UPMC Health System/University of Pittsburgh Institutional Review Board

APPLICATION for the CERTIFICATION OF HONEST BROKER SYSTEMS/PROCESSES

(Refer to UPMC Health System Policy: HS; Index Title: HIPAA; Subject: Honest Broker Certification Process for the De-Identification of Research Data)

1. Specify the School, Department, Division, or Center for which this Honest Broker System/Process is being developed:

This Honest Broker System has been developed primarily to support faculty, staff, and graduate students who perform collaborative research with the following inter-related groups: the 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 Women's Cancer Research Center (WCRC), UPMC ISD/Pathology Informatics, UPMC ISD/Oncology Informatics and the UPMC Network Cancer Registry/ UPMC Cancer Centers Registry Information Services (RIS).

Leadership of these Departments/Divisions includes:
Michael Becich, M.D., Ph.D, *Director, DBMI*
Rajiv Dhir, M.D., *Director, UPMC HSTB*
Susan M. Kelly, *Assistant Director, UPMC HSTB*
Jonas Johnson, M.D., *Professor and Chair, UPMC Department of Otolaryngology*
Liron Pantanowitz, M.D., *Associate Professor, UPMC Pathology and Biomedical Informatics*
Robert Edwards, M.D., *Professor and Chairman, Department of Obstetrics, Gynecology & Reproductive Medicine, University of Pittsburgh School of Medicine, and Co-director of Women's Health Services, UPMC; Co-Director, WCRC*
Adrian Lee, Ph.D., *Director, Magee Women's Cancer Research Center (WCRC)*
Scot Stevens, *Chief Information Officer, UPMC Cancer Centers IT (ISD/Oncology Informatics)*
Sharon Winters, MS, CTR., *Director, RIS/UPMC Network Cancer Registry*

2. Specify the individual who will assume responsibility for the appropriate management and oversight of this Honest Broker System/Process:

Name: Sharon Winters, MS, CTR
UPMC Facility: UPMC CancerCenter, UPMC Hospitals and Hospital Based Clinics
Title: Director, Registry Information Services, UPMC Network Cancer Registry
Address: Harbor Gardens, 1650 Metropolitan Street, Pittsburgh, PA 15233
Telephone Number: 412-647-6390
FAX Number: 412-623-2814
E-mail Address: winterssb@upmc.edu

3. Specify the names of all additional individuals who will be involved in performing honest broker services under this Honest Broker System/Process, identify whether each broker is a UPMC employee or UPMC Workforce member. For each UPMC Workforce member, identify the UPMC oversight/sponsor. The UPMC oversight/sponsor must be employed by UPMC:

Department / Division	Team Leader	Certified Brokers	UPMC Employee	UPMC Oversight / Sponsor
UPMC Pathology / Health Sciences Tissue Bank (HSTB)	Nicole Pistorius	Erika Benson	N	Rajiv Dhir, MD
		Theosevia Demertzis	N	Rajiv Dhir, MD
		Krishnaveni Dhir	N	Liron Pantanowitz, MD
		Caitlin Doherty	N	Rajiv Dhir, MD
		Anthony Green	N	Rajiv Dhir, MD
		Susan M. Kelly	N	Rajiv Dhir, MD
		Christina (Puet) Kline	N	Rajiv Dhir, MD
		Marianne Notaro	N	Rajiv Dhir, MD
		Kevin O'Connor	N	Rajiv Dhir, MD
		Nicole Pistorius	N	Rajiv Dhir, MD
		Katie Porreca	N	Rajiv Dhir, MD
		Nicole Roehrig	N	Rajiv Dhir, MD
		Philip Schumacher	N	Rajiv Dhir, MD
		Angela Scolieri	N	Rajiv Dhir, MD
		Merida Serrano	N	Rajiv Dhir, MD
		Amy Simcik	N	Rajiv Dhir, MD
		Tina Tomko	N	Rajiv Dhir, MD
		Luke Wiehagen	N	Rajiv Dhir, MD
UPMC Network Cancer Registry / Registry Information Services	Althea Schneider	Louise Mazur	Y	
		Jennifer Ridge-Hetrick	N	Sharon Winters, MS
		Althea Schneider	N	Sharon Winters, MS
		Karla Stewart	N	Sharon Winters, MS
		Kerry Trent	N	Sharon Winters, MS
		Sharon Winters	Y	
UPMC Department of Otolaryngology	Althea Schneider	Jennifer Ridge-Hetrick	N	Sharon Winters, MS
Magee Womens Hospital of UPMC Women's Cancer Research Center (WCRC)	Tracy Davis	Tracy Davis	Y	
		Angela Laslavic	Y	
		Louise Mazur	Y	
		Suping Wang	Y	
UPMC Cancer Centers Pathology / Oncology Informatics	Brenda Crocker	Brenda Crocker (Oncology)	Y	
		Paulette Faris (Oncology)	Y	
		Rick Nestler (Pathology)	Y	

