

Data Sharing: Select Legal Considerations

Jennifer S. Geetter

202-756-8205

jgeetter@mwe.com

Does not constitute
legal advice

www.mwe.com

Boston Brussels Chicago Düsseldorf Frankfurt Houston London Los Angeles Miami Milan Munich New York Orange County Paris Rome Silicon Valley Washington, D.C.
Strategic alliance with MWE China Law Offices (Shanghai)

© 2012 McDermott Will & Emery. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery AARPI, McDermott Will & Emery Belgium LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. These entities coordinate their activities through service agreements. This communication may be considered attorney advertising. Previous results are not a guarantee of future outcome.

- Significant public concern about privacy
- Disagreement about default settings
 - Model 1: Very restricted access with a presumption of non-disclosure
 - Model 2: “Rules of the road” emphasis with a presumption of balancing confidentiality with socially useful uses and disclosures
- Strong public demand for biomedical innovation
- On-going push/pull relationship with health information informed by the need at the time

- On-going rule making
- Lack of harmonization
- Potential pending guidance on important data sharing topics
- De-identifiability of human biospecimens
- Implementation of FDA “Part 11” Rule

- Preparatory to Research Exception
- Future Use
- CLIA Research Exception Limitations
- Contractual constraints in multi-institution collaborations

- Leveraging EHRs/Certification Standards
- PSOs
- ACOs