

Vax Mandates, the “Common Rule,” the Belmont Report and Brandon

"RESEARCH ON HUMAN SUBJECTS"

by [Joseph DeMaio](#), ©2021

THE BELMONT REPORT

Office of the Secretary

Ethical Principles and Guidelines for the Protection of Human
Subjects of Research

The National Commission for the Protection of Human Subjects of
Biomedical and Behavioral Research

April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the

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

(Dec. 8, 2021) — In a 9-part “docu-series” entitled “COVID REVEALED,” producer Patrick Gentempo assembles some extraordinary interviews with a variety of doctors, researchers, virologists, epidemiologists and victims of “adverse reactions” to the several types of C-19 “vaccines” now being used.

The term “vaccines” is considered by some of the interviewees to be a gross misnomer – some might call it “disinformation” – as they are in reality still experimental fluids being used under a continuation of the Food and Drug Administration’s “emergency use authorization” rather than the fluids having achieved final, official FDA “approval” which would normally occur only after the completion of at least two years of controlled clinical trials.

Thus, many of the docu-series interviewees contend that until the final formal FDA approval occurs – if ever – the fluids now being injected into the arms of Americans (but not the arms of illegal aliens who have been invited and permitted to flood over the border since the inception of the Goofball Regime) constitute experimental research activities being “allowed” – but not “approved” – under a purported “emergency” declaration by the FDA.

In effect, the ongoing coerced “jabbing” of the public is viewed by the interviewees to be merely an ersatz “clinical trial” where the “vaxxed” populace constitutes the body of “research subjects.” Several of the episodes have been addressed and profiled at *The P&E*, including [here](#), [here](#) and [here](#).

These episodes were to be viewed free of charge online for a 24-hour period before they were voluntarily de-posted by the producer. Suffice it to say that all of the episodes relate to challenging the propaganda narratives that the “vaccines” are the only way to address and fight the C-19 pandemic; that vaccination mandates are a proper and exclusive way to impose the goals of the narrative on the populace; that the fluids are “safe;” and that anyone who challenges the narratives must be censored, silenced and, in many cases, punished.

In true capitalistic form, Gentempo is offering the complete series in a variety of “sets,” including transcripts of the interviews, additional “non-streamed” episodes and jabbed patient “adverse reaction” stories for a variety of price ranges. As the intrepid *P&E* Editor has [noted](#), *The P&E* is not associated with the production of the series and neither encourages nor dissuades readers from making a purchase.

One reason why your humble servant will be making a purchase is to make sure a “hard copy” of the information contained in the interviews is secured, lest digital chicanery or cancel culture attacks become involved at some point in the future. Fight Memory-Holing! But I digress.

One of the persons interviewed is [Dr. James Lyons-Weiler](#). In one portion of his interview by Gentempo, Lyons-Weiler references a provision of the Code of Federal Regulations (“CFR”) which he claims provides a defense to any employee who is being coerced or forced by his/her employer (yes, Virginia, your humble servant subscribes to the theory that there are but two human species genders...) to “get the job” or be fired.

That provision is found at [CFR Part 45, § 46.101](#). That and following sections provide for the “protection of human subjects in research at 45 CFR 46 [and] include five subparts. [Subpart A](#), also known as the Common Rule, provides a robust set of protections for research subjects.” Unbeknownst to most people, there actually exists within the federal Department of Health and Human Services an “Office of Human Research Protections” (“[OHRP](#)”).

§ 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.
- (b) [Reserved]
- (c) 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.^[62]

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

That office is charged, supposedly, with enforcing the typically convoluted, complex and intertwined provisions of the statutes and regulations in order to, as the title suggests, effectuate “the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and *providing advice on ethical and regulatory issues in biomedical and social-behavioral research.*” (Emphasis added)

One of the provisions to be enforced is the “Common Rule,” summarized [here](#). The full text of the Common Rule is found [here](#). In the OHRP summary of the Common Rule, it is stated that “[t]he current U.S. system of protection for human research subjects is *heavily influenced by the Belmont Report*, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, *HHS and the Food and Drug Administration revised, and made as compatible as possible under their respective statutory authorities, their existing human subjects regulations.*” (Emphasis added)

[The Belmont Report](#), in turn, lays out in three main sections, the principles and ethical protocols which should underpin all decisions and activities involved in conducting human medical and bio-medical research and experimental treatments. The Report specifically references not only the physician’s [Hippocratic Oath](#), but also the [Nuremberg Code of 1947](#), enacted in the wake of the ghoulish medical experiments undertaken by Adolph Hitler’s “physicians” such as Josef Mengele, the “[Angel of Death](#).”

Interested readers should peruse the entire 10-page Belmont Report document in order to more fully understand what is now taking place in the nation regarding the maniacal insistence by the Goofball at 1600 that every living American over age 5 “get jabbed” to conquer C-19..., illegal aliens excepted, of course.

The Belmont Report states with respect to “informed consent,” for example, that “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall *or shall not* happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.” (Emphasis added) Informed consent is then categorized under the headings of “information,” “comprehension” and, most importantly, “voluntariness.”

The Report then states categorically: “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).

Returning to the requirements of 45 CFR § 46.101(a), it is there stated that it 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” Paragraph (c) of the regulation 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).

Finally, [45 CFR § 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.”

§46.116 General Requirements for Informed Consent.

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

- (1) Before 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.
- (2) An 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.
- (3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- (5) Except for broad consent obtained in accordance with paragraph (d) of this section:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revise-common-rule-regulatory-text/index.html#46.116>

Against this backdrop, faithful P&E reader, ask yourself these questions: are the current C-19 policies of (a) the Goofball at 1600; (b) Dr. Anthony Fauci; (c) the Centers for Disease “Control” [sic]; (d) the FDA; (e) the bulk of the mainstream media; and (f) Democrats in general consistent with the protocols of the Belmont Report? Or with 45 CFR Part 46? Or with the provisions of the Nuremberg Code of 1947? Or with the Hippocratic Oath? Think hard..., I’ll wait.

If you answered “no” to any one of the above questions – let alone several of them – and you are threatened with employment termination by a cowardly automaton “go-along-to-get-along” employer lacking the fortitude to resist the oppressive C-19 edicts spewing from the Beltway, you may want to engage a competent employment attorney and ask that professional whether the case for resistance based on the federal regulations and the Belmont Report might be relevant.

Do not rely on the fevered ruminations of your humble servant, who – surprise – thinks the Goofball, aka “[Brandon](#),” [needs to go](#). Now.