

SECTION 6: OTHER PRIVACY POLICIES AND PROCEDURES

6.4 Honest Broker System and Honest Broker Certification Process

POLICY

1. **Honest Broker Requirements:** An honest broker for research may be an individual, organization, or team certified to act for or on the behalf of a health-related tissue bank or databank to collect specified health information from the tissue or data bank, remove all patient identifiers, and provide the de-identified health information or tissue to research investigators in such a manner that it would not be reasonably possible for the investigators or other individuals to identify the patients directly or indirectly.
2. **Initial Review and Approval:** The University of Florida (UF) Privacy Office will review and approve honest broker applications and related documentations to determine that satisfactory evidence has been presented to meet or exceed the certification criteria. Honest Broker Program Materials, including detailed instructions and application forms are maintained in the Privacy Office and are only available by request. General information about the program, training materials, and this policy/procedure are maintained on the Privacy Office web site.
3. **Uses and Disclosures of PHI for Research:** The University of Florida (UF) will comply with privacy rule requirements of the Health Insurance Portability and Accountability Act (HIPAA) pertaining to the use and disclosure of protected health information (PHI) and de-identification of PHI used for research, as well as any applicable state laws that are not preempted by HIPAA.
4. **Limited Data Sets:** If the health information provided to research investigators is based on a limited data set, as defined by HIPAA, the investigators must also complete and obtain Institutional Review Board (IRB) approval of a UF Data Use Agreement for Limited Data Sets. This Agreement addresses various HIPAA-mandated conditions related to subsequent uses and disclosures of limited data sets; it is reviewed and approved by the Privacy Office at the time of execution (see also SECTION 3: Limited Data Sets and Data Use Agreements).
5. **Ongoing Review and Maintenance:** Each certified honest broker's individual status will be reviewed at least annually by the Privacy Office. Changes in Honest Broker status, including but not limited to additions or removals of honest brokers, will be documented, reviewed, and recertified within a reasonable time after receiving notice of the change.
6. **Applicability:** This policy applies to all UF entities and locations.

DEFINITIONS

1. **Honest Broker:** an individual, organization or team acting for, or on behalf of, the covered entity to collect health information, de-identify it, and provide it to research investigators in such a manner that it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly.
2. **Limited Data Set:** A limited data set is PHI which excludes the previously listed direct identifiers of the individual, or of relatives, employers, or household members of the individual, except for:
 - a. Town or city, State, and zip code; and
 - b. Dates

HONEST BROKER CERTIFICATION PRIVACY REQUIREMENTS

1. **Using De-Identified PHI:** PHI may only be used without patient authorization in a number of limited cases, one of which is where the PHI is de-identified. Prior written informed consent/authorization of patients for the research use of their de-identified existing health information is not required.
2. **De-Identification by Honest Brokers:**
 - a. PHI can either be de-identified by an honest broker that is part of the covered entity (designated components as defined by UF) or by an honest broker which is a business associate of the covered entity. The honest broker cannot be one of the investigators or associated with the research team for which the honest broker performs duties.
 - b. De-identified health information must not include any of the eighteen identifiers defined by HIPAA, or any other identifiers, that would allow a reasonable possibility for the investigators or other individuals to identify the patients directly or indirectly.
3. **Re-Identification Codes:** The information provided to the investigators by the honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries (i.e., a “re-identification code”), however the information linking this re-identification code to the patient’s identity must be retained by the honest broker, secured and separate from research documents; all subsequent inquiries are conducted through the honest broker.
4. **Recruitment Aids:** This approach can also be used to identify eligible patients for subsequent recruitment into clinical trials by providing a de-identified listing of the health information of potential eligible subjects, including re-identification code numbers, to the clinical trial investigators.
 - a. The honest broker would subsequently provide the names of the identified patients to the patients’ personal physicians who would contact the patients to:
 - i. Introduce the research study;
 - ii. Ascertain their interest in study participation; and
 - iii. Instruct the patients to contact the investigators or obtain their written authorization to share their interest in study participation with the investigators and to be contacted by them.
 - b. Note that direct contact of the patients by the honest broker would constitute “cold-calling”, which is prohibited.

