TIES

Text Information Extraction System

TIES Usage Policies

for University of Pittsburgh

Authors

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A. Document History

12/17/2008	New document created by extracting policy section from Implementation plan document. Rebranded document to TIES.
12/18/2008	Policy language modified to be more understandable in relation to new account submission workflows.
01/08/2009	Added requirement that only P.I. can request user accounts. Removed HIPAA certification check item from Research Study Checklist form since the Tissue Bank Manager no longer checks this. It is the P.I.'s responsibility to ensure that the user accounts that are being requested by him/her meet all required IRB guidelines.
01/07/2010	Updated password related software enforced policies. Data only research study requirements are now different than tissue research study requirements.
01/22/2010	Updated account creation policies and flowcharts to include new data only research study.
06/21/2010	Changed the Honest Broker account request policy and added checklist form to appendix. Dropped the :8443 from all TIES website links in the document. Changed HCSC to PISC in sample emails. Added Karma Edwards as author
07/20/2010	For clarification, changed the Honest Broker account request policy on D-14 – 3c. to read "Existing TIES Research Study Name."
09/13/11	For clarification, added D-2. "No Honest Broker can also serve as a Researcher on the same study due to conflict of interest." On D-5 - 4 added "and certifications:" and to D-5 – 4c added "or written summary of the proposed project."
07/23/2012	Changed Help Desk personnel to Casey Holderfield. Changed Training Co-coordinator to Elizabeth Legowski. Changed procedure for training. Users should contact the Help Desk if they need training. Updated checklist forms to have Bioinformatics Core Support Team email address. Changed PISC to Bioinformatics Core Support Team in sample emails.

	Added Elizabeth Legowski as an author
08/11/14	Changed HSTB Team Manager to “Team Leader” and added Vanessa Benkovich. Changed Help Desk personnel to Robert Guzman. Changed Run TIES button to Launch TIES button. Updated password requirements (length greater than 8 characters). Updated Preliminary User account request process to include adding user to Preliminary User Study.

B. TIES Application Access

The TIES website is located at: http://ties.upmc.com. The Launch TIES button on the TIES website can be used to launch the TIES application.

The TIES application can be launched directly using the following link:
http://ties.upmc.com/ties/ties.jnlp

B.1 Online account request forms

The online account request forms will be the used by the users to submit account requests to the HSTB Team Leader.

- Preliminary User Account Request: https://secure.opi.upmc.edu/caties/prelimreq.cfm
- Research Study (Data) Account Request: https://secure.opi.upmc.edu/caties/datareq.cfm
- Research Study (Tissue) Account Request: https://secure.opi.upmc.edu/caties/acctreq.cfm

C. Important Roles and Responsibilities

C.1 Help Desk – Robert Guzman, Jr.

- The Help Desk personnel will be responsible for creation of user accounts and distribution protocols in TIES in accordance with the policies in this document. They will be given Administrator access to TIES to facilitate this.
- The Help Desk personnel will be responsible for providing support for TIES. Any issues that cannot be resolved by them will be routed to the TIES development team.

C.2 Health Sciences Tissue Bank (HSTB) Team Leader – Vanessa Benkovich

- The HSTB Team Leader is responsible for approving account creation and distribution protocol creation for TIES.
- The HSTB Team Leader will be responsible for selecting honest brokers for each distribution protocol in the system. HSTB Team Leader will communicate this to the Help Desk along with the approval for distribution protocol creation.
- The HSTB Team Leader will be given Administrator access to assist in management activities.

C.3 TIES QA Administrator – Melissa Saul

- The QA Administrator is responsible for monitoring the de-identification performance of the TIES data store and report findings to the TIES Repository P.I.

C.4 TIES Repository P.I. – Dr. Rebecca Crowley Jacobson

- The TIES Repository P.I. is responsible for making decisions on whether any changes need to be made to actual TIES software or policies governing its use based on reports from the auditing and quality assurance processes

C.5 HSTB Director – Dr. Rajiv Dhir

- The HSTB Director is responsible for making decisions on whether any changes need to be made to the policies governing the use of TIES based on reports from the auditing process.

