

Second Regional Meeting of the Committee on Federal Research Regulations and Reporting Requirements

October 29, 2015

The need for intelligible principles to guide federal research regulations

Barbara J. Evans, Ph.D., J.D., LL.M.
Director, Center for Biotechnology & Law
University of Houston Law Center
713-743-2993 • bjevans@central.uh.edu

Standardless delegations and the Constitution

“[W]e repeatedly have said that when Congress confers decisionmaking authority upon agencies Congress must ‘lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.’”

U.S. Supreme Court, *Whitman v. American Trucking Ass’ns*, 531 U.S. 457, 472 (2001) *emphasis in original*, citing *J.W. Hampton & Co. v. United States*, 276 U.S. 394, 409 (1928)

In another legal context—admissibility of expert testimony in judicial proceedings—normative ethics experts (those who opine on what ethical practice ought to be) “disagree so much and so radically that we hesitate to say that they are experts.”

Spielman & Agich, The Future of Bioethics Testimony: Guidelines for Determining Qualifications, Reliability, and Helpfulness, 36 San Diego L. Rev. 1043, 1055 (1999)

Example of contestable bioethical views The ethics of biospecimen use according to General Ripper in the movie, *Dr. Strangelove*

There is a “conspiracy to sap and impurify all of our precious bodily fluids... without the knowledge of the individual, certainly without any choice”

This may lead to “loss of essence... life essence”

“It’s incredibly obvious, isn’t it?”

“I do deny them my essence!”

When the Common Rule was initially promulgated, Congress was aware of—and addressed—the standardless delegation problem

Authority to promulgate the Common Rule:

- 5 U.S.C. § 301: rules for agency's own operations
- 42 U.S.C. § 289: establishment of IRBs
- 42 U.S.C. § 300v-1: special mechanism to supply intelligible principles to guide the setting of substantive ethical duties

The NPRM claims authority only under the first two.

How did we get the cumbersome framework of research regulations that now exists?

The single-value agency problem: agencies charged with pursuing a single good (e.g., worker safety) can become prone to overzealousness

- Minimal regulation that sets a floor of protection under the assumption that more protection is always better
- Optimal regulation that sets a floor and a ceiling of protections, considering not only benefits vs. risks, but also risk vs. risk and risk vs. cost trade-offs
- Intelligible principles promote optimal regulation

How did we get the cumbersome framework of research regulations that now exists?

Vulnerable regulated entities → lack of pushback

- Even after moving OPRR to OHRP, is there adequate separation between the roles of research regulators and research funders?
- A general framework applicable to privately and publicly funded research is needed:
 - to ensure that human subjects of commercial research are protected
 - to ensure that academic researchers receive the “virtual protection” of commercial research entities that are willing to push back against regulatory excesses
- Research regulations need to be established by Congress under its commerce power, not the spending power

Points to move forward: the NPRM

In a learning healthcare system, the intent to produce generalizable knowledge is not the right criterion to distinguish research from treatment, QA/QI, public health activities, etc.

- *Everything creates generalizable knowledge, if we run our healthcare system right!*
- The Common Rule needs to define all of these terms, just as the HIPAA Privacy Rule has done.

Points to move forward: the NPRM

Many of the unresolved scientific questions of our time require collective action to resolve: extremely large-scale, inclusive, linked data resources for hundreds of millions of persons

- An extreme, atomistic notion of autonomy precludes organized, collective action to overcome the grand scientific challenges of our time
- The NPRM fosters Thomas Hobbes' "confusion of a disunited multitude" and disempowers us
- Institutions that allow collective action enhance individual autonomy

De-identification is dead. *You should assume that there's no such thing as de-identified data. Just as there's no such thing as a de-identified full-facial photo.* Yet we never took that to mean that we should “own” every photo that contains a facial image of us.

Your gait is uniquely identifying.

Cut the biospecimen exceptionalism. It's not just biospecimens that are intrinsically identifiable.

That doesn't mean we shouldn't use them. It just means we need legitimate, publicly accountable procedures for making decisions.

Points to move forward: the NPRM

The Common Rule's concept of coercion needs to be expanded to include unconsented informational studies that use data and biospecimens

- The fateful choice between dispositional and occurrent coercion
- Recognize that nonconsensual use of data and biospecimens is indeed coercive and requires appropriate procedural safeguards. Existing waiver provisions lack appropriate safeguards.
- Supply appropriate procedural protections and public-regarding norms to create a legitimate decision-making process, which does not now exist, to make decisions about nonconsensual data and biospecimen use
- **And stop blocking people's access to their own data!**

Individual Data holder	consents to data use	objects to data use
willing to share data	Quadrant 1 Data accessible for the use	Quadrant 2 No access unless use fits in consent exception.
not willing to share data	Quadrant 3 Individual's wish to share data is thwarted, without access-forcing mechanism	Quadrant 4 Data not accessible unless law requires access (e.g., public health, judicial subpoena)