5. HONEST BROKER CERTIFICATION CRITERIA

For an individual, organization or team to be an Honest Broker for UF, the proposed honest broker must be certified pursuant to the following process:

- a. **Sponsorship or Appointment:** Honest Brokers must be independent of and unassociated with the research teams they work for.
 - i. Individual Applicants: must be sponsored by, but not employed by, a UF research investigator who:
 - Is in good standing with a UF-recognized IRB of record, and
 - Intends to use the honest broker’s services.
 - ii. Research Teams: The Honest Broker applicants must be:
 - Appointed by a senior-level member of UF or UF Health Shands Administration

- Co-sponsored by the IRB Director
- b. **Education and Training:** The proposed honest brokers must complete education and training, currently mandated by the IRB for all research investigators, prior to submitting an application. Links for this education and training may be found on the IRB-01 website under Education/Training, and includes:
 - i. Reading the Belmont Report, the Code of Federal Regulations: 45 CFR 46, the IRB-01 Policies and Procedures, and Researcher Responsibilities.
 - ii. Completing the NIH Computer Based Training: Protecting Human Research Participants
 - iii. Completing UF's HIPAA for Researchers.
 - c. **Application:** The individual or the organization or team must submit an application to become part of the UF- and IRB-certified Honest Broker System.
 - i. The Honest Broker Certification applications are available by request from the UF Privacy Office.
 - ii. Applications should be submitted to the UF Privacy Office: by the sponsoring investigator, for an individual; or by the Research Team Leader, for an r research team.
 - d. **Attestation of Agreement:** All honest brokers must sign a written agreement that they will abide by all relevant UF and IRB guidelines, policies, and procedures, including continuing adherence to the UF honest broker certification criteria section of this policy, the duties and other requirements section (see Procedures, below), and the terms and conditions of the UF Business Associate Agreement for honest brokers (if applicable).

PROCEDURES

1. Certification, Approval, and Maintenance
 - a. Initial Review and Approval: The UF Privacy Office reviews honest broker applications and related documentation to determine whether the requirements specified in the honest broker application and certification forms are satisfied. Key criteria to be satisfied are described below.
 - i. Written documentation of the processes and/or systems to de-identify PHI.
 - ii. Written documentation of policies, procedures and controls necessary for:
 - Compliance with the HIPAA Privacy Rule and the Federal Policy regulations for human subject protections (45 CFR 46);
 - Security and management of PHI;
 - Audits and/or quality checks;
 - Retention of work-product documentation.
 - b. Ongoing Review and Maintenance: Changes in an honest broker's status should be reported immediately by the sponsoring investigator or team leader.
2. Adding and/or Removing Honest Brokers To/From a Research Team
 - a. Adding Honest Brokers:
 - i. New brokers must first complete the education/certification modules as noted in the honest broker certification section above.
 - ii. In accordance with UF policy, applicants who are not UF employees must complete and sign a Business Associate Agreement (BAA).