C.6 TIES Training Co-coordinator – Elizabeth Legowski

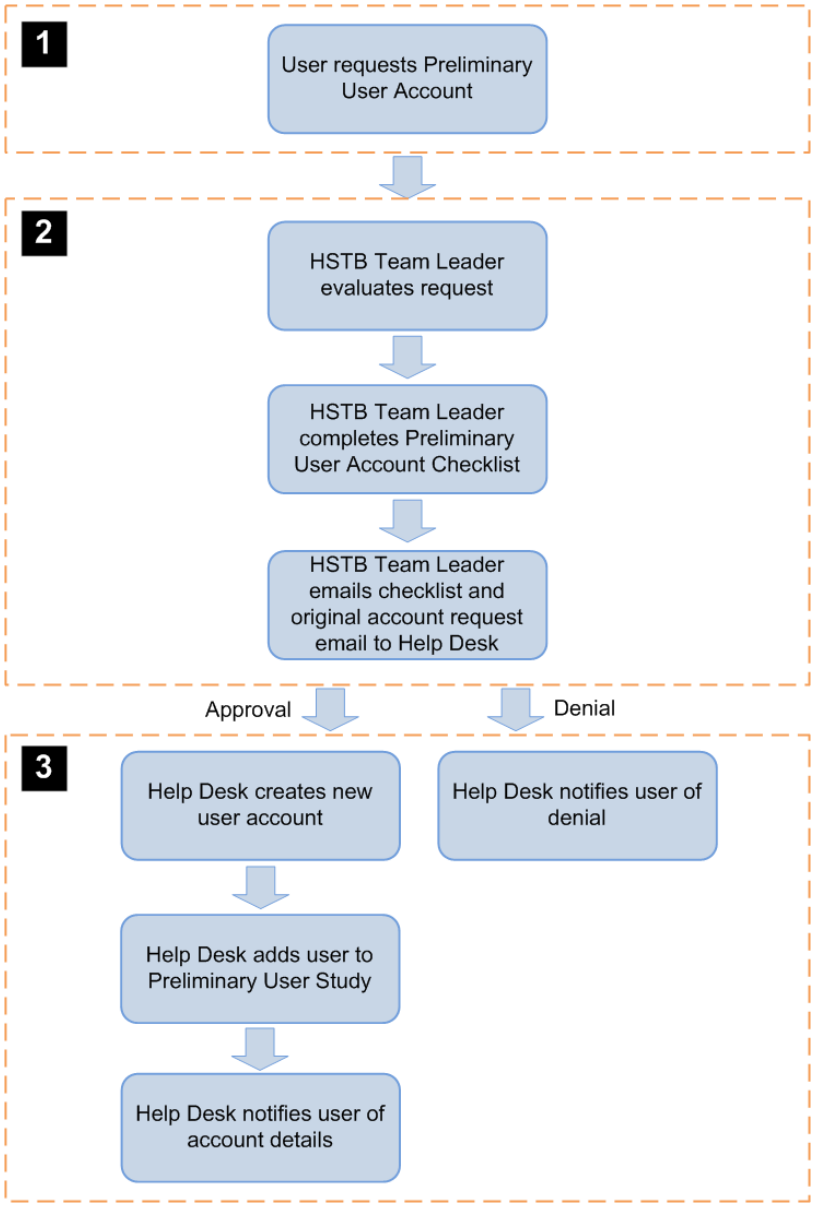
- The training co-coordinator is responsible for running the training sessions. TIES users can request training through the Help Desk.
- The training co-coordinator is responsible for scheduling training sessions at a reasonable interval based on demand.

D. Policies

D.1 Software Enforced Policies

- TIES users can take on four possible roles in the system: Preliminary Users, Researchers, Honest Brokers and Administrators.
- A user can take on multiple roles at the same time.
- The Preliminary User role does not require an IRB approved study protocol to be present.
- A researcher always must access TIES under a valid study/IRB protocol. Once the IRB protocol expires, and the researcher has no other active protocols in the system, his/her access to the system is disabled automatically.
- All Preliminary Users, Research Study Users (Data) and (Tissue) can search real pathology reports from all 18 UPMC hospitals and generate charts and tables from query results. Only Research Study Users (Data) and (Tissue) can see the de-identified pathology report text, and save queries and case sets. Only Research Study Users (Tissue) can order tissue associated with the report.
- Share queries and orders with other researchers on your research study
- Only the P.I. of the study can request tissue/data.
- Honest Brokers are not limited by any IRB protocol and always have access to the system. If they are specifically assigned to a particular study, they will then be able to view and fulfill any orders arising from researchers in that study.
- Only administrators can create new user accounts, assign user roles, and create new research studies in the system.
- By default, all distribution protocols will have an expiry date of 3 years after creation of the protocol in the system.
- Passwords must be changed by the user at first logon.
  Passwords must meet the following criteria:
  - Length greater than 8 characters
  - Contains both lowercase and uppercase characters
  - Contains numbers or symbols

