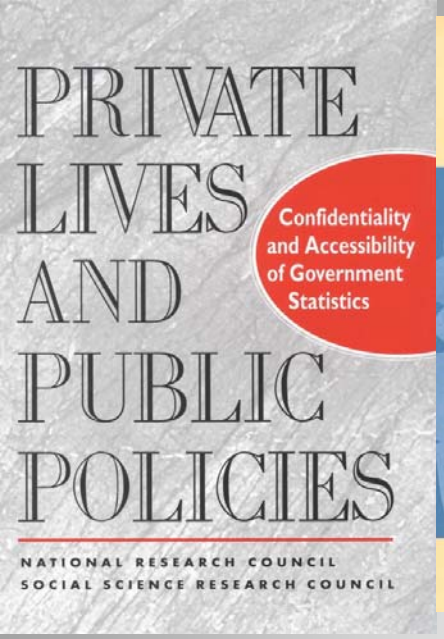
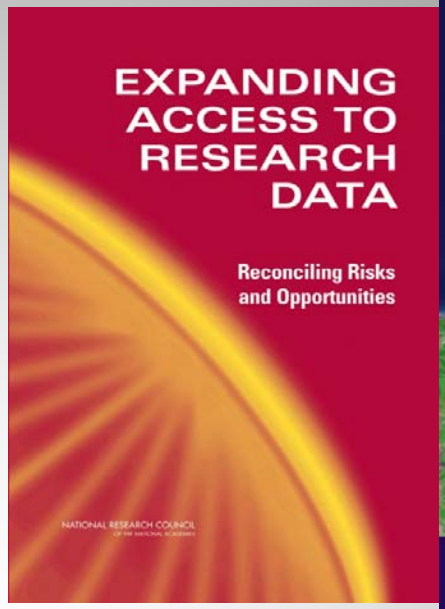
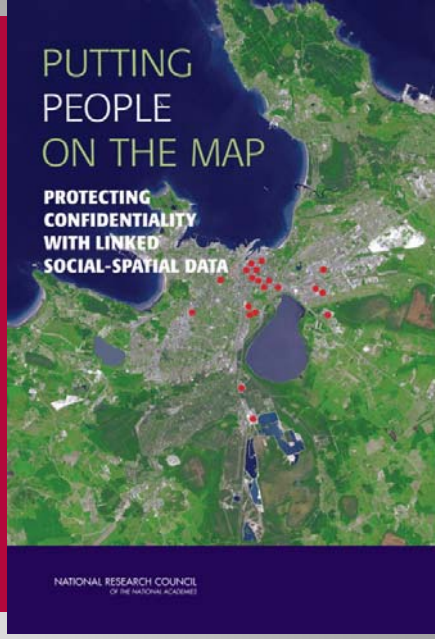







# Revisions to the Common Rule for the Behavioral and Social Sciences—Lessons from NRC/IOM Reports

Constance F. Citro, *Director, CNSTAT*

Washington, DC – March 21, 2013

# Long History of NRC/IOM Attention to HSP Issues

Plenitude of reports on privacy, confidentiality, and data access (often main issue for SBE):

1979 – *Privacy and Confidentiality as Factors in Survey Response*

1985 – *Sharing Research Data*


1993 – *Private Lives & Public Policies: Confidentiality and Accessibility of Government Statistics*

2000 – *Protecting Data Privacy in Health Services Research*

# Long History - 2

More on confidentiality/privacy/data access:

2000 – *Improving Access to and Confidentiality of Research Data: Report of a Workshop*

2005 – *Expanding Access to Research Data: Reconciling Risks and Opportunities*

2006 – *Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop*

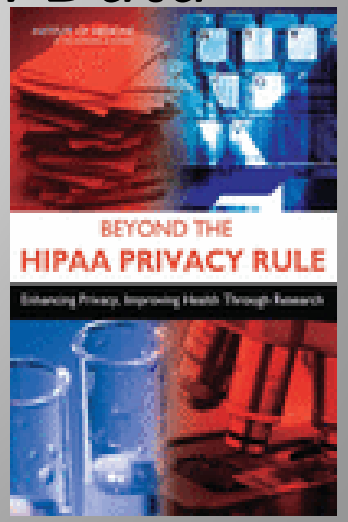

# Long History - 3

Still more on confidentiality/privacy/data access:

2007 – *Engaging Privacy and Technology in a Digital Age*

2007 – *Putting People on the Map: Protecting Confidentiality with Linked Social-Spatial Data*

2009 – *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*

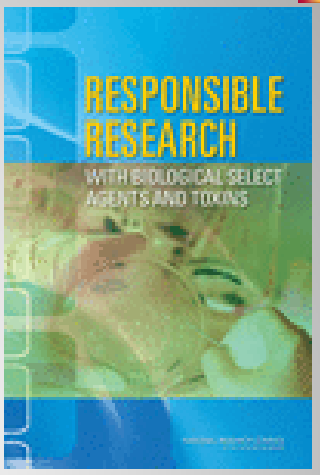



What will be next – Big Data???

# Long History - 4

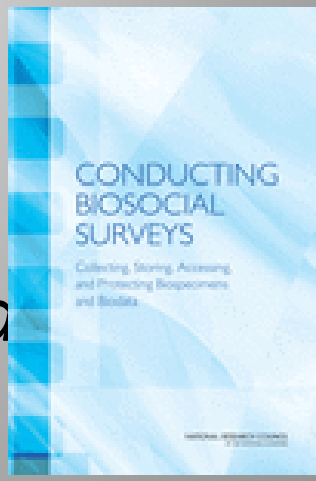
Two system-wide studies:

2002 – *Responsible Research: A Systems Approach to Protecting Research Participants* (biomed)




2003 – *Protecting Participants and Facilitating Social and Behavioral Sciences Research*

Plus: 2010 – *Conducting Biosocial Surveys: Collecting, Storing, Accessing, and Protecting Biospecimens and Biodata*



# Long History - 5

Studies on special populations:

2004 – *The Ethical Conduct of Clinical Research Involving Children*

*2005 – Ethical Considerations for Research on Housing-Related Health Hazards Involving Children*

*2007 – Ethical Considerations for Research Involving Prisoners*

2009 – *Protecting Student Records and Facilitating Education Research*

# Big-Picture Lessons

Why so many studies?

