

**Request for Determination of Exempt Status, or No Human Subjects Designation:
Medical Record Review with Certified Honest Broker**

Note: This application requires the use of an Honest Broker; neither the investigator nor any member of this research team can have access to (i.e., review or record) patients' identifiable medical record information!

If specimens will be used, do not use this form; use the Research with Biological Specimens form.

Title of Study: Deployment of TIES Text Information Extraction System

A. Will any information from this project be submitted to the FDA or held for inspection by the FDA? No Yes If Yes, **STOP** and contact the IRB at askirb@pitt.edu.

B. Specify the identity of the UPMC- and IRB-approved Honest Broker System/Process that will be used in obtaining the medical record information for this research study:

- 1. Honest Broker System or Process:** University of Pittsburgh Department of Biomedical Informatics (DBMI), UPMC Department of Pathology, Health Sciences Tissue Bank (HSTB), Department of Otolaryngology of the Eye and Ear Institute, Magee Women's Hospital of UPMC Gynecologic Oncology Division of the Department of Obstetrics, Gynecology, and Reproductive Sciences and Women's Health, UPMC ISD/Pathology Informatics, UPMC ISD/Oncology Informatics and the UPMC Network Cancer Registry/ UPMC Cancer Centers Registry Information Services (RIS), AND Department of Radiology
- 2. UPMC/IRB Honest Broker Approval Number:** HB015 and HB008
- 3. Name of individual who has agreed to provide Honest Broker service to this project:** LIST KNOWN INDIVIDUAL(S) WHO WILL BE HONEST BROKERS IN TIES. Additionally, any honest broker on a UPMC- and IRB-approved honest broker system can be a TIES honest broker.
- 4. An "Honest Broker Assurance Form" [copy attached to this application] must be completed by the investigator, signed by the honest broker, and uploaded (OSIRIS question E 2.0) and submitted with this application. This IRB submission cannot be processed without the honest broker's signature.**

C. How (i.e., in what format) will medical record information be provided to the investigators of this research study?

➤ Information about the HIPAA requirement: <http://www.irb.pitt.edu/hipaa>

- 1. De-identified** (HIPAA "safe harbor"; none of the 18 HIPAA identifiers will be included)
- 2. Limited Data Set** (includes dates and certain geographic information)
 - a. Justify why dates and/or geographical information from medical record are needed to perform this study:**
 - b. Justify the need for each of the requested medical record data elements that are specified under item 1c below:**
 - c. A completed UPMC Data Use Agreement Form must be uploaded into the OSIRIS Supporting Documentation section. Note that this IRB submission cannot be processed without this form, signed by the recipient.**

D. Are all data in existence as of the date the protocol is submitted to the IRB?

No If No, over what time period will these be collected, from what source, and who will collect the data? Data from MARS will be continually added to TIES.

If Yes, List the date range of records to be studied:

E. If data will be sent to another institution, have you consulted with the University of Pittsburgh Office of Research regarding any necessary agreements? <http://www.pitt.edu/~offres/>

No Why not?

Yes **Describe:** Studies using TIES Cancer Research Network (TCRN) will share data across TCRN sites. TCRN studies that involve tissue require a no-human subjects determination from the IRB at each site from which tissue will be obtained, as well as a Uniform Biological Material Transfer Agreement (UBMTA) which will be obtained through the Office of Research. An IRB determination is not needed for TCRN studies only needing access to de-identified reports or data preparatory to research (aggregate data).

N/A Data will not be sent to another institution

F. Are you explicitly requesting a 'no human subjects' determination [46.102(f)]? No Yes

If Yes, does your study meet both of the following requirements? No Yes

1. No member of the research team has interacted, for research purposes, with the individuals whose information will be studied and
2. No identifiable private information can be reviewed or recorded.

Note: If this project is NIH-funded, the grant application must explicitly indicate that at least a component of the study does not involve human subjects. For additional information, e-mail Chris Ryan, IRB Director, at ryancm@upmc.edu.

1. Medical Records to be studied

- a. Specify the inclusion/exclusion criteria for the selection of medical records requested for this study. All pathology and radiology reports within the MARS system are candidates for inclusion. These reports are existing data obtained in routine clinical care.
- b. Specify the approximate number of individual patient medical records that will be requested for the purpose of this study. Currently, TIES contains 4 million pathology reports, and 19 million radiology reports. This number will continue to grow as new reports are added to MARS.
- c. Describe or list the specific data elements that will be extracted from these medical records for the purpose of this study. The data elements will consist of the contents of standard pathology and radiology reports, as well as concept codes used for searching. Reports in TIES are concept coded using a natural language processing pipeline that maps free text to a subset of NCI Metathesaurus. Reports are de-identified using De-ID. Honest brokers will have access to both the de-identified and identified report. Re-identification is needed so that researchers obtaining de-identified data may ultimately be able to obtain de-identified tissue samples, slides, and images. Identified data is stored behind the UPMC firewall on a separate server from the de-

identified data and can only be accessed by users with honest broker privileges.

- d. Identify, if possible, the location of these medical records. Note that UPMC Certified Honest Brokers have access only to records in a UPMC facility. If medical records are outside of UPMC, please describe in detail. Records from all UPMC hospitals can be included in TIES.

2. Data Analysis

- a. How will the medical record information be analyzed to determine that the objectives aims of this study have been met? The objective of the project is to provide access to the application to honest brokers and investigators. Thus, the objectives of the study will be met if the intended users of the system are able to use the system to locate relevant data more effectively than they previously could.

3. Additional Information, Clarification, or Comments for the IRB Reviewer:

Honest Broker MUST complete and sign the Independent “Honest Broker” Assurance Form one copy should be retained by Honest Broker, and one copy should be uploaded into OSIRIS

Independent “Honest Broker” Assurance

By signing below, I agree / certify that:

1. I have reviewed this project with the Principal Investigator and agree to de-identify and, if applicable, to maintain linkage code information for data that will subsequently be accessed by the research team.
2. I will, under no circumstance, provide the PI or any member of the research team with information that would permit the identification of research subjects.
3. I will not intervene or interact with identified human subjects during the conduct of this research project.
4. I will maintain complete confidentiality of research subjects’ private information.

Title of Study: Deployment of TIES Text Information Extraction System

Principal Investigator: Rebecca Crowley Jacobson

Name:	Signature:	Date:
Position:	E-mail:	Phone:
Additional optional comments of Honest Broker:		
Name of Honest Broker System or Process: University of Pittsburgh Department of Biomedical Informatics (DBMI), UPMC Department of Pathology, Health Sciences Tissue Bank (HSTB), Department of Otolaryngology of the Eye and Ear Institute, Magee Womens Hospital of UPMC Gynecologic Oncology Division of the Department of Obstetrics, Gynecology, and Reproductive Sciences and Womens Health UPMC ISD/Pathology Informatics, UPMC ISD/Oncology Informatics and the UPMC Network Cancer Registry/ UPMC Cancer Centers Registry Information Services (RIS) AND Department of Radiology	UPMC/IRB Honest Broker Approval Number: HB015 and HB008	

Please scan or digitize (if needed) file – to include signature and upload into OSIRIS.