D.2 Request for Preliminary User access of TIES by End-User

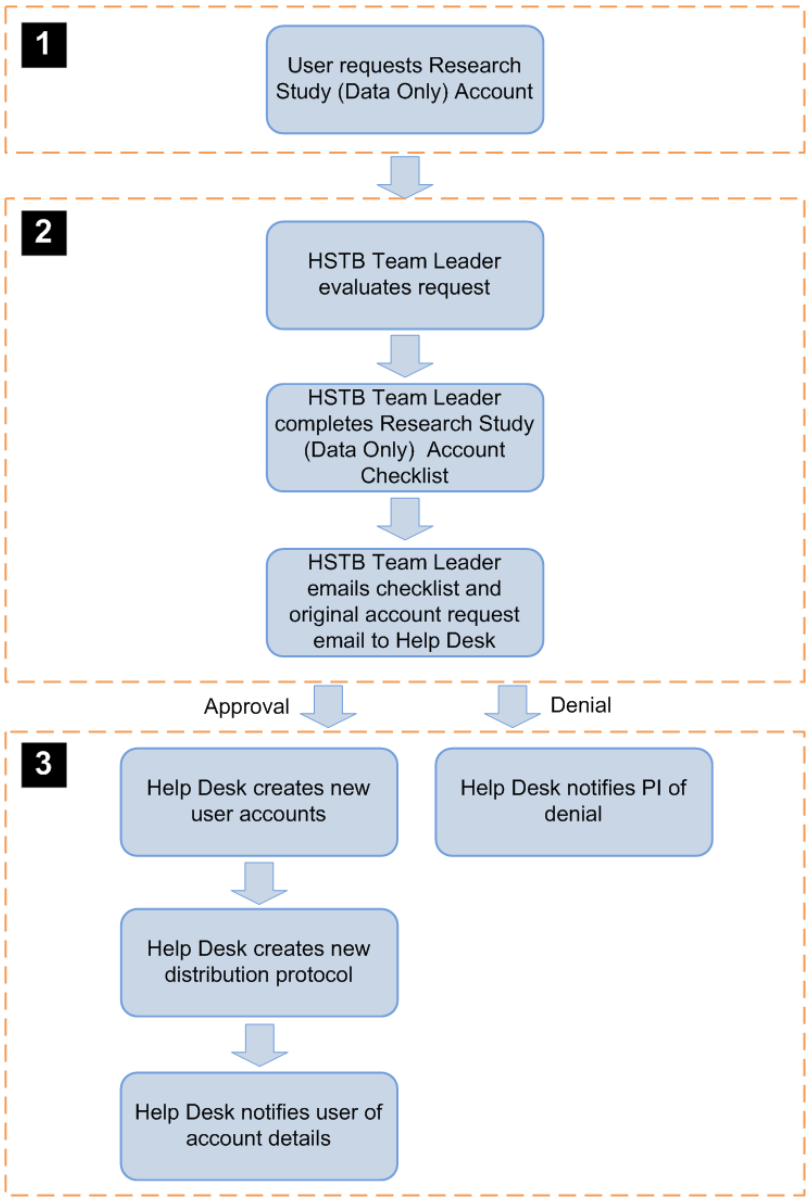


1. **Submission of study description by user**
    a. The PI will submit the following documents via online submission form to HSTB Team Leader.
        i. Research study description document. It is a document that describes the research study for which TIES access is requested.
    b. An account request email will be automatically generated and will be emailed to the HSTB Team Leader.
2. **Review of request by HSTB Team Leader**
    a. The HSTB Team Leader will verify if all required documents have been provided. If not all documents are attached, the HSTB Team Leader will contact the user directly for additional documentation. The user may continue to amend an incomplete application until it fulfills the required criteria
    b. The HSTB Team Leader will examine the study description to determine if it is appropriate use of aggregate data provided by TIES under the Preliminary User level access.
    c. The HSTB Team Leader will complete the “Preliminary User Checklist Form” (see Appendix)
    d. HSTB Team Leader will forward the original account request email and the “Preliminary User Checklist form” to the Help Desk.
    e. The HSTB Team Leader will save a copy of the filled checklist form along with the study description for auditing purposes.
    f. The HSTB Team Leader will give its decision within 5 business days after receipt of the account request email.
3. **Handling of HSTB Team Leader’s decision by Help Desk**
    a. In case of approval the Help Desk will do the following:
        i. If the user already has a TIES account, the Help Desk will add a ‘Preliminary User’ role to that user account.
        ii. If the user does not have a TIES account, the Help Desk will create a new user account for the user. The Help Desk will enter all the required address and contact information for each new user account using information submitted by the user. The user account will be given a ‘Preliminary User’ role.
        iii. The default expiry date of the role will be 3 years from the date of approval.
    b. The Help Desk will add the user to the Preliminary User Study as a “Researcher”.
    c. The Help Desk will email the user to indicate either

i. That the user account has been created and/or the preliminary user role has been added to the user account.
ii. That the new role cannot be added, along with reasons given by the HSTB Team Leader for denial.

See sample email in Appendix.

D.3 Request for new Research Study (Data Access) in TIES by PI



Only the Principal Investigator can submit account requests for themselves and any other users that will require access under that protocol.

