NOVA SOUTHEASTERN UNIVERSITY

Privacy of Protected Health Information in Research

Overview, Regulatory Support and References:

The Belmont Report's principles of Respect for Persons and Beneficence implies for us to protect the privacy of personal health information. Research, however, is dependent on the release of information to individuals that may not have the legal obligation or safeguards customarily found in a healthcare setting. Given that, an individual should know who will receive their data, what data is needed, when will it be released (or no longer released) and any other information surrounding the further use and disclosure of their data. With that knowledge, the subject may give their written authorization to release the data necessary to do the research.

Nova Southeastern University HIPAA RESEARCH USES AND DISCLOSURES POLICIES AND PROCEDURES Updated December 2009 applies to (1) all NSU covered health care clinics and departments that allow access to PHI by researchers for research ; and (2) all researchers

LINK TO HIPAA POLICY MANUAL & FORMS

http://www.nova.edu/irb/manual/forms/hipaa_general.pdf

- 45C.F.R. 164.502(a)(1)(i), 164.508, 164.512(i), 164.514(a), 164.514(b), 164.514(e)
- NIH's "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule" (April 14, 2003) http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf
- NIH's "Clinical Research and the HIPAA Privacy Rule" (February 5, 2004) http://privacyruleandresearch.nih.gov/pdf/clin_research.pdf
- Guidance for Industry: IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations (http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0204-gdl0001.pdf)