

Type of Policy:	<b>PROTECTION OF HUMAN RESEARCH PARTICIPANTS</b>	Category:	<b>Orlando Health Institutional Review Board (IRB)</b>
Title:	<b>Research on Decedents</b>	Policy #:	<b>0330-1018</b>
Page 1 of 2		Replaced #:	ORMC 6000-404; MDACCO 1000-0001
Issue Date:	<b>5/17/05</b>	Issued By:	Orlando Health Institutional Review Board
Revision Dates:	11/9/07, 8/11/14, 4/4/17, 4/21/20	Approved By:	Philip Giordano, MD Institutional Official <b>SIGNATURE ON FILE</b>

**I. PURPOSE:**

This policy establishes guidance on research involving decedents.

**II. DEFINITION:**

- A. Human subjects: Human subjects are defined by HHS Regulations at 45 CFR 46.102(f) as “a **living** individual about whom an investigator conducting research
  - i. obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or
  - ii. obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- B. Protected health information (PHI): Individually identifiable health information, held or maintained by an Orlando Health or its business associates acting, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable and other information relating to the past, present or future physical or mental health or condition of an individual, the provision of healthcare to an individual, or the past, or future payment for the provision of healthcare to an individual.

**III. POLICY:**

Decedents are afforded the same privacy protections as the living under HIPAA. The HIPAA Privacy Rule applies to individually identifiable health information of a decedent for 50 years following the date of death of the individual. However, HIPAA does make exceptions in the area of research on decedents. Research that is being done solely on decedents normally does not require prior approvals from the IRB because it usually does not meet the definition of “human subjects”. It does, however, require determination from Compliance & Ethics at Orlando Health who are also free to impose additional restrictions on access to information about decedents according to its own internal policies.

**IV. PROCEDURE:**

- A. The researcher must comply with 45 CFR 164.512(i)(1)(iii), “Research on decedents’ information”, where:
  - a. The use or disclosure being sought is solely for research on the decedents (not, e.g., for research on living relatives of decedents);
  - b. The decedents’ PHI being sought is necessary for the research; and
  - c. If requested by the covered entity (Compliance & Ethics at Orlando Health), documentation of the death of the individuals about whom PHI is being sought.
- B. The researcher may request an IRB determination letter from the IRB by using the appropriate IRB form.

**V. DOCUMENTATION:**

- A. Not Human Subjects Research Work Sheet/Cover Sheet.



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**VI. REFERENCES:**

- A. 45 CFR 164.512(i)(1)(iii)
- B. HIPAA Privacy Rule Guidance “Health Information of Deceased Individuals”
- C. Orlando Health, Inc. Uses and Disclosures (PHI) Research Purposes #8462
- D. IRBNet Forms and Templates

**VII. ATTACHMENTS:**

- A. None.