

UNIVERSITY OF FLORIDA
INFORMATION PRIVACY POLICIES & PROCEDURES
HEALTH INFORMATION OPERATIONAL GUIDELINES

I. Uses and Disclosures: Research

A. POLICY

Rev: 06/01/2009

Use and Disclosure: The University of Florida will use and disclose protected health information (PHI) for research involving human subjects in accordance with the federal privacy, security, and research regulations.

- a) *PHI may not be used or disclosed for research without the individual authorization of the patient or written approval from the IRB.*
- b) *“Perusing”, “trolling”, “chatting about”, or otherwise informally gathering health information about individuals with whom the researcher does not have a formal provider/patient relationship is prohibited.*

B. DEFINITIONS

1. **Research:** Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
2. **Institutional Review Board:** A committee established by the University of Florida to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the University. The IRB performs the functions of the privacy board for the University of Florida.
3. **Waiver of Authorization:** Approval by the IRB for a researcher to use and disclose PHI for a research activity, including but not limited to, identifying, recruiting, and/or enrolling subjects without the patient’s permission.
4. **Certification of Review:** Approval from the IRB for a researcher to access PHI either in preparation for conducting research, or for conducting research using decedent information.

C. PRIVACY REQUIREMENTS

1. **Authorization for Use and Disclosure:** The University of Florida may use or disclose PHI for research, regardless of the source of funding of the research, provided that the University:
 - a) *Obtains individual authorization from the patients whose PHI will be used or disclosed during the research; or*
 - b) *Obtains documentation that an Institutional Review Board (IRB) has approved a Waiver of the required individual authorizations.*
2. **Certification of Review Preparatory to Research** is available for researchers who are considering research studies and need to ensure that data is available.
 - a) *Certifications will only be considered if the researcher indicates that:*
 - (1) Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;

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- (2) No PHI will be recorded or removed from the covered entity by the researcher in the course of the review; and
 - (3) The PHI for which use or access is sought is necessary for the research purposes.
- b) *Since no identifiable information may be collected under this Certification of Review, sharing of PHI by any method is strictly prohibited.*
- 3. **Certification for Decedent Research** is available if a research study requires the use or disclosure of PHI of deceased individuals'. The researcher must show:
 - a) *That the use or disclosure sought is solely for research on the PHI of decedents;*
 - b) *Documentation, if requested, of the death of such individuals; and*
 - c) *That the PHI for which use or disclosure is sought is necessary for the research purposes.*
- 4. **Accounting of Disclosures:** Certain disclosures of PHI being used under a Waiver of Authorization or a Certification must be tracked for Accounting of Disclosures purposes. (See Accounting for Disclosures in this manual.)

D. PROCEDURES

1. Requests for Records or Health Data:

- a) *Prior to requesting or reviewing patient information, obtain authorization from the patients who are the subjects of the documentation, or if obtaining such authorizations is impracticable or impossible, apply for an IRB Certification for Review or Waiver of Authorization.*
- b) *When using a Waiver of Authorization, requests for patient information should be sent to the Decision Support Services of either UF or Shands.*
 - (1) Do not ask clinic or department managers to produce lists of identifiable patient information from their data access resources.
 - (2) You will be required to provide copies of IRB documentation, showing exactly what was approved for use under the waiver, to the UF or Shands Privacy Office, depending on which institution holds the patient information.

2. Document Storage:

- a) *Any paper documents or electronic media used in research that contain PHI or other restricted data must be stored in accordance with UF's information security standards. (See Retention, Archiving, and Storage)*
- b) *Any documentation specifically required by HIPAA regulations must be retained for a minimum of six years.*
- c) *HIPAA-mandated research documents may be imaged and stored electronically, provided that all security requirements are met. Electronic records must be backed up sufficiently to prevent loss of documentation in the event of electronic malfunctions or other events.*

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3. Improper Procedures:

- a) *In the event that a Principle Investigator (PI) fails to obtain proper Authorization from individual subjects before beginning research or reviews preparatory to research,*
- (1) The PI will either:
 - (a) *Reconsent: Obtain the IRB-approved authorization from individual subjects within 30 calendar days of identification of the faulty authorization; or*
 - (b) *Destroy Data: Immediately destroy all data and corresponding specimens collected under the faulty authorization.*
 - (2) The PI must attest to, in writing, which option (above) was chosen and its completion date in a letter to the Chief Privacy Officer.
 - (a) *For option a, Reconsenting:*
 - (i) The letter must be received in the Privacy Office within 5 business days after the 30-day cut-off date.
 - (ii) Authorizations may be obtained by mail from individual subjects. Letters requesting such authorization must be post-marked within the 30-day reconsenting period.
 - (b) *For option b, Destruction of Data and Specimens: The letter must be received in the Privacy Office within 5 business days after the failure to obtain a proper authorization is identified and reported.*
- b) *In the event that a PI fails to obtain a proper Certification or Waiver of Authorization from the IRB before beginning research or reviews preparatory to research,*
- (1) The PI will immediately destroy all data and corresponding specimens affected.
 - (2) The PI must attest in writing that the data and specimens were destroyed and the completion date in a letter to the Privacy Officer of the University of Florida. The letter must be received in the Privacy Office within 5 business days after the failure to obtain a proper waiver is identified and reported.

E. REFERENCES

1. **HIPAA:** 45 CFR §164.512(i) (Uses and disclosures for research purposes)
2. **UF HSC IRB-01 Policies and Procedures:** (II.L.) IRB Review of HIPAA Documentation in Human Subjects Research

F. EXHIBITS: None