Additionally, UPMC employees or workforce members acting in honest broker roles (listed above), primarily the HSTB, WCRC, Cancer Registry and Otolaryngology, may utilize support services provided by the following DBMI employees. These individuals also support research activities of UPMC physicians who may be users of TIES, H&N OSD, Clinical Research Resources and Facilities (CRRF) core software applications as part of the Clinical and Translational Research Centers (CTRCs) and Research Networks. To be part of this honest broker system/services, all of these indivduals have successfully completed the required educational modules but do not serve as honest brokers.

Waqas Amin, MD	Nickie Capella	Michele Morris	William Shirey
Allan Ashby	Girish R. Chavan	Johnson Paul	Eugene Tseytlin
Charles Borromeo	Julia Corrigan	Desheng Li	Zhou Yuan
Michael G. Capella	Michael Davis	John Milnes	Joyce Zelnis

4. HIPAA Complete (i.e., "Safe Harbor") De-Identification of Medical Record Information:

a. For electronic medical record information, address the processes and/or systems that will be used to fully de-identify (i.e., HIPAA "Safe Harbor" compliant) the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA "Safe Harbor" de-identification requirements.)

The CoPath Laboratory Information System (LIS) is used by the Department of Pathology for managing its clinical information. This LIS has the capability to generate de-identified reports using DeID software tools, as per the needs of Safe Harbor compliance.

The UPMC Network Cancer Registry has information in its archives based on requirements of both the American College of Surgeons Commission on Cancer (ACOS COC) and the Pennsylvania Department of Health (PADOH). Due to the PADOH being a public health agency, this registry process is exempt from HIPAA consenting processes. Elekta's METRIQ standardized cancer registry software is used for the Registry data collection process. When Registry-associated data is requested for Exempt or No Human Subject Involvement research, the Registry provides this information, de-identified per Safe Harbor requirements, using electronic as well as manual methods.

Head & Neck Organ Specific Database (H&N OSD) is a clinical database that collected data on all head/neck cancer patients treated at the Eye and Ear Institute. No researchers have access to any data unless appropriate IRB is obtained. When H&N OSD-associated data is requested for Exempt or No Human Subject Involvement research, the Department of Otolaryngology registrar provides this information, de-identified per Safe Harbor requirements, using electronic as well as manual methods.

Additional tools and services available to the brokers associated with this System include TIES (Text Information Extraction System) and other data integration services provided by DBMI and Pathology/Oncology Informatics support teams identified above, such as interaction with UPMC's Center for Connected Medicine and Enterprise Analytics for data integration services, Clinical Research Information Services for De-ID text and lab reports from MARS (via collaboration with Honest Broker System #HB0001). TIES is being used by our System as part of an IRB approved project (IRB approval# PRO07050292). It is a general purpose text information extraction tool to automate the process of converting fully de-identified free text surgical pathology reports into structured data and storing those data in a federated capacity, and to facilitate retrieval, advanced query and further analysis of the pathology information.

In all cases, the team leaders working with the Manager of this System assure proper IRB documentation is in place prior to releasing any tissue/data. This includes, but not necessarily limited to: Full IRB protocol (when appropriate), IRB exempt application with affixed signatures and dates (application to identify this System,

tissues/data needed and data sources to be used, including the Registry when applicable), IRB approval letter.

The above protocol will apply to all groups covered in this submission, primarily the HSTB, WCRC, Cancer Registry/RIS and Otolaryngology.

b. For paper-based medical record information, address the processes and/or systems that will be used to fully de-identify (i.e., HIPAA "Safe Harbor" compliant) the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA "Safe Harbor" de-identification requirements.)

