CIAAG
The Convergence of Public Health and Individual Rights

www.ciaag.net
774-262-6671
www.ciaag.net

Food & Drug Administration
Office of Good Clinical Practices (OGCP)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attention: Food & Drug Administration: Office of Good Clinical Practices,

In July 2017, the Food & Drug Administration (FDA) issued an "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects: Guidance for Sponsors, Investigators, and Institutional Review Boards."

The FDA is issued this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(3) without initially seeking prior comment. The FDA unilaterally determined that "prior public participation was not feasible or appropriate because this guidance presents a less burdensome policy that is consistent with public health."

This is highly inappropriate and deviates from the FDA's usual practice when proposing regulatory changes. The FDA's normal process includes sending out an email advising of the change in addition to providing a 60 day window for public commentary before adopting the proposed rule/regulatory change.

The FDA claimed that providing the public an opportunity to comment on the change was "not feasible or appropriate because this guidance presents a less burdensome policy that is consistent with public health" and acknowledged that they opted not to collect public comments under the guise of it being "not feasible". FDA provided information in the next paragraph stating the public could provide feedback in reference to the Federal Register (if they wanted - on their own accord) , demonstrating the FDA had the capability to provide the 60 day window for public feedback on the Federal Register in the first place.

Further, the FDA waiver claims that prior public participation was not appropriate because this guidance presents a less burdensome policy that is consistent with public health.

While skipping the public commentary period may be less burdensome, it is a primary role of the FDA (and standard practice with thousands of items on the Federal Register for consideration) to actively engage in the collection of public feedback. In addition, the FDA claims this guidance presents "policy that is consistent with public health." What policy is the FDA referring to? This is vague and does not provide any solid legal reasoning for not permitting the opportunity for public feedback.

Informed consent for human clinical trials is the cornerstone of conducting ethical, statistically reliable research. Failure to obtain informed consent in human clinical trials is a direct violation of the Belmont Agreement and the International Human Rights Agreement, both of which the United States has entered into agreement with.

The FDA has unilaterally changed the rules surrounding human clinical trials without providing any opportunity for public feedback. This is one of many changes undertaken by the FDA to permit clinical trial work to be conducted without patient knowledge or consent. The waiver claims to apply only when it is deemed minimal risk to the patient. However, it has been shown, the clinical trial work currently embedded into the private medical encounter is not "minimal risk."

Please provide a written response to the following inquiries regarding the FDA's issuance of this IRB Waiver of Informed Consent for Human Clinical Investigations by July 12, 2023.

- Who decides what is and is not minimal risk? Provide details on this process along with written protocols.
- Provide a copy of the legal guidance permitting the issuance of this waiver without public notice or opportunity for feedback.
- Provide a copy of the written policies showing the issuance is "consistent with public-health" as indicated by the FDA. Provide specific examples to illustrate that the actions taken were "consistent with public-health".
- Is there a centralized location for the public to review a list of all clinical trials conducted under the IRB Waiver of Informed Consent for Human Clinical Investigations Involving No More Than Minimal Risk to Human Subjects: Guidance for Sponsors, Investigators, and Institutional Review Boards. If so, please advise where this can be found. If not, why?

The FDA claimed this guidance would facilitate the conduct of certain minimal risk clinical investigations to address significant public health needs without compromising the rights, safety, or welfare of human subjects.

Who is responsible for determining and deciphering the minimal risk threshold for patients in a clinical trial?

- Provide a copy of the written policy that outlines the limits of these waivers.
- Is there a formal process to ensure proposed projects do not interfere with or impact the rights, safety and welfare of patients? If so, please provide a copy of this guidance.
- Are negative outcomes quantified and reported in the publication results of the trial.

The United States Policymakers have permitted the use of decentralized clinical trials and the integration of human clinical trials to be embedded into the private patient encounter; they are rewriting the rules and regulations to pave the way for desired research to be conducted by circumventing human consent.

If these trials are truly minimal risk, then there should be no difficulty obtaining informed consent from prospective participants. Further, we contend, FDA's claim that it is "burdensome" to collect consent is not a valid reason to modify and waive the basic rules. Failure to obtain informed consent violates a citizen's rights to privacy, personal autonomy and medical freedom.

Embedding clinical trials into the private patient encounter has changed the delivery of care to be primarily focused on satisfying the needs of the research community over attending to the needs of the patient in the pursuit of "filling knowledge gaps".

While the IRB Waiver was issued without public notification or opportunity for feedback, the waiver states: "Although this guidance document is immediately in effect, it remains subject to public comment in accordance with the Agency's good guidance practices regulation (21 CFR 10.115)."

This statement illustrates that the act of collecting public commentary was not an impractical task. It is our assessment that the FDA anticipated the potential for a negative public response which would hinder their ability to pass the desired changes; therefore, avoiding the customary notification and commentary process would be beneficial.

CIAAG is leading a campaign on behalf of the citizenry, asking our representatives for a formal inquiry into the issuance of the IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects and a review to determine and identify any possible oversteps the FDA may have taken in the process. Additionally, we seek to have Human Informed Consent provisions updated to ensure patient rights and safety are not put at risk during the pursuit of research.

The IRB Waiver states that the FDA must consider all comments received and revise the guidance as appropriate. As such, we are requesting the FDA to publish this regulatory change so the public may engage in the customary commentary process for the standard 60 days and collect the feedback for review (post fact).