1. **Submission of study description by user**
    a. The PI will submit the following documents via online submission form to HSTB Team Leader.
        i. Research study description document. It is a document that describes the research study for which TIES access is requested.
    b. An account request email will be automatically generated and will be emailed to the HSTB Team Leader.
2. **Review of request by Team Leader**
    a. The HSTB Team Leader will verify if all required documents have been provided. If not all documents are attached, the HSTB Team Leader will contact the user directly for additional documentation. The user may continue to amend an incomplete application until it fulfills the required criteria
    b. The HSTB Team Leader will examine the study description to determine if it is appropriate use of de-identified data provided by TIES under the Research Study Data Only level access.
    c. The HSTB Team Leader will complete the “Research Study Data Access Checklist Form” (see Appendix)
    d. HSTB Team Leader will forward the original account request email and the “Research Study Data Access Checklist form” to the Help Desk.
    e. The HSTB Team Leader will save a copy of the filled checklist form along with the study description for auditing purposes.
    f. The HSTB Team Leader will give its decision within 5 business days after receipt of the account request email.
3. **Handling of HSTB Team Leader’s decision by Help Desk**
    a. In case of approval Help Desk will do the following:
        i. The Help Desk will create any new user accounts for the PI and the study users if required. The Help Desk will enter all the required address and contact information for each new user account using information submitted by the PI. These user accounts will be assigned Researcher roles.
        ii. The Help Desk will create a new Distribution Protocol
            1. Assign it the title, short title and IRB approval no. specified in the communication from the HSTB Team Leader.
            2. Register organization as Data consumer.

3. Set an expiry date for the protocol if specified by the Team Leader. IF not specified, use the default system assigned expiry date, which is 3 years after date of creation.

iii. The Help Desk will assign the user account for the PI as a “Primary Investigator” for the newly created Distribution Protocol.

iv. The Help Desk will assign user accounts for all the study users as “Researchers” for the newly created Distribution Protocol.

v. The Help Desk will assign user accounts for honest brokers specified by the HSTB Team Leader as “Honest Broker” for the newly created Distribution Protocol.

