FDA Loosens Informed Consent Rules for Research

On January 22, 2024, amendments to the Food and Drug Administration (FDA) regulations (21 CFR 50) covering Institutional Review Boards (IRBs) were finalized and implemented. The amendments added a new section, 50.22, that allows for exceptions to informed consent requirements for minimal-risk research.

While the addition of section 50.22 harmonizes FDA IRB regulations with the Dept of Health and Human Services (DHHS) IRB regulations (known as the Common Rule: 45 CFR 46) that are administered by the Office for Human Research Protections (OHRP), the handling of the Covid shots over the past 3-4 years should raise red flags.

Currently, I am chair of an IRB at a private-not-for-profit outpatient healthcare agency that does research in which vulnerable populations are recruited. As such, I'm well aware that the foundational documents from which the OHRP developed the regulatory framework under which IRBs operate are the Nuremberg Code and the Belmont Report.

Back in October 2023, my first Brownstone post, Where is the Office for Human Research Protections, asked the question as to how the approval of a Phase 3 research pharmaceutical product (mRNA vaccines) could be done without the formal involvement of IRBs. Specifically, the Nuremberg Code, covering informed consent, and the Belmont Report, covering among other elements, bodily autonomy, which are foundational to oversight of human subject research, and the requirement for a data and safety monitoring plan were completely discarded. Was the OHRP consulted for its input, and if not, did anyone from OHRP express concern? Given that these protections were put in place in response to medical atrocities (the Holocaust and the Tuskegee experiments), you'd think that they'd be sacrosanct. Think again!

While not providing a direct answer to the question I posed, Debbie Lerman's posts, Covid mRNA Vaccines Required No Safety Oversight and Covid mRNA Vaccines Required No Safety Oversight: Part Two, and Sasha Latypova's post, EUA Countermeasures Are Neither Investigational nor Experimental, provided a detailed roadmap as to the actions that were actually taken in implementing Emergency Use Authorization (EUA) for the Covid shot. To me, the most significant finding was that the legality of using EUA in civilian populations is rather tenuous, at best.

With the foregoing as a backdrop, let's get into the nuts and bolts of the new FDA regulations, noting that in addition to being chair of an IRB, I am also a retired physician who has been in the healthcare field for 50 years. This includes 19 years of direct patient care in a rural setting as a Board Certified Internist, 17 years of clinical research at a private-not-for-profit outpatient healthcare agency, and over 35 years of involvement in public health, and health systems infrastructure and administration. As such, I bring a breadth of training, knowledge, and experience to this matter that is fairly unique.

The first thing I should point out is the header of the registration document for the IRB that I chair (and for all IRBs in the U.S.):

> *U.S. Department of Health and Human Services (HHS)*
>
> *Registration of an Institutional Review Board (IRB)*
>
> *This form is used by institutions or organizations operating IRBs that review:*
>
> *a) Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or*
>
> *b) Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services*

I have come to learn that the FDA began soliciting comments to their proposed regulatory changes back in 2018. While I regularly receive email communications from the OHRP, I never received any communication from the FDA regarding these regulatory changes. In view of item b) above, you'd think that I would have been near the top of the list. It is also not unreasonable to expect that this would have generated communications from the OHRP, given the close relationship between these agencies with respect to IRB functions. Nope!

Over the ensuing 5+ years, only 50 comments were received in response to the proposed regulatory changes. Not one of the comments mentioned exceptions to informed consent in the context of research involving a pharmaceutical product. I'll discuss the significance of this below. I'll also note that among one of the Brownstone chat groups, these changes elicited about two dozen comments over the course of 12 hours (7 pm to 7 am). It leads one to suspect that there was an

attempt to keep this matter under the radar to the extent possible. I'll discuss the significance of this, too.

In addition to harmonizing FDA and DHHS regulations, another justification for the regulatory changes was to reduce the administrative burden on IRBs. This brings to mind the decision by the leaders of the Covid response team (Fauci, Collins, Walensky, and Offit) to not accept infection-acquired (natural) immunity as valid due to the administrative headaches this would produce, upending 2,500 years of knowledge regarding immunity.

Getting back to what was done under EUA with a Phase 3 research pharmaceutical, it's hard not to suspect that the FDA regulatory changes were done, in part, to codify and mainstream EUA practices in order to give those practices a retroactive cloak of legitimacy that, in my opinion, is not warranted. No wonder the FDA wanted to keep the comment notice under wraps!

From my perspective, IRBs have become the firewall to protect patients from becoming unwitting research subjects. However, I'm chair of one small IRB that reviews, at most, about a dozen research protocols each year, and very few involve pharmaceutical products. What about those institutions that review hundreds of research projects each year involving pharmaceutical products? If you think this is unlikely to create problems, a reminder that the head of the Department of Bioethics at the National Institutes of Health Clinical Center (what is essentially the NIH's IRB) at the time when Covid therapies were being evaluated was Christine Grady, the wife of Anthony Fauci. So much for conflict-of-interest considerations!

Given the disrepute that our most important public health agencies currently face, which includes the FDA, you'd think that they would take this into account when trying to resuscitate their reputations. Instead, from where I sit, it

looks like they've decided to double down on a disastrous set of policy decisions. IRBs across the nation need to be made aware of these circumstances and react accordingly. All it takes is for IRBs to insist that any research project involving a pharmaceutical product must include informed consent; with no exceptions.

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