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 3	Developed By:	Orlando Health Institutional Review Board
Issue Date:	09/14/22	Approved By:	Philip Giordano, MD Institutional Official
Revision Dates:	07/15/25		**SIGNATURE ON FILE**

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:

Please refer to the IRB Definitions Policy.

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 (participant) 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.

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C. Research Study Team Member is responsible for:
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 (participants) 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

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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.

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