

Type of Policy:	PROTECTION OF HUMAN RESEARCH PARTICIPANTS	Category:	Orlando Health Institutional Review Board (IRB)
Title:	Research on Decedents	Policy #:	0330-1018
Page 1 of 2		Replaced #:	ORMC 6000-404; MDACCO 1000-0001
Issue Date:	5/17/05	Issued By:	Orlando Health Institutional Review Board
		Approved By:	Philip Giordano, MD Institutional Official SIGNATURE ON FILE
Revision Dates:	11/9/07, 8/11/14, 4/4/17, 4/21/20, 7/12/23, 7/15/25		

I. PURPOSE:

This policy establishes guidance on research involving decedents.

II. DEFINITION:

Please refer to the IRB Definition Policy.

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.

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

Type of Policy:	<i>PROTECTION OF HUMAN RESEARCH PARTICIPANTS</i>	Category:	Orlando Health Institutional Review Board (IRB)
Title:	<i>Research on Decedents</i>	Policy #:	0330-1018
		Replaced #:	ORMC 6000-404; MDACCO 1000-0001
Page 2 of 2		Issued By:	Orlando Health Institutional Review Board
Issue Date:	5/17/05	Approved By:	
			Philip Giordano, MD Institutional Official SIGNATURE ON FILE
Revision Dates:	11/9/07, 8/11/14, 4/4/17, 4/21/20, 7/12/23, 7/15/25		

VII. ATTACHMENTS:

A. None.