b. The Help Desk will email the New Study PI to indicate either

i. that the New Study has been created

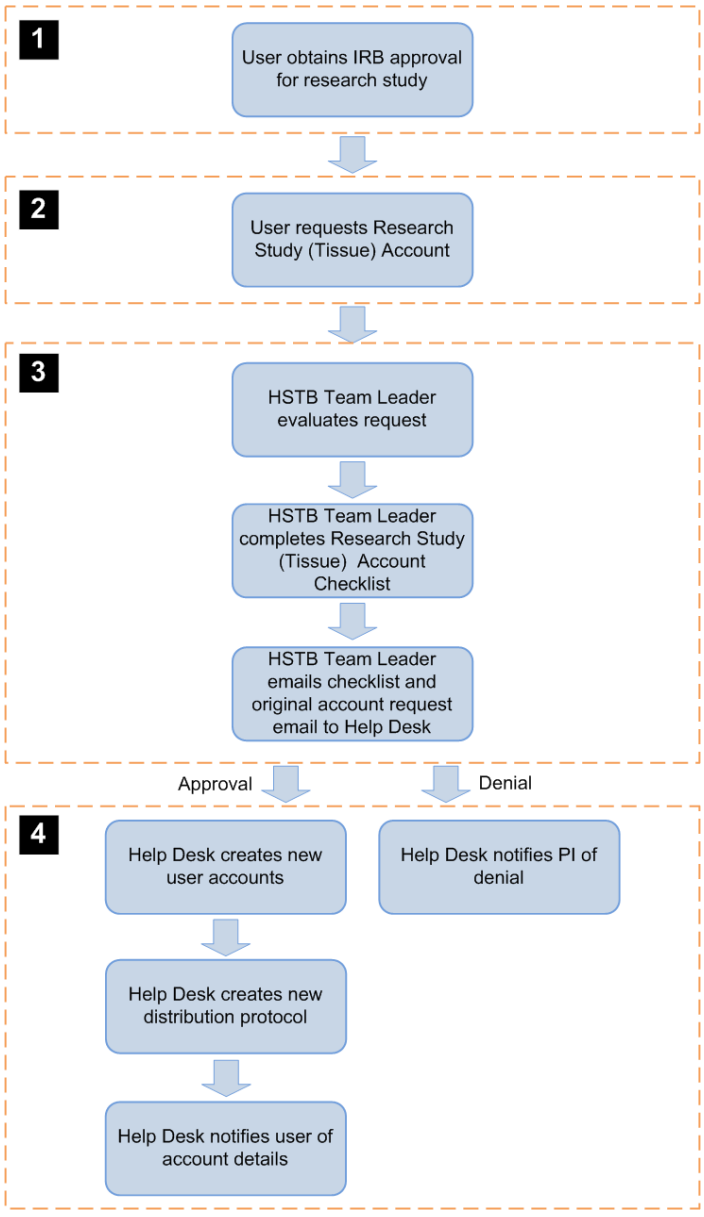
ii. that the New Study cannot be created, along with reasons given by the HSTB Team Leader for denial.

See sample emails in Appendix.

c. New Studies will be created within 7 business days of a completed application.

d. Help Desk will destroy all documents provided by the PI after the study has been created.

D.4 Request for new Research Study (Tissue Access) in TIES by PI



Only the Principal Investigator can submit account requests for themselves and any other users that will require access under that protocol.

1. **IRB approval for use of TIES by PI**
    a. The Study Principal Investigator (PI) must first obtain an approved IRB protocol, exemption or waiver for use of TIES.
        i. The IRB protocol should indicate whether the study involves obtaining (a) Data only or (b) Data and Tissue.
2. **Submission of New Study Request by PI**
    a. The PI will submit the following documents via online submission form to HSTB Team Leader.
        i. IRB protocol application and/or waiver form
        ii. IRB approval including approval or waiver number
        iii. List of all additional users other than the PI that will require access to TIES under this IRB protocol.
            1. TIES users must have completed any Human Subjects research training and HIPAA training required by the Organizational Review Board for use of clinical data.
            2. PI will indicate if any of the users have existing TIES accounts.
            3. For users that will require new TIES accounts, the PI will provide user contact information, including address, phone, email and fax information.
3. **Review of request by HSTB Team Leader**
    a. The HSTB Team Leader will verify if all required documents have been provided. If not all documents are attached, the HSTB Team Leader will contact the user directly for additional documentation. The user may continue to amend an incomplete application until it fulfills the required criteria
    b. The HSTB Team Leader will examine the IRB approval in conjunction to the application, protocol or waiver form to verify that:
        i. The name of the study is identical on the approval and application, protocol or waiver form.
        ii. The use of TIES data is specified within the application, protocol or waiver form.
        iii. The IRB approval has not expired (the date of expiration must be in the future.)
        iv. The IRB protocol includes use of remainder tissue.

v. The name and contact details of the collaborating pathologist are mentioned in the IRB documents.
vi. All users that require access are mentioned on the IRB protocol.

c. The HSTB Team Leader will complete the "Research Study Tissue Access Checklist Form" (See Appendix)
d. The HSTB Team Leader will save a copy of the IRB approval, the protocol, and the research study checklist form for auditing purposes.
e. The HSTB Team Leader will give its decision within 5 business days after request of approval from the Help Desk.