The practice of embedding human clinical trials into the private medical encounter has shown not to be "minimal risk" as patients' health and well-being are put at risk for the sake of gathering desired clinical research data. Patients are being forced to utilize alternative modalities as treatment in order to develop a body of research to support its use. That is not a study but rather an agenda. These projects seem to have preordained outcomes with subject selection based on perceived ability to create favorable outcomes. By embedding the clinical trials into the healthcare system and mandating the implementation of (unproven) public-health policy changes, clinical researchers are able to data-mine the patient's electronic medical record to perform research that most patients would not agree to participate in if they were afforded a choice. Proposed changes in patient care must first be tested in private clinical trials to determine if they are safe and efficacious prior to utilization as a treatment option. The increasing use of "real-world" clinical trials is directly impacting patients' ability to access necessary and effective medications/treatments.

Through the use of federal guidelines, recommendations are issued that influence physician decision making during the delivery of care. These newly issued medical guidelines have not been shown to be safe and effective. In fact, many of the recommendations contained in the new guidance documents have been identified as "needing more research" as can be seen in CIAAG's Analysis of the 2022 CDC Opioid Prescribing Guideline Analysis.(1) Treatment options once considered the "standard of care" are now replaced in favor of the new (unproven) recommendations. The patient's progress/outcomes are documented by the provider directly into the electronic medical record where research professionals are able to obtain the necessary data to perform clinical investigations. This process has been widely accepted in regards to testing alternative modalities for the treatment of pain resulting from chronic illness and other conditions. However, this practice is far from minimal risk.

Patients have flocked to the internet for over 5 years, desperate for help, speaking out about the harms they suffered as a result of these new public health policy changes. As a nation, we have a duty to ensure and preserve the rights and safety of all citizens.

The current practice of waiving informed consent for human clinical trials is not in compliance with international laws, including the Belmont Agreement and the International Agreement on Human Rights. Additionally, the United Nations Office of Drugs and Crime released guidance on the use of public, private-partnerships in the drug-control and health policy arena to which CIAAG served as a Subject Matter Expert. The resultant guidance made it clear that:

"Oversight must ensure that evidence-based practices are developed based on rigorous science and informed consent, with no corners cut. Furthermore, experts suggested that any regulatory or rule changes should be communicated to the public for their feedback, rather than be decided upon solely between public-private partners with no oversight. Experts were clear that the public deserves transparency over all activities."

---

1. CIAAG's Analysis of the 2022 CDC Opioid Prescribing Guidelines (draft report) by Lauren L. Deluca and Shasta Rayne. https://uploads.documents.cimpress.io/v1/uploads/71da9192-6384-421c-ab4b-416014339c7a~110/original?tenant=vbu-digital Date Accessed:June 10, 2023 at 10:08am.

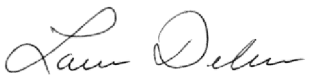
The current structure for the development of a new-evidence base in the practice of medicine is not in compliance with the necessary components outlined by national and international guidance documents. Federal and state agencies are changing the rules and regulations to clear the obstacles that hinder the engagement of their desired research agendas. However, these so-called obstacles (otherwise known as the citizenry's basic civil and human rights), includes that of informed consent to know what is happening to one's own body and the ability to decline participation. The current system ensures patients are left unaware that their care is being manipulated and that their data is being used to develop policies and laws that may not reflect their values or needs.

As we move into the next decade of the national strategic work related to the healthcare system, it is imperative we examine the impact recent policy changes are having on both public and individual health outcomes. Additionally, we need to address any disparities and inequities these policy changes have created.

We appreciate your time and consideration. This is an issue of national importance and one that must be addressed to ensure the safety of the citizenry and scientific integrity of the evidence-base used to create public-health policy.

We look forward to your thoughtful response by July 12, 2023. Our executive team is available to meet for further discussion.

Thank you,



Lauren L. Deluca
Executive Director
CIAAG

cc:

Food & Drug Administration
Commissioner Robert M. Califf M.D.
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

Health & Human Services
Secretary Xavier Becerra
200 Independence Avenue, S.W.
Washington, D.C. 20201

Health & Human Services
Office of Human Research Protections
Division of Compliance & Oversight
email: OHRP-DCO@HHS.gov

Health & Human Services
Office of the Inspector General
Inspector General Christi Grimm
email:Christi.Grimm@oig.hhs.gov

Health & Human Services
Office of Civil Rights
% Melanie Fontes Rainer
email: Melanie.Rainer@hhs.gov

HHS Office of the Inspector General
Office of Investigations
% Christian J. Schrank
email: Christian.Schrank@oig.hhs.gov

Food & Drug Administration
Center for Drug Evaluation & Research
email: druginfo@fda.hhs.gov

Food & Drug Administration
Office of Good Clinical Practice
email: gcp.questions@fda.hhs.gov

Food & Drug Administration
Center of Biologics Evaluation & Research
email: ocod@fda.hhs.gov

Food & Drug Administration
Center for Devices & Radiological
email: Ellen.Flannery@fda.hhs.gov

Health & Human Services
Office of Good Clinical Practice (OGCP)
5630 Fishers Lane, Room. 1061
Rockville, MD 20852

President Joe Biden
White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Health & Human Services
Office of Research Protections
200 Independence Avenue, S.W.
Washington DC 20201