



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 1 of 9

1 PURPOSE

This document outlines procedures to ensure subject privacy and confidentiality of data during the review and conduct of human subject research (HSR) at the University of Miami (UM). The policy is for investigators when conducting HSR and the IRB in reviewing and approving, human subject research.

- 1.1 The process begins upon receipt or creation of any identifiable health information.
- 1.2 The process ends when the identifiers relating to the subject in the study are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 GUIDING PRINCIPLES

- 3.1 UM is committed to protecting the privacy of human subjects and the confidentiality of all data obtained, collected or created to the fullest extent possible during the conduct of HSR.
- 3.2 Except as permitted in Section 8.1 and 8.3 of this policy, no person may conduct HSR involving use or disclosure of identifiable patient information or creation of health information about a study participant without submitting a completed application to the IRB through the eProst electronic system and receiving approval of said application. This requirement includes, but is not limited to, persons who propose to conduct research that:
 - 3.2.1 Is exempt from IRB review under the Common Rule but involves patients of a Covered Entity or accesses, obtains or creates identifiable patient information about a study participant;
 - 4.1.1 Involves the use of human biological materials or tissues that are individually identifiable.

4 DEFINITIONS

- 4.2 **“Authorization for use and disclosure of protected health information”** means a written document used by the individual to allow access to, and use and disclosure of, identifiable health information about them for a specific purpose by an entity covered by the HIPAA Privacy Rule. The authorization must include the information described in federal regulation 45 CFR 164.508 and must be signed and dated by the individual or the individual’s legally authorized representative.
- 4.3 **“Coded”** means
 - 4.3.1 The removal of identifying information (see the information listed in Table 4.6 below)) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain; and
 - 4.3.2 The use of a code or other means of record identification to replace the identifiers provided that the code is not derived from or related to information about the individual and could not be translated to identify the individual;
 - 4.3.3 The existence of a key to decipher the code, enabling linkage of the identifying information to the private information or specimens; and



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 2 of 9

4.3.4 The protocol, a data use agreement, or other requirement prohibits the Covered Entity or individual responsible for maintaining the code from disclosing the identity of the individual to whom the information or specimen pertains. Coded data that meet the requirements above are not considered identifiable under the HIPAA Privacy Rule.

4.4 **“Confidentiality”** refers to the principle in medical ethics and law that the information a patient reveals to a health care provider is private and has limits on how and when disclosure to a third party is permitted.

4.5 **“Covered Entity”** refers to an entity that must comply with the HIPAA Privacy and Security Rules. Such entities include:

4.5.1 Health care providers that transmit information in an electronic form for certain purposes;

4.5.2 Health plans that provide or pay the cost of medical care;

4.5.3 Health care clearinghouses that process nonstandard information they receive from another entity into a standard format or vice versa.

4.5.4 Business Associates that create, maintain, receive, or transmit protected health information when performing certain functions or activities on behalf of, or providing certain services to, a Covered Entity.

4.6 **“De-identified data”** means:

4.6.1 The data elements listed in Table 4.6 relating to an individual, the individual’s relatives, employers, or household members are (removed) not included with information or specimen; or

4.6.2 An expert in rendering information not individually identifiable determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, to identify the individual who is the subject of the information.

Table 4.6 Elements of Identification

<ul style="list-style-type: none"> • Name • Geographic subdivisions smaller than a state (address, city zip code) • Dates relating to the subject except for year for individuals < age 90 • Telephone numbers • Fax numbers • Social Security Numbers • Medical record numbers • Health plan beneficiary numbers • Account numbers 	<ul style="list-style-type: none"> • Certificate/license numbers • Device identifiers and serial numbers • Web Universal Resource Locators (URLs) • Internet Protocol (IP) address numbers • Email addresses • Biometric identifiers, including finger and voice prints • Full face photographic images and any comparable images;
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 3 of 9

<ul style="list-style-type: none"> • Vehicle identifiers, serial numbers, including license plate numbers 	<ul style="list-style-type: none"> • Any other unique identifying number, characteristic, or code except a code assigned to allow for information de-identified to be re-identified by the covered entity.
--------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

