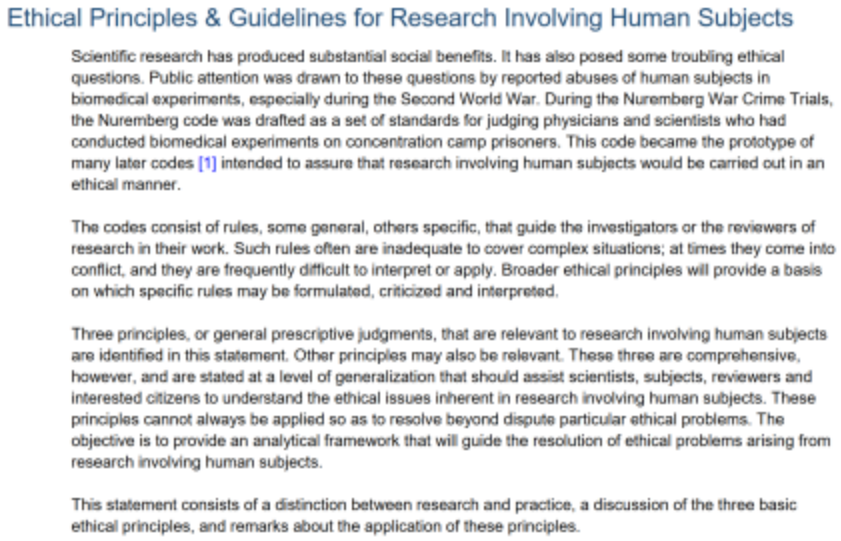
“No Legal Consequence”

by Joseph DeMaio, ©2021



Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes [1] intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

(Dec. 16, 2021) — On occasion, interested individuals will offer comments on your humble servant’s P&E postings. Normally, a response to such comments would appear in the comments section following the post. In other situations, a more thorough response will take the form of a longer, follow-up formal post.

Such is the case with regard to the 12:48 PM, 12/15/21 comment of one Garret Hobart – presumably no relation to former Vice-President Garret Hobart in the administration of President William McKinley – received and posted here.

Hobart asserts in his comment: “Neither the Nuremberg Code nor the Belmont Report is the law, so any perceived or imagined violation of them has no legal consequence.” That assertion merits closer examination.

Both the Nuremberg Code of 1947 and the Belmont Report, while mentioned in the “Pandemic of the Mendacious” post, are discussed in more detail here.

Both documents, in turn, constitute the conceptual underpinnings of Title 45, Part 46 of the Code of Federal Regulations. Mr. Hobart’s asserted fact that the Nuremberg Code and the Belmont Report have not been “codified” in the United States does not mean that their principles and ethical protocols, as incorporated and articulated in the Code of Federal Regulations (“CFR”), import “no legal consequence” for their violation. Indeed, just the opposite is true.

The provisions of 45 CFR Part 46 governing the "Federal Policy for the Protection of Human Subjects" were published, following public comment, in the Federal Register on Jan. 19, 2017, 82 FR 7149, and effective Jan. 19, 2018.

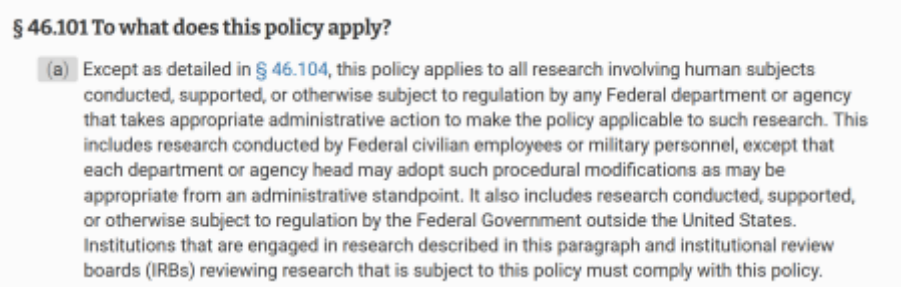
Once an agency rule has been opened to public comment and published as a "final rule" in the Federal Register, under Supreme Court precedent it is accorded the "force and effect of law." *See Perez v. Mortgage Banker's Association*, 575 U.S. 92, 96 (2015), *citing Chrysler Corp. v. Brown*, 441 U.S. 281, 302-303 (1979). In fact, as noted by Justice Sotomayor in *Perez*, such properly noticed and finalized rules are frequently referred to as "legislative rules" and "have the force and effect of law." *Perez*, 575 U.S. at 96.

https://www.federalregister.gov/documents/2011/07/26/2011-18792/human-subjects-research-protections-enhancing-protections-for-research-subjects-and-reducing-burden

Because the rules comprising the regulations articulating the federal policy for the protection of human subjects were opened up to public comment – originally in 2011 and again in 2015, it is clear that the final rules are legislative rules rather than merely "interpretive rules" which are not normally accorded the same "force and effect of law" stature of the former. *See Perez* at 96.

That the rules in question were opened to public comment cannot be disputed, since the Executive Summary of the "final rule" confirms: "Public comments on both the ANPRM [*i.e.*, Advance Notice of Proposed Rulemaking] and the NPRM [*i.e.*, Notice of Proposed Rulemaking] have informed the final rule that is now being promulgated." *See* 82 FR at 7150.

Accordingly, turning to the principles underpinning the final rules here at issue regarding Mr. Hobart's comment, the Belmont Report categorically states: "An agreement to participate in research constitutes a valid consent ***only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.***" (Emphasis added). The Goofball's edict to OSHA to threaten employers of more than 100 employees to "get jabbed" or "get fired" seems suspect.



§ 46.101 To what does this policy apply?

(a) Except as detailed in § 46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.101

In this regard, 45 CFR, Part 46, § 46.101(a) mandates its application to "***all research involving human subjects*** conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research." (Emphasis added) Moreover, 45 CFR, Part 46, § 46.101(c) states: "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment ***shall be exercised consistent with the ethical principles of the Belmont Report.***" (Emphasis added). Again, the Goofball's OSHA edict is now intubated.

Finally, 45 CFR, Part 46, § 46.116 (a)(1) mandates that "***[b]efore*** involving a human subject in research covered by this policy, an investigator ***shall obtain the legally effective informed consent of the subject*** or the subject's legally authorized representative." (Emphasis added) Subparagraph (a)(2) of the regulation then requires that "[a]n investigator ***shall seek informed consent only*** under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss ***and consider whether or not to participate*** and that minimize the possibility of coercion or undue influence." (Emphasis added) The term "investigator" is not separately defined in the rules, but instead is loosely characterized as a person conducting the "research on human subjects."

Collectively, these restrictive CFR mandates – having the "force and effect of law" as "legislative rules" under controlling U.S. Supreme Court decisions – are violated by concealment of applicability or ***any*** coerced requirement that an unwilling human subject submit to being vaccinated with an experimental fluid or risk punitive sanctions, whether in the form of loss of vested benefits, loss of employment or consequential quarantine. That is the plain language and plain import of the regulations. Arguments to the contrary are fatuous…, and misinformed.

Against this backdrop, Mr. Hobart – or anyone else of a similar mindset, including the Goofball at 1600 or his marionette-masters – is invited to explain why "any perceived or imagined violation of … [the CFR rules] has no legal consequence."

Your humble servant will wait.