HONEST BROKER PROGRAM

Policies and Certification Procedures
So much PHI...

- Protected health information (PHI) may only be used without patient authorization in a limited number of cases. One such case is where the PHI is de-identified.
  - 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.
- Prior written informed consent/authorization of patients for the research use of their de-identified existing health information is not required.
Definitions

- **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.

- The honest broker cannot be one of the investigators.
Definitions

- **De-Identification**: Removing identifiers from protected health information so that it is not possible to connect it directly or indirectly with a specific patient.
  - 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.

- **Limited Data Set**: A limited data set is protected health information which excludes the HIPAA-defined direct identifiers of the individual, or of relatives, employers, or household members of the individual, except for:
  1. Town or city, State, and zip code; and
  2. Dates
Re-identification

• The anonymized information provided to investigators by the honest broker may include linkage codes to permit easier organization of the information and/or linking for subsequent inquiries.
• However, any 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.
Using De-identified Data

• The primary use of de-identified data in health services research focuses on outcomes information for:
  • Assessing the impact of different therapeutic regimens, and
  • Assessing quality and safety of healthcare.

• De-identified data can also be used as a first step to identify eligible patients for subsequent recruitment into clinical trials.
  • A de-identified listing of the health information of potential subjects, including re-identification codes, is provided to the clinical trial investigators for review of necessary criteria.
Using Data for Recruiting Subjects

• After reviewing the de-identified list, the investigator chooses patients who would potentially be good subjects in his or her research.

• The Honest Broker would then provide the names of the identified patients to the patients’ personal physicians, who would contact the patients to:
  1. Introduce the research study;
  2. Ascertain their interest in study participation; and
  3. Instruct the patients to contact the investigators directly or obtain the patients’ written authorization to share their interest in study participation with the investigators and to be contacted by the investigators.

• Note that direct contact of the patients by the honest broker would constitute “cold-calling”, which is prohibited, just as it is for researchers.
Certification Process

• For an individual, organization or team to be an Honest Broker for UF, the proposed honest broker must be certified

• Certification includes the following steps:
  • Education and Training
  • Sponsorship and Application
  • Verification of the Honest Broker’s Policies and Procedures
  • Approval and Certification
Education and Training

• Proposed honest brokers must complete education and training, currently mandated by the IRB for all research investigators, prior to submitting an application. This education and training includes materials found on the IRB-01 website under Education / Training:
  • Reading:
    • The Belmont Report,
    • Code of Federal Regulations: 45 CFR 46,
    • IRB-01 Policies and Procedures, and
    • Researcher Responsibilities
  • Completing:
    • NIH Computer Based Training: Protecting Human Research Participants, and
    • UF’s HIPAA for Researchers on-line training module
Sponsorship & Appointment

• The individual honest broker applicant must be sponsored by investigators who:
  • Are in good standing with a UF-recognized IRB of record AND
  • Intend to use the honest broker’s services.

• Organizations or teams applying for honest broker certification must be:
  • Appointed by a senior-level member of UF or Shands Administration
  • Co-sponsored by the IRB Director

• Applications should be submitted to the IRB (of record) by the sponsoring investigator for an individual, and by the Team Leader for an organization or team.
Approval and Certification

• Once the Honest Broker Application is previewed by the IRB, it will be forwarded to the UF Privacy Office for final approval.

• 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,
  • The duties and other requirements of the Honest Broker, and
  • The terms and conditions of the UF Business Associate Agreement for Honest Brokers (if applicable).
The Application

• The Honest Broker Application and related documentation must include written policies, procedures and controls necessary for:
  • The de-identification processes and/or systems the Honest Broker will use to develop both fully de-identified health information data sets and limited data sets, for both electronic and paper-based records, as appropriate to the record storage system.
  • Compliance with the HIPAA Privacy Rule, the Federal Policy regulations for human subject protections (45 CFR 46) and UF’s Business Associate Agreement;
  • Security and management of all PHI in the Honest Broker’s possession during the performance of honest broker functions, including security and management of re-identification keys;
  • Audits and/or quality checks to determine the efficacy of de-identification mechanisms; and
  • Maintenance and retention of work-product documentation for all work performed (for whom, what was provided, IRB approval info, etc.).
Duties and Other Requirements

- 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:
  - Business Associate Agreements for non-UF Honest Brokers;
  - Adherence to all terms and conditions of IRB-approved study protocols; and
  - Adherence to all terms and conditions for Limited Data Sets.
Business Associate Agreements

• Non-UF Honest Brokers must execute a Business Associate Agreement with UF.

• The terms of the BAA will specify continuing confidentiality requirements, duties, and other expectations UF has of an honest broker service.

• 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.
Adherence to IRB Terms

- Certified Honest Brokers must ensure that IRB approval has been obtained before acting on a request for de-identified PHI from an investigator for a research study. This process may be as simple as being copied on an IRB approval letter from the IRB to the investigator.

- Likewise, an Honest Broker specified in a research study application must already be certified in order for the IRB to approve the research application.

- Certified Honest Brokers must also adhere to any terms and conditions specified by the IRB of record for any research study for which the Honest Broker will perform de-identification services.
Limited Data Sets

• The IRB of record may require evidence of a completed Data Use Agreement as part of the application process for approval of the proposed research involving the use of a Limited Data Set.

• If an investigator requests a Limited Data Set, 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.

• For organizations or Honest Broker Teams, a Data Use Agreement will provide necessary evidence, for audit purposes, of UF-required details about disclosures:
  • Where (within 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; and,
  • Who (names, titles, addresses) will access, use and disclose the Limited Data Set information other than the principal investigator.
Data Requests Are Documented

- All requests for de-identified data must be documented.
- Elements to be recorded for each request include:
  - Information from the investigator initiating the request
  - Information from the Honest Broker handling the request
  - Billing information, if the services provided will be compensated through an institutional account rather than through grant-funded mechanisms.
  - Final disposition of the request
Adding and Removing Brokers

• New brokers must first pass the education/certification modules as mentioned in the Honest Broker certification section above.

• In accordance with UF policy, applicants who are not UF employees must complete and sign a business associate agreement (BAA).

• A complete revision of the application must be submitted to the IRB with any brokers to be added or removed reflected in the revision. A copy of any relevant BAAs must accompany the revision documents. After the IRB and the Privacy Office approve the revision, a copy of the signed revised documents will be sent to the Team Leader of the service for distribution to members of the service.
Non-Compliance

- Failure by a UF-employed Honest Broker to abide by this policy will result in the suspension of the 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 University regulations and UF policy.
- Both employed and non-employee workforce members may also be sanctioned in accordance with applicable UF procedures.
- Failure of 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/or immediate termination of their Business Associate Agreement with UF.
Questions

• Questions regarding this program should be directed to the UF Privacy Office: 352-273-1212