Big Data and Legal Barriers to Scientific Discovery: Patient & Data Owner Interactions

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Culture Change

• permissioning data: a culture change from privacy protection
  - donating genomic data to databases,
  - risks,
  - facilitation.

• informed consent for complex discovery.
  - changing definition; an outdated model?
(Self) Assessment Tests

- big data platforms for large scale test validation (ie. heart disease risk assessment, stroke risk, etc. [http://hp2010.nhlbihin.net/atpiii/calculator.asp](http://hp2010.nhlbihin.net/atpiii/calculator.asp))

- downstream acceptance: implementing recommendations for breast cancer and other provider based tests.
Driver: Data Availability

• legal templates, health care system reforms, technological insertion, legal reform (FDA requirements on validation data vs trade secrets), education (ie http://weconsent.us), ...

• examples and prototypes that are around today? community standards for sharing, protocols, ...

• rewarding information sharing: returning results, examples of impact, ...
Data Donors

- Central repository for (identified) patient data,
  - points / award levels for sharing / citation
  - identification of potential donors
  - permissioning claims data
  - shielding patient genomic data / anonymization technics
  - integration of clinical trials of I