The generation of "Safe Harbor" compliant data also uses manual means. Although the clinical computer applications utilized by the brokers within this System store data in purely electronic form, there is the capability of generating files and reports based on the needs of the requestor. The HSTB, WCRC and RIS have been utilizing a system of linkage codes for specimens and annotating data. The linkage codes are retained by the brokers on password protected secure servers behind UPMC HIPAA Security-compliant firewalls. Any printed records of these linkage codes and associated data are stored in a secure, locked filing space and maintained by the individual brokers.

The use of paper recording is strongly discouraged. The predominant mechanism used is electronic files on secure computers. Any excess paper reports generated are destroyed using paper shredders and secure University/ UPMC contracted disposal contractors.

In all cases, the team leaders working with the Manager of this System assure proper IRB documentation is in place prior to releasing any tissue/data. This includes, but not necessarily limited to: Full IRB protocol (when appropriate), IRB exempt application with affixed signatures and dates (application to identify this System, tissues/data needed and data sources to be used, including the Registry when applicable), IRB approval letter.

The above protocol will apply to all groups covered in this submission, primarily the HSTB, WCRC, Cancer Registry/RIS and Otolaryngology.

5. Limited Data Sets of Medical Record Information:

a. For electronic medical record information, address the processes and/or systems that will be used to develop Limited Data Sets of the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA Limited Data Set requirements.)

The process followed for generation of "Limited Data Sets" will be a combination of electronic and manual methods. The electronic systems are coded to generate information that follows the "Safe Harbor regulations" as described in above sections,

however, CoPath, METRIQ and H&N OSD applications also have the capability for extracting additional information according to specified additional data fields. Since the "Limited Data Set" requirements permit sharing of additional data elements such as dates and geographic details, as compared to the "Safe Harbor" requirements, these elements will be extracted, and provided, electronically, where possible. In addition there will be instances when this might not be possible. Manual methods, as described above, will be used. Any additional information to be provided will be manually extracted and added to the "Limited Data Set" compliant documents. The records of this additional information needed will be placed in secure, locked filing cabinets.

As mentioned in the previous section, the Head & Neck Organ Specific Database (H&N OSD) is a clinical database that collected data on all head/neck cancer patients treated at the Eye and Ear Institute. No researchers have access to any data unless appropriate IRB is obtained. When H&N OSD-associated data is requested for Exempt or No Human Subject Involvement research, the Department of Otolaryngology registrar provides this information, de-identified per Limited Data Set requirements, using electronic as well as manual methods.

If the request is for Exempt or No Human Subject Involvement research activities, a Data Use Agreement (DUA) is completed as part of the investigators IRB application. In all cases, the team leaders working with the Manager of this System assure proper IRB documentation is in place prior to releasing any tissue/data. This includes, but not necessarily limited to: Full IRB protocol (when appropriate), IRB exempt application with affixed signatures and dates (application to identify this System, tissues/data needed and data sources to be used, including the Registry when applicable), IRB approval letter.

The above protocol will apply to all groups covered in this submission, however are primarily the HSTB, WCRC, Cancer Registry/RIS and Otolaryngology.

b. For <u>paper-based</u> medical record information, address the processes and/or systems that will be used to develop Limited Data Sets of the information for subsequent use by your affiliated researchers. (Note: See Attachment A for HIPAA Limited Data Set requirements.)

The generation of "Limited Data Sets" from paper-based medical record information will be similar to that for the fully de-identified data described above. The generation of "Safe Harbor" compliant data also uses manual means. Although the clinical computer applications utilized by the brokers within this System store data in purely electronic form, there is of course the capability of generating files and reports based on the needs of the requestor. The HSTB, WCRC and RIS have been utilizing a system of linkage codes for specimens and annotating data. The linkage codes are retained by the brokers on password protected secure servers behind UPMC HIPAA Security-compliant firewalls. Any printed records of these linkage codes and associated data are stored in a secure, locked filing space and maintained by the individual brokers.

The use of paper recording is strongly discouraged. The predominant mechanism used is electronic files on secure computers. Any excess paper reports generated are destroyed using paper shredders and secure University/ UPMC contracted disposal contractors.