4. Handling of HSTB Team Leader's decision by Help Desk

a. In case of approval Help Desk will do the following:
   i. The Help Desk will create any new user accounts for the PI and the study users if required. The Help Desk will enter all the required address and contact information for each new user account using information submitted by the PI. These user accounts will be assigned Researcher roles.
   ii. The Help Desk will create a new Distribution Protocol
      1. Assign it the title, short title and IRB approval no. specified in the communication from the HSTB Team Leader.
      2. Register organization as Tissue Consumer.
      3. Set an expiry date for the protocol if specified by the Team Leader. IF not specified, use the default system assigned expiry date, which is 3 years after date of creation.
   iii. The Help Desk will assign the user account for the PI as a "Primary Investigator" for the newly created Distribution Protocol.
   iv. The Help Desk will assign user accounts for all the study users as "Researchers" for the newly created Distribution Protocol.
   v. The Help Desk will assign user accounts for honest brokers specified by the HSTB Team Leader as "Honest Broker" for the newly created Distribution Protocol.
b. The Help Desk will email the New Study PI to indicate either
   i. that the New Study has been created.
   ii. that the New Study cannot be created, along with reasons given by the HSTB Team Leader for denial.

   See sample emails in Appendix.
c. New Studies will be created within 7 business days of a completed application.

d. Help Desk will destroy all IRB submission and approval documents provided by the PI after the study has been created.

D.5 Addition of new Honest Brokers to TIES

1. All requests for new Honest Brokers will be approved by the HSTB Team Leader only.
2. No Honest Broker can also serve as a Researcher on the same study due to conflict of interest.
3. Primary Investigators may contact the HSTB Team Leader directly to request the assignment of an Honest Broker for their study. This person must currently be or become a TIES Honest Broker.
4. To become a TIES Honest Broker, any existing Honest Broker chosen by a Primary Investigator must provide the HSTB Team Leader with the following TIES Account Request materials:
    a. Original UPMC Honest Broker Application;
    b. Honest Broker Approval Letter demonstrating final UPMC Honest Broker Certification; and,
    c. Existing TIES Research Study Name or written summary of the proposed project.
    d. The Honest Broker must agree at the time of their TIES Account Request, and at each and every TIES login, that they:
        i. have access to identified pathology reports through coPath or MARS as part of their daily workflow
        ii. will use TIES for the purposes of their current research only
        iii. will follow all applicable criteria outlined in the UPMC Policy and Procedure Manual. Specifically - Policy: HS-EC1807; Index Title: Ethics and Compliance; Subject: Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker. Source document located at: http://www.irb.pitt.edu/hipaa/HSEC1807.pdf
5. HSTB Team Leader will provide the name and contact information including address, telephone no., fax no, and email address of the new honest broker to the Help Desk.
6. The HSTB Team Leader will indicate whether the new honest broker will also be requiring Administrator access.
7. The Help Desk will create a user account in TIES with the above information. This new user will be assigned the Honest Broker role in the system.

8. If the HSTB Team Leader also requested Administrator access, the Help Desk will also assign the Administrator role to the newly created user.

D.6 Tissue Order Fulfillment for a Study Protocol by HSTB

1. **Verification of IRB approval, exemption or waiver**
    a. The HSTB Team Leader will receive a Tissue Data Request Form (TDRF) from any user who submits a tissue request through TIES.
    b. The HSTB Team Leader will forward the TDRF to the appropriate Honest Broker handling the research study.
    c. The Honest Broker will verify that the specific tissue order falls within the bounds of the Tissue Consumer IRB protocol by inspecting the Tissue Consumer's IRB protocol.
    d. Specifically, the Honest Broker will ascertain that the tissue type, years of inclusion and patient demographics match the constraints of the user's approved IRB protocol.
2. **Constrain request with local requirements governing use of remainder Tissue Transfer**
    a. The Honest Broker will constrain the requested tissue based on local policies governing use of remainder tissues. These policies may emanate from the Tissue Utilization Committee or any other appropriate body governing use of Tissue at the Tissue Provider's organization.
3. **Tissue Dispersal**
    a. Tissue will be dispersed by the Honest Broker or their proxy only after Steps 1 and 2 have been completed.
    b. Any local policies governing use or return of Tissue remainders will be included with dispersed tissues.