- 4.7 **“Individually identifiable health information”** is information, including demographic data, that:
 - 4.7.1 Is created or received by a health care provider, health plan, employer or health care clearinghouse; and
 - 4.7.2 Relates to:
 - 4.7.2.1 The individual’s past, present or future physical or mental health or condition;
 - 4.7.2.2 The provision of health care to the individual; or
 - 4.7.2.3 The past, present, or future payment for the provision of health care to the individual; and
 identifies the individual or for which there is a reasonable basis to believe that it can be used to identify the individual.
- 4.8 **“Legally Authorized Representative”** or **“LAR”** for research purposes means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research or to authorize the use and disclosure of the individual’s identifiable health information for research purposes.
- 4.9 **“Limited Data Set”** refers to protected health information from which the identifiers listed in Table 4.6 have been removed with the exception of dates relating to the data subject (including their age) and city, state and zip code relating to the data subject. A limited data set may be used and disclosed for research, provided the data recipient enters into a [data use agreement](#) promising specified safeguards for the protected health information within the limited data set.
- 4.10 **“Personally Identifiable Information”** or **“PII”** means any information that (i) can be used to identify, contact, or locate an individual, either alone or combined with other data, including without limitation, name, fingerprints or other biometric (including genetic) data, email address, telephone number, dates, social security number, or any other unique identifying number or characteristics.
- 4.11 **“Protected health information”** or **“PHI”** refers to all individually identifiable health information (see Table 4.6) maintained or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 4 of 9

4.12 “Waiver of Authorization” means a determination made by an IRB or Privacy Board to waive the requirement for an authorization from the individual to use that individual’s identifiable health information.

5 RESPONSIBLE INDIVIDUALS

5.1 Any investigator or research team member who accesses, obtains, or creates identifiable health information for purposes HSR.

5.2 HSRO staff and IRB members who review HSR.

6 PROCEDURES – Investigators and research team members

6.1 In most instances, investigators who propose to conduct research procedures using identifiable patient information maintained by or on behalf of a Covered Entity, or resulting in the creation of health information about a study participant, shall submit a proposal to the IRB through eProst.

6.2 Notwithstanding the above general prohibition and other provisions in this policy, a clinician may review the Covered Entity’s records relating to his or her own patients for purposes of developing a research protocol and identifying and recruiting research participants.

6.3 In addition, investigators may review the Covered Entity’s records of patients who are not his or her own patients for purposes of developing a research protocol and/or identifying potential research subjects under the following conditions:

6.3.1 Investigators must submit to the HSRO a signed investigator [Certification for Reviews Preparatory to Research \(Form E\)](#) and receive acknowledgement from the HSRO; or

6.3.2 Include in an IRB submission, a request for a waiver of the requirement for an authorization from the individual to access the individual’s PHI and receiving approval of a Waiver of Authorization for Recruitment (See Section 6.4.4).

6.4 With the exceptions cited in Section 6.3.1 and 6.3.2 above, investigators and research team members must not obtain, use, create or disclose identifiable patient information for research purposes unless one of the following conditions are satisfied:

6.4.1 Authorization - Each participating subject (or the subject’s legally authorized representative) signs and dates a completed written authorization in, compliance with Section 7.5 below, permitting the use and disclosure of the participant’s information for the research purposes;

6.4.2 Limited Data Set with Data Use Agreement - The information is furnished to the investigator in a Limited Data Set (See Section 4.9) and the recipient signs a data use agreement for disclosure of the Limited Data Set;

6.4.3 [Investigator Certification for Research with Decedents’ Information \(Form D\)](#) – Access to PHI relating to deceased individuals is permitted when an investigator submits a completed and signed FORM D to the IRB and receives an acknowledgement from the IRB (see Section 7.5.2).