If the request is for Exempt or No Human Subject Involvement research activities, a Data Use Agreement (DUA) is completed as part of the investigators IRB application. In all cases, the team leaders working with the Manager of this System assure proper IRB documentation is in place prior to releasing any tissue/data. This includes, but not necessarily limited to: Full IRB protocol (when appropriate), IRB exempt application with affixed signatures and dates (application to identify this System, tissues/data needed and data sources to be used, including the Registry when applicable), IRB approval letter.

The above protocol will apply to all groups covered in this submission, primarily the HSTB, WCRC, Cancer Registry/RIS and Otolaryngology.

c. Address your policies, procedures and controls for ensuring that Limited Data Sets of medical record information that you proved to your affiliated researchers contain only the minimum necessary information needed to perform the research. (Note: These policies should include statements specifying that the medical record information provided to researchers under a Limited Data Set will be consistent with the specific data elements requested in the corresponding IRB-approved research application and Data Use Agreement.)

The policies and procedures in place currently focus on the following major issues:

1. ***IRB approval:*** *The UPMC employees or workforce members acting in honest broker roles covered in this submission, primarily the HSTB, WCRC, Cancer Registry/RIS and the Otolaryngology, ask the researcher to provide a copy of the IRB submission and the IRB approval. This ensures that appropriate institutional approvals have been obtained. The IRB submission and approval processes guide us to utilize the minimum information needed for the research project. The IRB submission also provides specific details regarding the data elements requested in the research IRB submission. Thus, the medical record information provided to researchers under a Limited Data Set will be consistent with the specific data elements requested in the corresponding IRB-approved research application and Data Use Agreement.*

2. ***De-identification****: In the event biological materials are needed, a biological specimen user agreement would need to be submitted along with the previous described IRB documentation. The biological specimens, along with any annotating information as requested, are provided to the researchers totally devoid of any identifiers. Linkage codes are used as appropriate and the*

coding information is stored on password-protected computers. Any paper trail generated is stored in secure, locked filing cabinets. It is the responsibility of the team leaders to ensure that the protocols are being followed. They are encouraged to seek guidance from the faculty in charge of these. In addition there are regular meetings to discuss any potential issues.

3. ***Oversight, request tracking and training****: As further described below, electronic request tracking tools are utilized to document all requests received by this system. A quarterly review (once every three months) of the protocols and procedures will be performed by the manager of this Honest Broker System with cooperation from the team leaders. Compliance will be documented. Currently, the team leaders meet with their respective brokers regularly to review electronic and paper trail of requests generated and fulfilled. Any issues or questions pertaining to the workflow are discussed.*

There are three main UPMC intranet-based, password-protected, request tracking and monitoring tools utilized by members of this System.

- *The HSTB team utilizes a tool titled the "Health Sciences Tissue Bank Project Management System" enabling them to track requests for biological materials.*
- *The Registry Information Services team utilizes a tool titled "HB015 Honest Broker System Data Request Tracking Tool" This tool enables brokers to attach relevant IRB documents, data use agreements, and other project related documents to the details of the request. It enables storage of information related to the requestor, associated brokers, IRB-specific details, identification of data requirements, approval of data requests, reference to time spent and final status.*
- *The UPMC CancerCenter Information Technology division uses a tool called "JIRA" purchased for the CancerCenter to track Software Development and service requests. https://www.atlassian.com/software/jira*

In addition there are periodic review sessions where protocols and policies, and possible issues and clarifications, are discussed. The faculty members on this submission periodically present on issues of importance and interest (informal didactic teaching). These sessions focus primarily on issues pertaining to IRB, confidentiality and advances in techniques and methods.

6. Assignment of Re-Identification Codes to De-Identified (HIPAA "Safe Harbor") Medical Record Information and Limited Data Sets:

   a. Address your policies, procedures and controls for the assignment of re-identification codes to the de-identified (HIPAA "Safe Harbor") medical record information and/or Limited Data Sets of medical record information provided to your affiliated researchers. (Note: These policies should include statements specifying that the assignment of re-identification codes will be based on project-by-project verification that the IRB granted approval of the use of re-identification codes. In addition, include statements addressing how re-

identification codes will be appropriately managed by the honest broker so as to prevent researcher access to information linking these codes with corresponding patient-subject identifiers.)

