Bio International Convention

The Global Event for Biotechnology

May 18–21, 2009, Monday–Thursday
Georgia World Congress Center
Atlanta, GA USA

Heal, Fuel, Feed The World.

# Transforming the Research Paradigm

## *21st Century Models to Unify Discover Research and Clinical Care*

**Date:** Tuesday, May 19th

**Time:** 10:00am

**Speaker:** Rachel Nosowsky, JD (Senior Counsel, Miller, Canfield, Paddock and Stone, PLC)

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# *Privacy and Research Regulations for Clinical Research and Health Information Exchange*

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OHRP "Doing it right...together"

AAHRPP Association for the Accreditation of Human Research Protection Programs, Inc.®

FDA

NATIONAL INSTITUTES OF HEALTH

CMS Centers for Medicare & Medicaid Services

ORI

DEPARTMENT OF JUSTICE

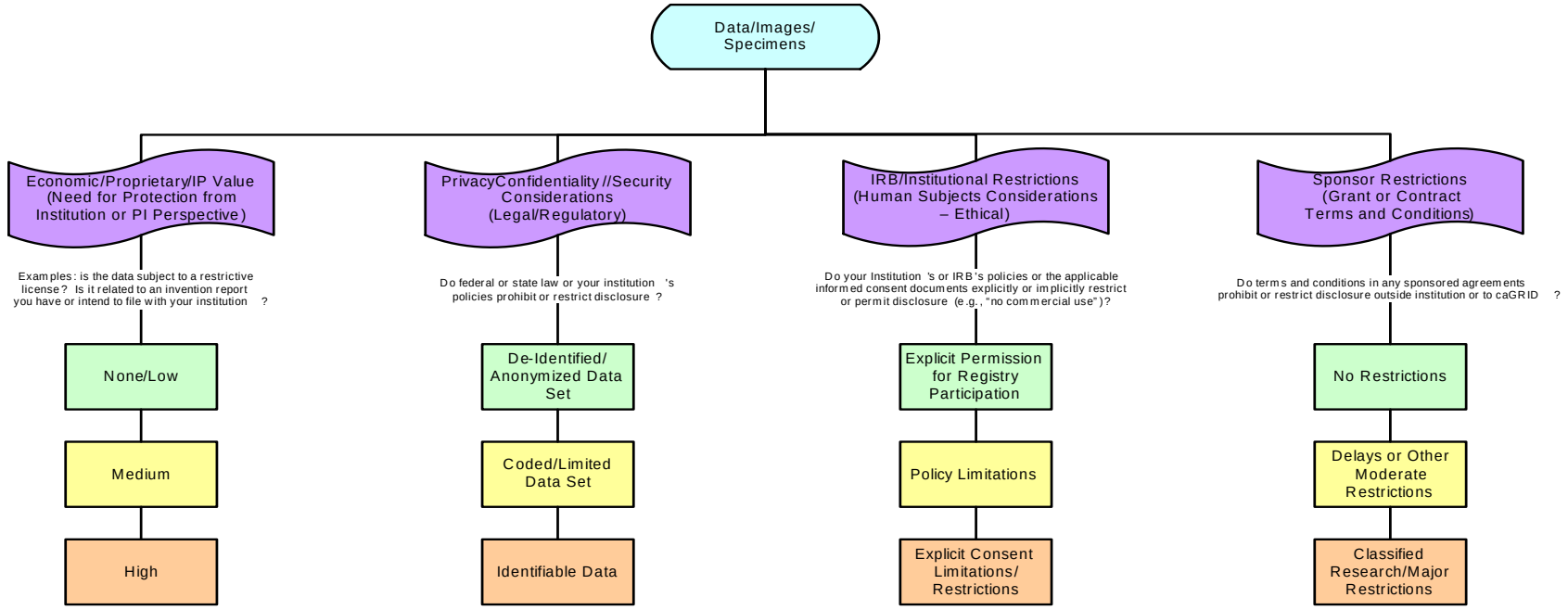
United States Department of Health & Human Services