- Humans (their biology, psychology), the environment (physical, social, economic, technological), and the research enterprise (methods, ethical principles, management) are complex
- All three components and our knowledge of them keep changing, which means HSP protection needs to continually adapt

# Big-Picture Takeaways

- Mandating one-size-fits-all is likely to have unintended consequences and may do harm
- Don’t unnecessarily reinvent the wheel—where there are models, use them
- Aristotle’s “golden mean” is very applicable, although hard to implement in regulations
- Social, behavioral, and economic sciences need to be continually vigilant and proactive to achieve useful improvements in regulations

# Changing Environment—Confidentiality/Data Access

- 1960 – Hard to collect and disseminate information (think printed census reports), so less data available, easier to protect
- 1970-1980 – Computerization led to richer data, PUMS files, harder to protect (Privacy Act)
- 1995 – Internet  ballooned availability of data and difficulties of protection
- 2000s – Biosocial, geospatial, linked survey & administrative data – raised the ante

# Confidentiality/ Data Access Seesaw

With the Internet et al., statistical agencies went into a crouch—tightened rules on access

But, with prodding and ideas from academia, developed new ways and means of access

- ✓ Synthesized PUMS files
- ✓ Research Data Centers
- ✓ Licensing
- ✓ Remote monitored access

Adopted by nonprofit archives (ICPSR, NORC)

# Confidentiality/Data Access 101 for the Common Rule

IRBs need help, but HIPAA is not the answer (2006, 2009 reports): set in stone, outmoded even for its own domain; overprotects (geog.), underprotects (re-identification)

Don’t reinvent the wheel (2003, 2005 reports):

Exempt secondary research using data from federal statistical agencies and archives that certify their confidentiality protection methods (could generate positive feedback loop)—some IRBs already do this

# Risks and Harms—Where's the Beef?

The lack of empirical evidence on risks of SBE research remains astounding

2003 report recommended that:

- Researchers debrief participants on perceived risk and harm as standard practice
- OHRP and funding agencies support research on perceived risks and actual harms to inform guidance on "minimal risk" to hit the golden mean between over and under protection

As of 2006, *JERHRE* started to fill that gap

# Informed Consent—Over- and Underprotection

2003 report concluded:

- After years of research, consent forms remain unreadable to many and focused more on the research institution
- IRB efforts to revise consent forms do not often improve matters and use up valuable time
- Written consent for most surveys is overkill and counterproductive

# Informed Consent—Reconsent: When and Why?

- Reconsenting participants who previously consented for research purposes has not been considered in NRC/IOM reports and would undoubtedly be opposed; seems hard to imagine how reconsenting would not hurt research or offer benefits unless the original consent was very limited and specific
- Consent for use of administrative records in research is another matter; 2003 report urged effort for consent at the outset

# Informed Consent—Guidance Rather Than Rules

2003 report recommended:

- Guidance from OHRP (as in detailed examples) for waiving written consent, omitting some elements of consent, etc.
- This is where Aristotle comes in (again)—examples can help IRBs avoid extremes of over and under protection—but regulatory bodies, including IRBs, and their legal counsel, are uncomfortable with ambiguity—might performance guidelines help?

# Data System/Research for IRBs

Little evidence on actual functioning of IRBs

2003 report recommended (similar to 2002):

- OHRP request yearly information from IRBs on operating procedures and outcomes—e.g., percentage exempted, expedited, full review
- OHRP use the results to identify and work with outliers (e.g., IRBs that rarely expedite)
- Feds fund in-depth research on functioning of IRBs that can lead to performance guidelines

# Data System/Research for IRBs

2003 report likened IRB reviews of protocols to elements of a large production process

For such a process, one wants to allow for appropriate variation and to minimize the extremes

This metaphor could become reality with an ongoing data system and underlying research

Regardless, it may help frame the discussions in today's workshop

# SBE Challenges

- SBE has usually been the step-child in the history of human subjects protection vis-à-vis biomedical research
- SBE community reacted vigorously to 1974 DHEW regs (1st version of Common Rule) and to 1979 revisions; achieved some success in categories for exemption and expedited review (although IRBs were slow to use them); also some success in 1998 list for expedited review

# SBE Challenges - 2

- In late 1990s some major problems with biomedical research led to establishment and beefing up of OHRP, which led to tightened IRB scrutiny, which led to heightened SBE frustration with one-size-fits-all approach
- IOM study (2002) commissioned by HHS focused on biomedical issues; DBASSE (CNSTAT) self-funded SBE study (2003) so that SBE issues would not get lost

# SBE Challenges – Here We Go Again with the ANPRM

From the perspective of previous NRC/IOM studies, the ANPRM is well-intentioned with regard to SBE research but—

- Does not reflect hard-won knowledge in such areas as confidentiality protection/data access and informed consent, or
- The role that detailed, evidence-based guidance and guidelines (and effective training on same) could play instead of hard rules (whether for more or less IRB review)

# Our Challenge Today

Speaking personally, I'm delighted that so many organizations have made it possible to hold this workshop

Based on past experience, workshop participants and committee will need to push hard and continually for improvements to the Common Rule and to IRB implementation that appropriately protect participants and facilitate SBE research

Thank you!