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 5 of 9

- 6.4.4 Waiver of Authorization – Investigators request a Waiver of Authorization from the IRB or Privacy Board and receive approval of the waiver in writing from the IRB or Privacy Board.
 - 6.4.4.1 A waiver of authorization may be for specific research procedures such as recruitment or for the entire research protocol.
 - 6.4.4.2 The IRB will approve a waiver of authorization for the minimum amount of PHI necessary to conduct the research procedures covered by the waiver.
 - 6.4.4.3 The IRB will approve a waiver of authorization for a specific research study and investigators are not permitted to use subjects’ identifiable health information accessed, obtained or created under the waiver for any purpose that is not part of the original research study.
 - 6.4.4.4 To obtain IRB approval of a waiver of authorization for use and disclosure of PHI, the investigator must include the following information in the IRB submission:
 - 6.4.4.4.1 A description of an adequate plan to protect the identifiers (see Table 4.6) from improper use and disclosure; and
 - 6.4.4.4.2 A description of an adequate plan to destroy the identifiers at the earliest opportunity;
 - 6.4.4.4.3 Written assurances that the PHI will not be reused or disclosed to any other person or entity except as required by law, for oversight of the research or for other research for which an authorization or waiver of authorization is obtained;
 - 6.4.4.4.4 Sufficient information for the IRB to determine the proposed research could not be practicably conducted without the waiver; and
 - 6.4.4.4.5 Sufficient information for the IRB to determine the proposed research could not be practicably conducted without access to and use of the PHI.
- 6.5 For access to UHealth and Jackson Health System records, investigators must use [Authorization to Use and Disclose Health Information \(FORM B\)](#), unless the institution grants an exception.
 - 6.5.1 Each authorization is for one specific research study.
 - 6.5.2 Investigators must carefully review the authorization document (Form B) and select the specific categories of they will access, obtain or create.
 - 6.5.3 Investigators must not combine the authorization with any other document, including the informed consent document unless specifically permitted by a UM IRB.
 - 6.5.4 Investigators must include a copy of the proposed completed Form B in the IRB submission.



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 6 of 9

- 6.5.5 When an authorization is required to access, obtain or create PHI of non-English speaking subjects for research purposes, investigators must obtain a translation of the completed Form B in the language the subject can understand; or obtain the services of a translator to provide translation when obtaining authorization from the subject.
- 6.5.6 Subjects who agree to authorize the use and disclosure of their PHI, as described in the authorization, must sign and date the authorization.
 - 6.5.6.1 If the subject lacks capacity to authorize the use and disclosure of the PHI, the subject’s LAR must sign and date the authorization.
 - 6.5.6.1.1 The individual obtaining the authorization must document the authority of the LAR to authorize the use and disclosure of the PHI on behalf of the subject in addition to the obtaining the signature and date from the LAR.
- 6.5.7 The research participant or the LAR must be given a copy of the signed and dated authorization at the time of signature.
- 6.5.8 As soon as reasonably possible after it has been signed, the investigator shall place a copy of the authorization in the participant’s medical record from which information about the participant will be accessed or disclosed.
- 6.6 Tracking Disclosures – Investigators must comply with UM policy relating to tracking all disclosures of patient information by completing [HIPAA Attachment 45 – Accounting for Disclosures](#) and submitting the form to the UM Privacy Office in a timely manner. A simplified Accounting of Disclosure may be done when disclosures of PHI for a particular research purpose are for 50 individuals or more. Investigators must track disclosures whenever identifiable patient information is accessed through:
 - 6.6.1 Certification for Reviews Preparatory to Research (Form E);
 - 6.6.2 A Waiver of Authorization from an IRB or Privacy Board; and
 - 6.6.3 Certification for Research with Decedents’ Information.
- 6.7 Upon learning of inappropriate access, loss or theft of PHI or PII, investigators and research team members must immediately report the event to the [University of Miami Office of Privacy & Data Security](#) using [HIPAA SECURITY INCIDENT REPORT FORM](#). If the inappropriate access, loss or theft of PHI occurs as part of the conduct of HSR, the event must also be reported to the HSRO.
- 7 PROCEDURES – IRB Members and HSRO Staff**
 - 7.1 Data Security Ancillary Committee Review
 - 7.1.1 When ancillary review by the Data Security Ancillary Review Committee is triggered through the eProst submission, ensure the Research Data Security Assessment Form is submitted.



