CRISMA Center
Data Management Core
Standard Operating Procedures

Honest Broker Services
### Purpose
This document describes the CRISMA Center’s policies for Honest Broker services for ensuring compliance with the Health Insurance Portability and Accountability Act (HIPAA) and US Department of Health and Human Services Office for Human Research Protections (OHRP) regulations regarding human subject data.

### Scope
This document applies to all personnel employed by or using any computer owned and operated by CRISMA; all computers owned or operated by CRISMA; and all human subject data managed by CRISMA and determined by regulatory agencies to require Honest Broker services.

### Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protected Health Information (PHI).</strong></td>
<td>Any information about health status, provision of health care or payment of health care that can be linked to a specific individual.</td>
</tr>
<tr>
<td><strong>HIPAA Privacy Rule.</strong></td>
<td>The portion of the Health Insurance Portability and Accountability Act of 1996 that governs use and disclosure of PHI. Under the privacy rule, PHI can be used for research purposes with either patient approval or waiver by an authorized regulatory agency.</td>
</tr>
<tr>
<td><strong>Common Rule.</strong></td>
<td>US Federal regulations for protection of human subjects in research, described by the Department of Health and Human Services in the Code of Federal Regulations Title 45 Part 46.</td>
</tr>
<tr>
<td><strong>Unique identifiers.</strong></td>
<td>Variables defined by HIPAA as uniquely identifying individuals, including names; geographical subdivisions smaller than a state except the initial three digits of a ZIP code as long as that ZIP code contains more than 20,000 people; all elements of dates except year and all ages over 89; phone numbers; fax numbers; e-mail address; social security numbers; medical record numbers; health plan numbers; account numbers; certificate/license numbers; vehicle numbers; web URLs; IP addresses; biometric identifiers; full face photos; and any other unique identifying numbers.</td>
</tr>
<tr>
<td><strong>De-identified data.</strong></td>
<td>Health data that does not contain unique identifiers as defined by HIPAA.</td>
</tr>
<tr>
<td><strong>Limited data set.</strong></td>
<td>A de-identified data set that contains either (a) geographic subdivisions not smaller than a town, city, state and ZIP code; (b) dates, or (c) ages over 89</td>
</tr>
<tr>
<td><strong>Safe harbor data set.</strong></td>
<td>A de-identified data set that does not contain any of the unique identifiers as defined by HIPAA.</td>
</tr>
<tr>
<td><strong>Researcher.</strong></td>
<td>As defined by the Common Rule, any individual conducting or assisting in the conduct of a systematic investigation designed to develop or contribute generalizable knowledge.</td>
</tr>
</tbody>
</table>
**Honest Broker.** An individual serving as a disinterested intermediary between the researcher and PHI, ensuring that the researcher does not have access to identifiable information.

### Responsibilities

**Research team responsibilities**

*Regulatory approval.* All CRISMA research projects involving PHI must be reviewed and approved by the University of Pittsburgh Institutional Review Board (IRB). CRISMA researchers are responsible for adhering to IRB-approved data storage and analysis policies at all times, including seeking the services of an Honest Broker when required.

*Data security.* CRISMA researchers or agents working with CRISMA data must maintain appropriate electronic and physical data security procedures at all times. Electronic security procedures include developing secure passwords, disabling automatic logons, locking computers when unattended, and reporting all suspicious electronic events. Physical security procedures include keeping all hard-copy PHI in locked filing cabinets in locked offices, shredding all paper records when finished, and securely delivering all hard-copy PHI to an Honest Broker as required by IRB policies.

**Honest Broker responsibilities**

*Honest Broker agreement.* The Honest Broker must execute and maintain an up-to-date Business Associate Agreement with UPMC and/or the University of Pittsburgh, the terms of which will specify the continuing confidentiality requirements, duties and other expectations of an Honest Broker service.

*Data security.* The Honest Broker must maintain all data containing PHI according to the data security procedures set out in the CRISMA Standard Operating Procedures for Data Management.

*Confirmation of IRB approval.* The Honest Broker must ensure IRB approval for the research study for which Honest Broker services are requested.

*Adherence to IRB terms.* The Honest Broker must adhere to all of the terms and conditions specified by the IRB of record for any research study for which Honest Broker services are requested, including the type of data requested (Limited Data Set or Safe Harbor Data Set) and the identity of the researchers granted access to the data.

*Ensure proper de-identification.* The Honest Broker will produce the requested dataset (either Limited Data Set or Safe Harbor Data Set) from the PHI as required by the investigator and approved by the IRB.

Maintain documentation. The Honest Broker will maintain documentation of the processes and/or systems used to develop de-identified datasets from PHI.
## Procedures

### Receipt of data
- When the Honest Broker receives PHI, the Honest Broker will upload it onto a secure data storage system as described in the CRISMA Data Management Standard Operating Procedure. Access to the PHI shall be restricted to only the Honest Broker.
- If the PHI is received via e-mail or network, the Honest Broker will ensure that the original and all copies of the file are deleted after uploading.
- If the PHI is received via paper or electronic media, the Honest Broker will lock the media in a secure file cabinet in a secure office after uploading it the appropriate secure data storage system.

### De-identification of data
- The Honest Broker will confirm IRB approval for the individual requesting data and the type of dataset requested.
- If a limited data set is requested, the Honest Broker will create a new data set containing all the data present in the original data set except for the appropriate unique identifiers. The Honest Broker will create a new study identifier and retain a crosswalk between this identifier and unique identifiers in the PHI, storing this crosswalk in a secure location.
- If a safe-harbor data set is requested, the Honest Broker will create a dataset containing all the data present in the original data except for any unique identifiers.

### Re-identification
- If re-identification of data is necessary for research and approved by the IRB, the Honest Broker will use study identifiers in the retained crosswalk to link datasets to PHI. This process will be performed in a secure computing environment as described in the CRISMA Data Management SOPs.

### Documentation
- The Honest Broker will keep a record of each data transaction, including the transaction date and time; the identity of the researcher; the name of the study; the nature of the data set; the name and location of the crosswalk file; and the corresponding IRB approval numbers. This record will kept in a secure data file as described in the CRISMA Data Management SOPs.

## Approval
- This CRISMA Standard Operating Procedure was approved by the CRISMA Executive Committee on 3.4.2013.