The de-identified information is a subset of the data available in the repositories of the HSTB, WCRC, Cancer Registry/RIS or Otolaryngology or a subset of the data available in Pathology LIS or UPMC clinical databases. The HSTB, WCRC, Cancer Registry/RIS and/or Otolaryngology groups will generate the "Safe Harbor" and limited data sets of information from the already existing information, as described above. Linkage codes will be used, as appropriate, to enable the tissue and data repositories to access further information pertaining to the individuals in the studies. Certified brokers within this System work together when tissue and data are both needed within a particular project to assure proper matching of such materials is intact. This process will be initiated only when it is mandated by the IRB and is part of the initial IRB submission, or any modification thereof.

It will be the responsibility of the manager of this Honest Broker System and team leaders to ensure that the protocols are being followed. They will be encouraged to seek help from the faculty in charge of these facilities. In addition there will be regular meetings to discuss any potential issues. There will also be periodic assessment by the manager of this Honest Broker System of the system in place by evaluating the records in place and the problems encountered. These overview sessions will be performed on a regular basis.

7. Documentation and Quality Assurance:

   a. Address your policies, procedures and controls for ensuring that Institutional Review Board approval has been granted for the use of de-identified (HIPAA "Safe Harbor) medical record information or a Limited Data Set of medical record information <u>prior</u> to providing such to your affiliated researchers.

UPMC employees or workforce members acting in honest broker roles, primarily the HSTB, WCRC, Cancer Registry/RIS and Otolaryngology will not provide access to any information to any researcher until IRB submission and approval documentation is provided. No requests are entertained without prior IRB approval. The facilities will make no exceptions on this issue.

As part of the oversight process, regular reviews by the manager of this Honest Broker System and team leaders will be performed to evaluate the requests fulfilled. This exercise will focus on the information provided and make sure that this was consistent with the IRB submission and approval. This exercise will also assess the temporal workflow and make sure that information was released only after the appropriate approvals were in place. Any discrepancies and errors will be initially locally evaluated and corrective measures taken, including teaching and training. The IRB will also be informed of any errors.

b. Address your policies and procedures for documenting each honest broker transaction with your affiliated researchers (e.g., documentation of the identity of researcher, identity of the research study, the nature of the information provided, corresponding IRB approval information, etc.).

The historical HSTB requests for biological materials are logged via the electronic submission into the project management online tool. Research histology requests for paraffin blocks and/or slides that are not submitted through the online project management tool, are submitted by the researchers on a paper requisition given directly to research histology staff. These paper requisitions become part of the HSTB files. Any paper trail generated is stored in secure, locked filing cabinets. An electronic tracking log is generated that contains information on the paper requisitions and is housed on a secure firewall protected UPMC computer.

Registry Information Services and Otolaryngology has been using an intranet based, password protected, request tracking and monitoring tool since the original inception of this System in 2003. This tool enables storage of information related to the requestor, associated brokers, IRB-specific details, identification of tissue/data needed and approvals of requests. Time spent on each request is also stored. Standard and ad-hoc reporting is available with this tool to assess trending of services provides and other purposes. The HSTB has adopted this approach in 2008 and the WCRC adopted this approach in November 2009.

This logging process also documents the identity of the researcher. The broker involved in this logging process must contact the team leader to make sure that the requesting individual is recognized and accepted as part of the University of Pittsburgh and/or UPMC community. In instances where the identity is in doubt or if the request is from a researcher outside the University of Pittsburgh/UPMC, the faculty supervisor is responsible for making contact with the researcher, documenting the contact and communicating the decision back to the technician (generally via E-mail). The technician stores this information and proceeds accordingly.

The process of collecting the information starts only after the researcher provides the IRB submission and approval. This allows documentation of the magnitude of the approval provided to the researcher. In no instance will the information gathering process be allowed to start if the requesting individual does not have appropriate IRB mandates.

The next step in this workflow is to document the date and time the information, and biological material (if any), is provided to the researcher. If the transmission of data is electronic (probably in all cases), there will be an electronic trail of transmission of information. If the transmission of information is via hard copy, the researcher, or their designee, will need to sign a form certifying receipt of the information.

c. Address your policies and procedures for routine monitoring (auditing) of de-

identified (HIPAA "Safe Harbor") medical record information and Limited Data Sets of medical record information provided to affiliated researchers so as to ensure that this information has been de-identified in compliance with respective HIPAA requirements.