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 7 of 9

- 7.1.2 Review Data Security Ancillary Committee submissions on eProst to determine if the investigator must address any deficiencies in the data privacy plan;
- 7.1.3 When the Data Security Ancillary Review Committee requests modifications to the data privacy plan, review the revised privacy plan to see if the modification is consistent with the requirements of the Committee;
- 7.2 Authorization to Use and Disclose Health Information (Form B)
 - 7.2.1 IRB Reviewers must review Form B to ensure the investigator has selected the appropriate categories of information and has added the required information to the document.
- 7.3 Investigator Certification for Reviews Preparatory to Research (Form E)
 - 7.3.1 Upon receipt of a Form E, the IRB staff member will review the form to determine if it is complete and includes the investigator's signature;
 - 7.3.2 Upon a determination that Form E is complete, the IRB staff member will send an acknowledgement communication to the investigator.
 - 7.3.3 The HSRO will maintain all Form Ds and acknowledgement communications for a minimum of six (6) years from (i) the date of the investigator's signature or (ii) the date the deceased individual's or participant's information was last disclosed pursuant to the certification, whichever is later. Prior to destroying these records, the IRB will contact the investigator to determine the last date the deceased individual's information was accessed.
- 7.4 Waivers of Authorization
 - 7.4.1 HSRO staff members and IRB members will review research submissions to determine:
 - 7.4.1.1 Whether a Waiver of Authorization is necessary for the conduct of the proposed research;
 - 7.4.1.2 Whether the submission includes adequate provisions to protect the data accessed under the waiver;
 - 7.4.1.3 Whether the submission includes the required representations (see Section 6.4.4.4).
 - 7.4.2 Waiver of Authorization determinations may be made:
 - 7.4.2.1 By a majority of the members present voting in favor of the waiver at a convened IRB meeting; or
 - 7.4.2.2 By a designated reviewer using the expedited review procedure when the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is requested.
 - 7.4.2.2.1 When the requirements are satisfied, a designated reviewer may approve a waiver of authorization during initial



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 8 of 9

review of proposed research or during review of a minor modification to previously approved research.

7.4.2.3 IRB members and designated reviewers use CHECKLIST Waiver of Authorization (HRP-441) to document that the criteria for the waiver are satisfied.

7.4.2.3.1 The HSRO retains completed CHECKLISTS Waiver of Authorization (HRP-441) in eProst indefinitely.

7.4.2.4 HSRO staff must notify investigators of a determination to approve a Waiver of Authorization in the correspondence used to notify investigators that the IRB approved a submission.

7.5 Investigator Certification for Research with Decedents' Information (Form D)

7.5.1 Upon receipt of a Form D, the HSRO staff member will review the form to determine if it is complete and includes the investigator's signature.

7.5.2 Upon a determination that Form D is complete, the HSRO staff member will send an acknowledgement communication to the investigator.

7.5.3 The HSRO will maintain all Form Ds and acknowledgement communications for a minimum of six (6) years from (i) the date of the investigator's signature or (ii) the date the deceased individual's information was last disclosed pursuant to the certification, whichever is later. Prior to destroying these records, the IRB will contact the investigator to determine the last date the deceased individual's information was accessed.

7.6 Upon learning of inappropriate access, loss or theft of PHI or PII, HSRO staff and IRB Committee Members must immediately report the event to the [University of Miami Office of Privacy & Data Security](#) using the HIPAA SECURITY INCIDENT REPORT FORM.

8 REFERENCES

- 8.1 45 CFR 160, 164 AND 164
- 8.2 Data Security Ancillary committee Standard Operating Procedure
- 8.3 [OCR HIPAA Privacy](#)
- 8.4 [Guidance on HIPAA and Individual Authorization of Uses and Disclosures of Protected Health Information for Research](#)
- 8.5 [HIPAA Privacy Booklet for Research](#)
- 8.6 [Authorization to Use and Disclose Health Information \(FORM B\)](#)
- 8.7 [Investigator Certification for Research with Decedents' Information \(Form D\)](#)
- 8.8 [Certification for Reviews Preparatory to Research \(Form E\)](#)
- 8.9 [HRP 441: CHECKLIST: HIPAA Waiver of Authorization](#)
- 8.10 [Data Use Agreements](#)
- 8.11 [HIPAA Attachment 45 – Accounting for Disclosures](#)
- 8.12 [HIPAA SECURITY INCIDENT REPORT FORM](#)



SOP: PRIVACY & SECURITY PROCEDURES FOR HUMAN SUBJECT RESEARCH

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-098	06/06/2019	C.Gates	J. Bixby	Page 9 of 9