ORLANDO HEALTH®

1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

Type of Policy:	**PROTECTION OF HUMAN RESEARCH PARTICIPANTS**	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***HIPAA Research and Privacy Board Policy***	Policy #:	**0330-1024**
		Replaces #:	
Page:	1 of 4	Developed By:	Orlando Health Institutional Review Board
Issue Date:	**09/14/22,**	Approved By:	Philip Giordano, MD Institutional Official SIGNATURE ON FILE
Revision Dates:			

I. PURPOSE:

This policy is to provide researchers with information they will need to comply with the Privacy Rule associated with the Health Insurance Protability and Accountability Act of 1996 ("HIPAA").

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Authorization: is permission to gain access to PHI. Authorization may be obtained by signing a separate document or incoproating authorization language into a consent form.

B. Protected Health Information (PHI): Data, including demographic information, collected from an individual and created or received by Orlando Health that:
   1. Relates to the past, present, or future physical or mental health conditions of an individual, the provisions of healthcare to an individual, or the past, present, or future payment for the provision of healthcare to an individual; and
   2. Identifies or can be used to identify the individual

C. HIPAA (Health Insurance Portability and Accountability Act) – HIPAA regulates the transfer and collection of PHI between and within covered entities defined as:
   1. (a) health care plans;
   2. Health care clearing house; and health care providers who electronically transmit any health information.

D. Covered Entity: HIPAA applies to "Covered Entites" defined by tehe Privacy Rule as a healthcare provider that conducts certain transations in electronic form, a healthcare clearinghouse, a health plan, or a business associate (Person or organization) performing a function on behalf of the Covered Entity for which access to protected health information is needed.

E. Privacy Rule: established the minimum federal standards for safeguarding the privacy of individually indentifable health information (also referred to as protected health information (PHI)). The Department of Health and Human Services (DHHS) issued the privacy rule in order to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which required compliance as of April 14, 2003 (see 45 CFR part 160 and subparts A and E of part 164).

F. Research Privacy Board: a review body which acts upon the HIPAA Privacy Rule's authorization requirements for use or disclose of PHI for specific research protocol. The Privacy Board's authority is limited to approval of privacy lanauge; approval of the use of PHI from individuyals and review of HIPAA compiliance allegations. Orlando Health and its affiliated hospital empower the Orlando Health IRB to act as Privacy Board on behalf of each covered entity.

G. Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research **(**Stand Alone HIPAA Form): A stand-alone HIPAA authorization (for research) is used to obtain permission from an individual for a covered entity to use and/or disclose the individual's identifiable health information for a research study, and that is not combined with an informed consent document to participate in the research. This form is utilized by Orlando Health for use of External IRBs.

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III. POLICY:

The HIPAA Privacy regulations are focused on health care protection. If a research study either uses or creates health care information, HIPAA documentation requirements apply to those research uses of health care information in addition to relevant privacy and confidentiality protections that are required by ethics and federal regulation for human research subject protection.

IV. PROCEDURE:

A. Any research study involving collection or use of PHI must comply with HIPAA. It is the responsibility of the investigator to comply with HIPAA Authorization/Privacy Rule requriemetns and the polices related to use of PHI in research as outlined by Orlando Health HIPAA Policies. The Orlando Health HRPP and the IRB offices utilize Orlando Health Patient Care Policy's # 8462 and #8380 for research purposes.
   1. Within Patient Care Policy #8380 Titled Limited Data Sets, it describes research involving PHI or limited data sets.
   2. Within Patient Care Policy #8462 III & IV (A), sets requirements for authorizations.
   3. Within Patient Care Policy #8462 III & IV (B), sets requirements for waiver of authorization.
   4. Within Patient Care Policy #8355, titled De-identification of Protected Health Information, describes the process for HIPAA de-identification.
   5. Within Patient Care Policy #8462 IV (B) 2 describes requirements for using PHI preparatory to research.
   6. Within Patient Care Policy #8380 (B) 4, data use agreements requirement is described.

B. Principal Investigator is responsible for:
   1. Accurate and complete representation of the study's use and disclosure of PHI and data privacy practices to the IRB.
   2. Compliance of all research study team members with this policy in accessing and using PHI for research. Although an investigator or a research study team member may have access to PHI for her/his clinical roles, PHI may not be transferred from clinical or other health care provider records to research use except in policies as described in Section A.
   3. Compliance of all research study team members with the PHI access procedures of any Covered Entity from whose records an OH researcher seeks PHI for research.
   4. Compliance of all research study team members in using and disclosing PHI only in accord with the terms and conditions of the permissions under which the PHI was received for research, which may include: informed consent, authorization, IRB waiver of informed consent, IRB waiver of authorization, limited waiver of authorization, data use agreement, sponsored research agreement, or access for review preparatory to research or solely for decedents.

C. Research Study Team Member is responsible for:

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1. Compliance with this policy in accessing and using PHI for research. Although a research study team member may have access to PHI for her/his clinical roles, PHI may not be transferred from clinical or other health care provider records to research use except in policies as described in Section A.
2. Compliance with the PHI access procedures of any Covered Entity from whose records the researcher seeks PHI for research.
3. Use and disclosure of PHI only in accord with the terms and conditions of the permissions under which the PHI was received for research, which may include: informed consent, authorization, IRB waiver of informed consent, IRB waiver of authorization, limited waiver of authorization, data use agreement, sponsored research agreement, or access for review preparatory to research or solely for decedents.

D. Orlando Health Privacy Officer is responsible for:
1. Assistance to the IRBs in resolving human subjects research review or performance issues related to HIPAA privacy regulations.
2. Assistance to Covered Entities in obtaining information required for their compliance with HIPAA regarding Orlando Health research access and use of PHI in the Covered Entities' designated record sets.
3. The Privacy Officer, rather than the patient or the covered entity, will make contact with the IRB and researchers as necessary and will be responsible for the response to the request.
4. Orlando Health response to complaints of privacy violations in the conduct of Orlando Health research.

E. The Institutional Review Board will perform the following HIPAA review and approval responsibilities within the larger context of its responsibilities for the protection of human research participants which include review of privacy and confidentiality issues broader than those covered by HIPAA:
1. Review and approval of all authorization documents used by Orlando Health researchers in the informed consent process for research.
2. Review and approval of all waivers of authorization, included limited waivers of authorization, for access, use and/or disclosure of PHI for research purposes.

V. DOCUMENTATION:

NONE

VI. REFERENCES:

A. The Orlando Health HRPP and the IRB offices utilize Patient Care Policy# 8462 and #8380 for research purposes.
B. 1. Within Patient Care Policy #8380 Titled Limited Data Sets, it describes research involving PHI or limited data sets.
C. 2. Within Patient Care Policy #8462 III & IV (A), sets requirements for authorizations.
D. 3. Within Patient Care Policy #8462 III & IV (B), sets requirements for waiver of authorization.
E. 4. Within Patient Care Policy #8355, titled De-identification of Protected Health Information, describes the process for HIPAA de-identification.
F. 5. Within Patient Care Policy #8462 IV (B) 2 describes requirements for using PHI preparatory to research.
G. 6. Within Patient Care Policy #8380 (B) 4, data use agreements requirement is described.

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VII. ATTACHMENTS:

Waiver of Consent, documentation, or Use of PHI Form
Authorization (Permission) to Use or Disclose (Release) identifiable Health Information for Research Form (Stand alone HIPAA Agreement)
Data Use Agreement and Approval