

**Exhibit 3**



Katherine Eban &lt;ebanvf40@gmail.com&gt;

## Seeking Clarification on FOIA Request

Zdrovitz, Kristine (OS/ASPA) <Kristine.Zdrovitz@hhs.gov>  
To: "EbanVF40@gmail.com" <EbanVF40@gmail.com>

Mon, Dec 20, 2021 at 7:46 AM

Good morning,

I'm contacting you regarding your recent FOIA request with HHS, 2022-00220-FOIA-PHS. Your request seeks:

*We are journalist reporting on a clinical experiment. We are requesting documents and records from the HHS regarding Mount Sinai's Living Brain Project. Attached is our full request.*

*The timeframe for my below request is January 1, 2013 through the date the search for responsive records is conducted.*

### **MOUNT SINAI RESEARCH DOCUMENTS**

? *All Institutional Review Board registration, updates, and renewal forms and applications submitted to the HHS via the Office of Human Research Protections by the Mount Sinai Icahn School of Medicine, 1 Gustave L. Levy Place New York, NY 10029-5674.*

? *Please also include any emails and communications between any Mount Sinai staff and the Office of Human Research Protections at HHS related to these forms.*

? *Copies of any and all Federalwide Assurance declarations sent to Mount Sinai from the HHS Office of Human Research Protections.*

? *Any documentation related to audits of research studies at Mount Sinai conducted by the HHS Office of Human Research Protections, including but not limited to emails, letters, analysis, reports, memos, communications with outside experts.*

**"A MULTISCALE INVESTIGATION OF THE LIVING HUMAN BRAIN" HEREAFTER REFERRED TO AS "THE LIVING BRAIN PROJECT"**

*All complaints to the Office of Human Research Protections citing the ongoing study at Mount Sinai filed on the National Institute of Health website under the number 1R01AG069976-01.*

? *Please also include any emails and communications between Mount Sinai staff and HHS officials related to these complaints.*

? *Please include any internal HHS emails, letters, analyses, reports, memos, communications with outside experts, other federal or state agencies, or any other individuals related to these complaints.*

? *Please also include any emails, letters, analyses, reports, memos or other communications that mention the Living Brain Project sent between HHS officials.*

? *All reports submitted to the Office of Human Research Protections related to the Living Brain Project including:*

? *Any and all documentation of adverse events, up to and including death.*

? *Any and all compliance oversight reports of Mount Sinai filed by the Office of Human Research Protections.*

? *Please also include any emails and communications between Mount Sinai and HHS related to these reports.*

? *Please include any internal HHS emails, letters, analyses, reports, memos, communications with outside experts or other agencies related to these reports.*

? *Any patient consent forms for the Living Brain Project, filed from the year 2013 through. 2021.*

*(Date Range for Record Search: From 01/01/2013 To 12/31/2021)*

OHRP is asking you to narrow the scope of this assignment. **There have been 52 IRB registration applications submitted by Mount Sinai to our office in the timeframe specified (from 1 Jan 2013 onward). While printing all of the applications in HATS was relatively straightforward, opening the logs for each of the 52 applications to search for initial correspondence through HATS, and then asking our team to search emails related to each of those 52 applications, will be quite burdensome and may not yield any correspondence.**

**Is it possible to provide the 52 applications and see whether the requester would consider rescoping the request to focus on correspondence related to a smaller subset of the applications (e.g. the most recent application)?**

Until our office receives further clarification from you, your request will remain on hold. If you have not contacted our office within 30 business days from the date of this letter, your request will be administratively closed. Therefore, no action on your part is needed, if you no longer have a need for the records.

Respectfully,

Kris Zadrovitz  
Government Information Specialist, FOI/ Privacy Acts Division  
Office of the Assistant Secretary for Public Affairs (ASPA)  
Department of Health and Human Services (HHS)

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