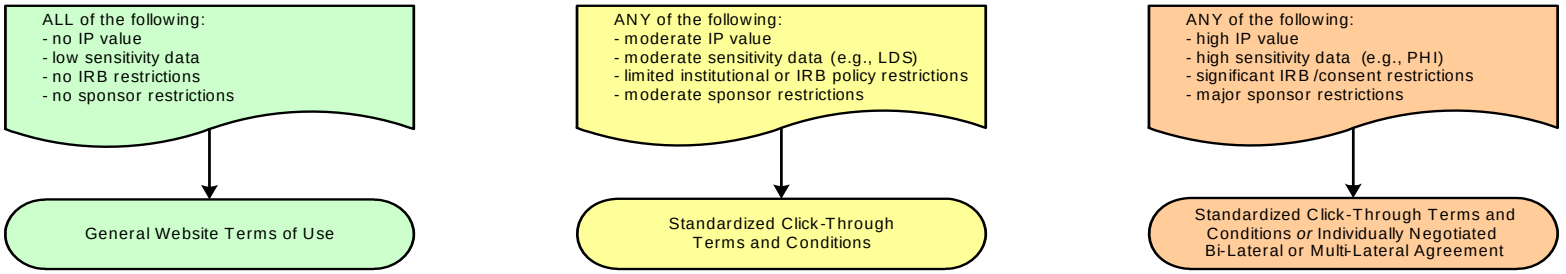
# OCR PRIVACY BRIEF

# Challenges

- Lots of Rules
  - Common Rule, FDA Regulations (Human Subjects, Informed Consent)
  - FDA Regulations (Data Integrity/Security)
  - HIPAA (Privacy, Security) … GINA … HITECH
  - State Laws and Regulations
  - Sponsor Policies (e.g., NIH)
  - Institutional Policies
- Rules often are vague or complex internally and inconsistent with one another
- This leads to inconsistent interpretation, particularly problematic in multi-site research

