

FDA FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL

January 1, 2024

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: *Communications Concerning Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations (IR#1109)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network (“ICAN”). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

All communications sent or received by Lauren Milner and Robert Califf from January 1, 2018 through the date of the search concerning the proposed or final rule titled, “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.”¹

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and other medical treatments, and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates scientifically based health information regarding the safety of vaccines and other medical treatments, for free through its website,² a weekly health news and talk show,³ and through press events and releases. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 190,000 followers and 1 to 2.5 million impressions in a 28-day period. On Rumble, The HighWire has approximately 83,000 followers and growing. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Critical to ICAN's mission is its proven ability

¹ <https://public-inspection.federalregister.gov/2023-27935.pdf>.

² <https://www.icandecide.org/>.

³ <https://thehighwire.com/>.

to find and review critical scientific and governmental records and meaningfully report about their social impacts. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA). ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.