN team will provide support and resources to access the data.

CS16.0 Special Research Subject Populations: Check the categories that apply to this research
study.
* None

CS17.0 Does your research involve the experimental use of any type of human stem cell?
Answer this question appropriately

OSIRIS Section 1 – Study Objective, Specific Aims, Background and Significance

Answer this section appropriately

OSIRIS Section 2 – Research Design and Methods

2.14 Will protected health information from a UPMC/Pitt HIPAA covered entity be obtained for research purposes or will research data be placed in the UPMC/Pitt medical record?
*No

2.14.1 Will protected health information from a non-UPMC/Pitt HIPAA covered entity be obtained for research purposes or will research data be placed in the non-UPMC/Pitt medical record?
*No

2.19 Will this research be conducted in (a) a foreign country and/or (b) at a site (e.g., Navajo Nation) where the cultural background of the subject population differs substantially from that of Pittsburgh and its surrounding communities?
*No

OSIRIS Section 6 – Costs and Payments

6.2 Will subjects be compensated in any way for their participation in this research study?
*No

OSIRIS Section 7 - Qualifications of Investigators and Sources of Research Study

Answer this section appropriately

Request for Determination that Project does not involve Human Subjects:
TCRN Protocols *ONLY*

Title of Study:

Name of Investigator:

> **NOTE:** This application requires the use of TCRN-approved honest brokers. Any information provided to the researcher will include a unique code provided by the honest broker, but no personal identifiers will be provided. That is, all data returned to investigators will meet either HIPAA 'safe harbor' or 'limited data set' criteria.

1. **What is being studied? (Select one):**

   ☐   Only medical record information will be studied.

   ☒   Specimens, as well as medical record information, will likely be studied.

2. **Will de-identified medical record information from outside the TIES system be sought?**

   Y ☐; N ☐

   a. If yes, will that information include dates and certain geographic information? Y ☐; N ☐

   b. If yes, justify your need for this information (i.e., request for a limited data set):

3. **If specimens are obtained, address the following questions** (not applicable ☐):

   a. If possible, identify the bank/biorepository by name (e.g., Health Sciences Tissue Bank):

   b. If paraffin tissue blocks from UPMC will be studied, provide the name of the pathologist who has reviewed this project and approved the allocation of tissue:

   Name: ; e-mail:

4. **Will data and/or specimens be sent to another institution?** Y ☐; N ☐

   a. If yes, have you consulted with the University of Pittsburgh Office of Research or the TCRN Executive Committee or Staff regarding any necessary agreements? Y ☐; N ☐. If not, why?

5. **Does your study meet BOTH of the following requirements?** Y ☐; N ☐

a. No member of my research team has interacted, for research purposes, with the individuals whose information and specimens will be studied in this new set of analyses

b. No identifiable private information will be reviewed or recorded by me or members of my research team

6. **Do you certify that you will follow the policies and procedures of the TCRN and protect the integrity of the information you receive from UPMC/Pitt?** Y ☐; N☐

Comment [EAL7]: Answer this question appropriately for your study.