D.7 Audit of compliance to TIES IRB Review Policies

1. On a biannual basis, the HSTB Team Leader will determine:
    a. The number of active Study Protocols currently in the TIES system (N)
    b. The number of Study Protocols entered into the TIES system during the 6 month last audit period (M)
    c. If the number of Study Protocols currently in the TIES system (N) is less than 20,
        i. The HSTB Team Leader will determine how many Study Protocols have been accompanied by:

1. An IRB protocol, application or waiver form
2. An IRB approval, exemption, or waiver
3. A Materials Transfer Agreement

ii. The HSTB Team Leader will determine if any of the Study Protocols are not accompanied by the appropriate documents

d. If the number of Study Protocols is greater than 20

i. The Honest Broker will randomly select (20+N/10) of Study Protocols from the total pool of active protocols and determine how many of the randomly selected Study Protocols have been accompanied by:

1. An IRB protocol, application or waiver form
2. An IRB approval, exemption, or waiver
3. A Materials Transfer Agreement

ii. The HSTB Team Leader will determine if any of the selected Study Protocols are not accompanied by the appropriate documents

2. Following every bi-annual audit, the HSTB Team Leader will forward the following statistics to the TIES Repository PI and HSTB Director:

a. Total number of IRB protocols, waiver forms or applications missing/Number of Study Protocols inspected

b. Total number of IRB approvals, waivers or exemptions missing/Number of Study Protocols inspected

c. Total number of Materials Transfer Agreements missing/Number of Study Protocols inspected

D.8 Audit of Quarantined Data by QA Administrator

1. On a monthly basis, the QA Administrator will review quarantined data using the TIES QA Tab, and complete the Quarantine Data Report Form (see Appendix D.4).

2. On a monthly basis, the QA Administrator will forward monthly statistics to the TIES Repository PI for review.

3. The TIES Repository PI will determine whether investigation and modification of local de-identification processes are warranted.

4. On a yearly basis, the QA Administrator will perform a QA check of a random selection of documents for de-identification errors (N to be determined).

5. On a yearly basis, the TIES Repository PI will submit a report to the HSTB Director detailing statistics for the previous year.

E. Appendix

E.1 Research Study Tissue Access Checklist Form

New Research Study (Tissue) Checklist Form To be filled by HSTB Team Leader. Forward filled form to bicsupp@pitt.edu along with original account request email.	☐ **Approved**	☐ **Denied**

Title:	
Short Title:	
P.I. Name:	
IRB/QI Approval No.:	
Expiry Date:	**If not specified, it is 3 years after date of approval.**
Assigned Honest Broker:	

Application Review	**Use: (✓) / (✗) / (NA)**
	IRB/QI Application received.
	IRB/QI Approval received.
	The name of the study on IRB/QI Application and IRB/QI Approval is the same
	The IRB/QI approval has not expired
	The use of TIES data is specified within the application, protocol and waiver form.
	The IRB application/approval specifies whether study involves obtaining data only or data and tissue. In case of tissue name of collaborating pathologist is mentioned.
	All users have valid UPMC NT accounts. (Check for QI studies only)

Comments

Reviewed By: _____ **Date:** _ _ / _ _ / _ _ _ _

Comment [GRC1]: Full title of the study. **Required Field**.

Comment [GRC2]: A 4 letter short title. **Required Field**.

Comment [GRC3]: **Required Field**.

Comment [GRC4]: **Required Field**.

Comment [GRC5]: Specify an expiry date if available. If not specified all studies have a 3 year expiry date. **Required Field**.

Comment [GRC6]: A TIES honest broker that will be handling all data/tissue requests coming from this study. **Required Field**.

Comment [GRC7]: Mention any additional comments in this section. In case of denial of request give reason for denial in this section.

E.2 Research Study Data Access Checklist Form

New Research Study (Data) Checklist Form To be filled by HSTB Team Leader. Forward filled form to bicsupp@pitt.edu along with original account request email.	☐ **Approved**	☐ **Denied**
Title:		
Short Title:		
P.I. Name:		
IRB/QI Approval No.:	**IRB Not Required**	
Expiry Date:	**If not specified, it is 3 years after date of approval.**	
Assigned Honest Broker:		
Application Review	**Use: (✓) / (✗) / (NA)**	
Research Description document received.		
Comments		
Reviewed By: _____	**Date: _ _ / _ _ / _ _ _ _**	

Comment [GRC8]: Full title of the study. **Required Field**.