We have designed software tools that will allow electronic de-identification, per the needs of HIPAA. The technicians will still do a visual check of the data generated on all requests to make sure that the information provided is consistent with the requirements of "Safe Harbor" and "Limited Data Set" requirement, as appropriate for the request.

The manager of this Honest Broker System also will perform regular reviews with assistance from the team leaders for requests fulfilled.

This policy will be revisited periodically, depending on the efficacy of the electronic system and the time spent on these reviews.

d. Address your policies and procedures for managing and ensuring the security of all identifiable medical record information that is in the Honest Broker's possession during the performance of its de-identification (HIPAA "Safe Harbor") or creation of Limited Data Set functions.

The data is stored electronically on current state-of-the-art databases. The process of creation of "Safe Harbor" is primarily electronic. The "Limited Data Sets" will contain additional data elements that will be added after the "Safe Harbor" data set is created.

We will be making some modifications to our software tools to enable automatic generation of "Limited Data Sets" in a manner analogous to what is in place for the "Safe Harbor" data sets. This method would make the whole process electronic.

The access to the electronic systems is password protected. The logging on to these systems is monitored in accordance with UPMC HIPAA System Security policies and procedures. The staff are trained as certified honest brokers via UPMC/Pitt Research Fundamentals Modules. They will be aware of their responsibilities in keeping passwords secure and contacting the appropriate personnel in case they think their passwords has been compromised or if there is any other breach of confidentiality.

In some instances there might be a need to create a paper hard copy. These hard copies will be stored in locked, secure filing cabinets located in safe areas in Harbor Gardens--3rd floor, UPMC Shadyside, UPMC Presbyterian, Magee Womens Hospital, or Shadyside Medical Building, depending on the primary location of the designated honest broker per project.

8. Business Associate Agreement: Attach to this Application a completed UPMC Business Associate Agreement. (Note: the standard UPMC Business Associate Agreement can be found at http://purchasing.upmc.com).

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CERTIFICATION OF HONEST BROKER RESPONSIBILITIES

By signing below I agree/certify that:

1. I am cognizant of and will comply with the Federal Policy (Common Rule) and HIPAA regulations and the IRB and UPMC policies governing research involving the use of identifiable medical record information.
2. I have reviewed this Honest Broker System/Process application in its entirety and I am fully aware of and in agreement with all submitted statements.
3. I will ensure that the Honest Broker System/Processes will be implemented and followed in strict accordance with this application.
4. I will request and obtain IRB and UPMC Privacy Officer approval for any proposed modifications to this application prior to implementing such modifications.
5. I will ensure that all individuals involved in providing the Honest Broker System/Process services are provided with a copy of this current version of this application.
6. I and/or my Honest Broker staff will not provide identifiable medical record information, de-identified medical record information, or Limited Data Sets of medical record information to affiliate researchers until evidence of IRB approval of the corresponding research study is provided.
7. I will respond promptly to all requests for information or materials solicited by the UPMCHS Privacy Officer or the IRB.
8. I will maintain adequate documentation of all Honest Broker transactions with affiliated researchers.
9. I and/or my Honest Broker staff will, under no circumstances, provide the researchers with information that would permit de-identified (HIPAA "Safe Harbor") medical record information or Limited Data Sets of medical record information to be linked to patient identifiers.
10. I and/or my Honest Broker staff will not intervene or interact with patients in the conduct of Honest Broker functions.
11. I and/or my Honest Broker staff will maintain complete confidentiality of identifiable medical record information in our possession during the performance of Honest Broker functions.

11/30/2016

_____ _____

Signature of Individual Responsible for Honest Broker System/Processes | Date

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Honest Broker System/Process Application Approved:

_____ _____

UPMC HS Privacy Officer | Date

_____ _____

IRB Chair/Vice Chair | Date

ATTACHMENT A

APPLICATION for the CERTIFICATION OF HONEST BROKER SYSTEMS/PROCESSES

A. HIPAA "Safe Harbor" De-Identification of Medical Record Information

HIPAA requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de- identified (HIPAA "Safe Harbor")

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:

    a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
    b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people is changes to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers; license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

B. Limited Data Sets

For Limited Data Sets, HIPAA requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information.

1. Names
2. Postal address information, other than town or city, State, and zip code
3. Telephone numbers
4. FAX numbers
5. Electronic mail addresses
6. Social security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers; license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers
16. Full face photographic images and any comparable images