- iii. A complete revision of the application must be submitted to the Privacy Office with any brokers to be added reflected in the revision. A copy of any relevant BAAs must accompany the revision documents. After the Privacy Office approves the revision, a copy of the signed revised documents will be sent to the Research Team Leader. .
 - b. Removing Brokers:
 - i. A complete revision of the application must be submitted to the Privacy Office with any brokers to be removed and the reason for the removal reflected in the revision.
 - ii. After Privacy Office and the IRB approve the revision, a copy of the signed revised documents will be sent to the Research Team Leader.
3. Duties and Other Requirements of the Honest Broker:
 - a. In order for a certified honest broker to work on behalf of investigators to de-identify PHI that is owned/held by UF, the honest broker must perform the following UF-defined duties and adhere to the following UF-defined requirements.
 - b. Non-UF honest brokers must execute a Business Associate Agreement with UF:
 - i. The terms of the BAA will specify continuing confidentiality requirements, duties and other expectations UF has of an honest broker service.
 - ii. The generic UF Business Associate Agreement can be viewed at <http://purchasing.ufl.edu>. The generic Business Associate Agreement will be customized by UF to reflect the specific duties and other requirements UF specifies for honest broker services.
 - c. All certified honest brokers must ensure that approval of the IRB of record has been obtained for a research study before the honest broker acts on a request for de-identified PHI (from an investigator that is served by the IRB of record). This process may be as simple as being copied on an IRB approval letter from the IRB to the investigator. Likewise, the honest broker specified in a research application must have been prior-certified by the IRB of record in order for the IRB to approve the research application.
 - d. All certified honest brokers must adhere to any and all terms and conditions specified by the IRB of record for any research study for which the honest broker will perform de-identification services.
 - e. If an investigator requests a Limited Data Set, rather than a fully/completely de-identified data set:
 - i. The IRB of record may require evidence of a completed Data Use Agreement for a Limited Data Set as part of its application process for approval of the proposed research involving the use of a Limited Data Set.
 - ii. An individual honest broker for the investigator must obtain (and retain) evidence of an appropriately executed Data Use Agreement in order to be granted access to the UF-held PHI.
 - iii. For organizations or Honest Broker Teams, a Data Use Agreement will provide necessary evidence, for audit purposes, of UF-required detailed disclosures (honest broker data set specifications) relative to:
 - Where (in what UF entity) the PHI is located;
 - What HIPAA-defined Limited Data Set elements are needed for the research;
 - The purpose of the Limited Data Set request (detailed uses pertinent to the limited data set);

- Who (names, titles, addresses) will access, use and disclose the Limited Data Set information other than the principal investigator.
4. Honest Broker Data Requests: All requests for de-identified data must be documented. Elements to be recorded for each request include:
- a. Information from the investigator initiating the request:
 - i. The Investigator's name
 - ii. The date and time of the request entry
 - iii. The name of the study and the IRB approval number
 - iv. A detailed description of the needed data
 - v. The requested turnaround time for the report
 - vi. Any special instructions
 - b. Information from the honest broker handling the request:
 - i. The name of the individual honest broker, whether working alone or as part of an organization or team
 - ii. The purpose of the request
 - iii. The data source(s) to be used
 - iv. The fields required to retrieve the data
 - v. The method of output for the data
 - vi. Any special conditions, terms or instructions from the IRB
 - c. Billing information, if the services provided will be compensated through an institutional account rather than through grant-funded mechanisms.
 - d. Final disposition of the request:
 - i. Date the data was retrieved
 - ii. Date the report was delivered
 - iii. Name of the honest broker delivering the report, if different from the one entering the request
 - iv. The name of the person to whom the data report was delivered
5. Non-Compliance
- a. Failure by a UF-employed honest broker to abide by this policy will result in the suspension of the research protocol while non-compliant actions are investigated. Non-compliance may result in disciplinary action for both the honest broker and the principal investigator pursuant to UF regulations and UF policy. Both employed and non-employee workforce members may also be sanctioned in accordance with applicable UF procedures.
 - b. Failure by any honest broker, including business associates, to abide by this policy may result in immediate termination of their UF certification to serve as an approved honest broker and immediate termination of their business associate agreement with UF.
 - c. Questions regarding this policy should be directed to the UF Privacy Office.

REFERENCES

1. HIPAA: 45 CFR §164.302-318 (Security Standards); §164.514(d) (Minimum Necessary Requirements), §164.530 (Administrative Requirements)

EXHIBITS:

1. Honest Broker Applications are available upon request from the from Privacy Office at, <http://privacy.ufl.edu/contact-us/>