# Opportunity: Standardization

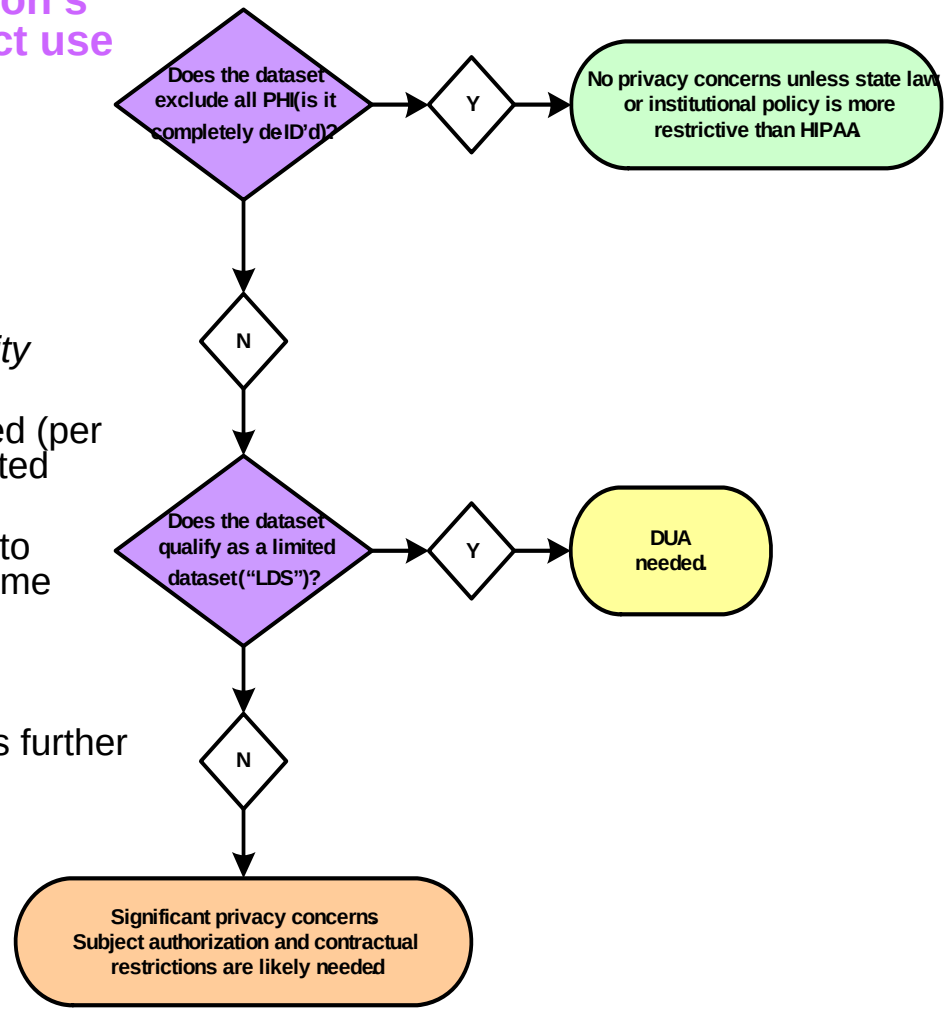


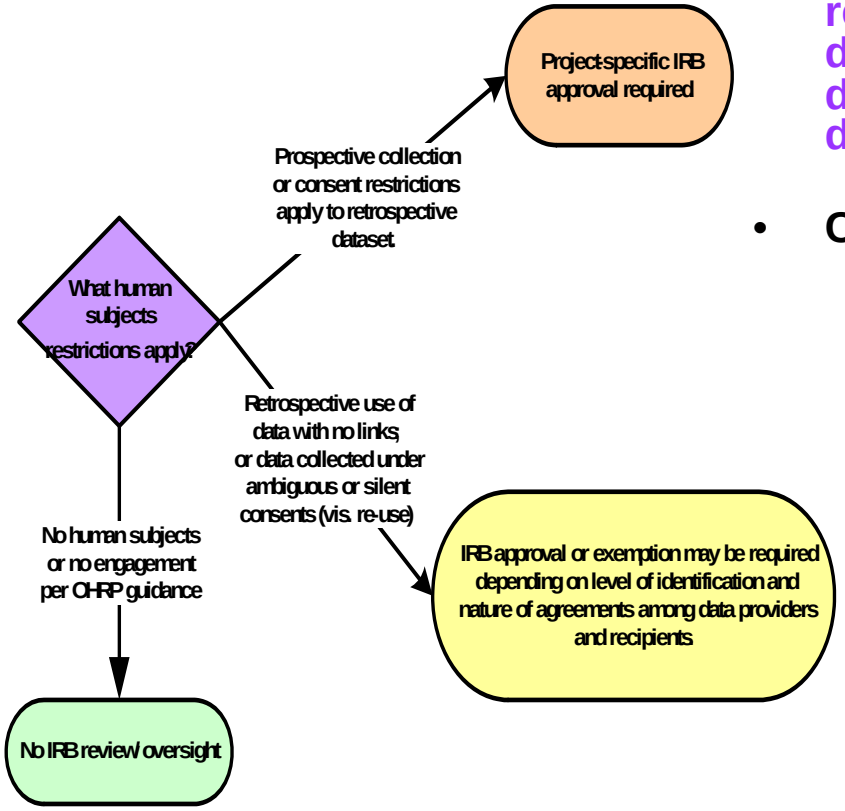
# Privacy Considerations

- **Do federal or state laws, or your institution's privacy or confidentiality policies, restrict use or disclosure for research (research/IRB policies are addressed separately under "ethics")?**

- **Questions/Issues**
  - *Are data collected primarily for health care operations (e.g., disease management, quality improvement), rather than research?*
  - Are data to be shared completely de-identified (per HIPAA definition)? Do they qualify as a "limited data set"?
  - Are the data otherwise identifiable (linkable) to individuals (e.g., SNP data where there is some reference dataset reasonably available to recipients)?
  - Do state laws further restrict disclosure?
  - Do institutional privacy/confidentiality policies further restrict disclosure?
  - Are there any mandates to disclose (e.g., funding agencies, ICMJE, www.clinicaltrials.gov, BMT)



# Human Research Considerations




- **Do the Common Rule, FDA regulations, or your institutional research or IRB policies restrict the proposed disclosure, or were the data collected under an informed consent document (or process) that would prohibit the disclosure?**

- **Common Questions/Issues**
  - Is the project "human subjects research" or a "clinical investigation" under the Common Rule, FDA, or local institutional policies? Is the data provider "engaged" in the research
  - Is the research potentially eligible for an exemption from continuing IRB oversight; does it involve "secondary" use of data originally collected under consents that approved re-use or were silent or ambiguous?
  - What were the circumstances of the original data collection (purpose, consent documents, etc.)?
  - Are there any explicit restrictions on data sharing?
    - Would disclosure be inconsistent with protocol or policies under which data originally were collected?
    - Would disclosure be inconsistent with the original consent (or IRB-approved waiver of consent), or has consent been withdrawn?

# Related Considerations

- Risk evaluation
  - Regulatory, ethical, and institutional implications
    - Nature of consent required
    - Requirements for mitigation strategies
    - Willingness to exchange data
  - Understanding of risk is evolving (*cf.* TGEN)

- Security considerations impact risk evaluation for regulators, research institutions, and research participants
  - Challenge: no consensus standards even within large organizations
  - Solution: standards development: ARRA/HITECH may help

# Moving Forward

- Stop thinking and working in silos
  - Medical advances depend on research and evaluation activities that require access to data and specimens … we need to do a better job of explaining to the public that you don't get one without the other
- Reduce unnecessary burdens
  - Encourage standards development, even if standards may evolve over time
- Focus on what's really important
  - Transparency and accountability in research uses of data and specimens, rather than individual control over disposition
- Start somewhere … don't get mired in the details
  - It is possible to move forward both within organizations (Vanderbilt, Kaiser, etc.) and among them (TCGA, eMERGE, etc.)

http://tinyurl.com/BHC-Rational