Comment [GRC9]: A 4 letter short title. **Required Field**.

Comment [GRC10]: **Required Field**.

Comment [GRC11]: **Required Field**.

Comment [GRC12]: Specify an expiry date if available. If not specified all studies have a 3 year expiry date. **Required Field**.

Comment [GRC13]: A TIES honest broker that will be handling all data/tissue requests coming from this study. **Required Field**.

Comment [GRC14]: Mention any additional comments in this section. In case of denial of request give reason for denial in this section.

E.3 Preliminary User Checklist Form

Preliminary User Checklist Form To be filled by HSTB Team Leader. Forward filled form to bicsupp@pitt.edu along with original account request email.	☐ **Approved**	☐ **Denied**
Application Review	**Use: (✓) / (✗) / (NA)**	
Research Description document received.		
Comments		
Reviewed By: _____	**Date: _ _ / _ _ / _ _ _ _**	

Comment [GRC15]: Mention any additional comments in this section. In case of denial of request give reason for denial in this section.

E.4 Honest Broker Checklist Form

Honest Broker Checklist Form To be filled by HSTB Team Leader. Forward filled form to bicsupp@pitt.edu along with original account request email.	☐ **Approved**	☐ **Denied**

Application Review	**Use: (✓) / (✗) / (NA)**
	UPMC Honest Broker application received
	HB approval letter demonstrating final UPMC HB Certification received
	Written summary of the proposed project received
	Access to identified pathology reports through coPath or MARS as part of their daily workflow

Comments

Reviewed By: _____ **Date:** _ _ / _ _ / _ _ _ _

Comment [GRC16]: Mention any additional comments in this section. In case of denial of request give reason for denial in this section.

E.5 Sample Email for new Preliminary User account

Dear Sir/Madam,

A TIES account has been created for you with “Preliminary User” permissions.

Login Information :
Username: <username>
Password: <password>

To access the TIES application directly you may use the following link:
http://ties.upmc.com

You can learn about how to use TIES at the TIES Website (http://ties.upmc.com)

Please contact the Bioinformatics Core Support Team @ 412-624-8555 if you have any questions or concerns.

Thanks

Bioinformatics Core Support Team

E.6 Sample Email for new research study account

Dear Sir/Madam,

A TIES account has been created for you with “Researcher” permissions.

Login Information :
Username: <username>
Password: <password>

You have also been registered as a “<role>” on the study titled “<The full title of the distribution protocol>”
It should now appear in your list of available distribution protocols.

To access the TIES application directly you may use the following link:
http://ties.upmc.com

You can learn about how to use TIES at the TIES Website (http://ties.upmc.com)

Please contact the Bioinformatics Core Support Team @ 412-624-8555 if you have any questions or concerns.

Thanks

Bioinformatics Core Support Team

E.7 Sample Email for new study role for existing TIES user

Dear Sir/Madam,

You have been registered as a “<role>” on the study titled “<The full title of the distribution protocol>”
It should now appear in your list of available distribution protocols.

To access the TIES application directly you may use the following link:
http://ties.upmc.com

You can learn about how to use TIES at the TIES Website (http://ties.upmc.com)

Please contact the Bioinformatics Core Support Team @ 412-624-8555 if you have any questions or concerns.

Thanks
Bioinformatics Core Support Team

E.8 Sample Email for denial of request

Dear Sir/Madam,

Your request for a TIES account has been denied due to the following reason:
<Reason given by HSTB Team Leader for denial>

You may re-submit an amended request at any time.

Please contact the Bioinformatics Core Support Team @ 412-624-8555 if you have any questions or concerns.

Thanks
Bioinformatics Core Support Team

E.9 Sample Quarantine Data Report Form

TIES Quarantined Data Report Form

Audit Period _____ **to** _____

Total Number of Quarantined Reports _____

Total Number of Quarantined Reports Examined During Audit _____

Description of Identifiers Not Removed by De-Identification Software

Identifier	Number Not Removed in ALL Reports	Comments/Specify
Names		
Geographic subdivisions smaller than a State (including street address, city, county, zip-code)		
Dates		
Telephone Numbers		
Fax Numbers		
E-mail addresses		
Social Security Numbers		
Medical Record Numbers		