# BLAIN v. STATE UNIVERSITY OF NEW YORK DOWNSTATE MEDICAL CENTER, ET AL., 22 cv 3022 (FB) (EDNY)

DEFENDANTS' OPPOSITION TO PLAINTIFF'S APPLICATION FOR A P.I. (9-30-2022)

# Defendants' EXHIBIT 23 ("DX23")

# Colucci, Clement

From:

David Christini

Sent:

Thursday, May 26, 2022 5:54 PM

To:

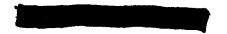
William Versfelt; Shoshana Milstein; Sharon Sealy

Subject:

FW: [EXTERNAL] SUNY Downstate - Stacy Blain

**Attachments:** 

SUNY Downstate - Stacy Blain - 02 mgbulls.pdf



From: Flash-Zapata, Ki-Cha (NIH/OD) [E] <ki-cha.flash@nih.gov>

Date: Tuesday, January 25, 2022 at 6:13 PM

To: David Christini < David. Christini@downstate.edu>

Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>, Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>, Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>, Compliance Review

<ComplianceReview@mail.nih.gov>

Subject: [EXTERNAL] SUNY Downstate - Stacy Blain

# External email

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This letter is sent on behalf of Ms. Michelle G. Bulls, Director of Office of Policy for Extramural Research Administration, OER.

## Ki-Cha Flash-Zapata, MS, MBA

Deputy Director, Division of Grants Compliance and Oversight Office of Policy for Extramural Research Administration, OER National Institutes of Health, HHS 6705 Rockledge Drive, Suite 800 MSC 7974 Bethesda, MD 20892-7974 301-827-9310 Flashk@mail.nih.gov



### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

January 25, 2022

David Christini, Ph.D Vice President for Research Office of Research Administration SUNY Downstate Health Sciences University Office of Research Administration 450 Clarkson Avenue Brooklyn, NY 11203 david.christini@downstate.edu

Dear Dr. Christini,

In follow-up to our Zoom meeting yesterday, we noted that NIH issues awards to institutions, and institutions in turn designate Principal Investigators (PD/PI) and/or Key Personnel (NIH GPS 2.1.2). Specifically, a PI "is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award."

You have informed us that Dr. Stacy Blain is in violation of your institution's policies. You stated that in the course of a misconduct investigation, "she declined multiple requests to review the notebooks and identify the data that she asserts supports the figures in the manuscript and was, therefore, in violation of SUNY Downstate's policy."

We also noted during our discussion that "The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel." Furthermore, "Generally, the decision to modify the terms of an award ... is discretionary on the part of the NIH awarding IC and is not appealable." (NIH GPS 8.5.1).

In addition, NIH requires additional information in order to address why NIH funds were withdrawn during the time where your institution was conducting investigative proceedings with regard to the research misconduct activities. Specifically, please provide the following:

- Why funds in the amount of \$52,763.37 were withdrawn for grant R01 CA249667, as SUNY Downstate indicated that no funds would be withdrawn to protect the Federal funds during the research misconduct proceedings.
- Details on the work performed for both grants during the investigation, as well as invoices to support the costs for the aforementioned amounts, including Dr. Blain's involvement.
- Categorical breakdown of each incurred cost for both grants reflect the direct, indirect, and total costs associated.

As discussed during our Zoom meeting on January 24, 2022, NIH expects that SUNY Downstate will designate a new PD/PI for grants R21 CA252585 and R01 CA249667. If you are unable to appoint a new PD/PI for one or both of these grants, please submit a request for bilateral termination. Your response must be submitted by the AOR directly to Ms. Crystal Wolfrey (wolfreyc@mail.nih.gov), NCI Chief Grants Management Officer (CGMO) and Ms. Ki-Cha Flash-Zapata (Flashk@mail.nih.gov), Deputy Director, Division of Grants Compliance and Oversight, within the next 30 days.

Sincerely,

Michelle G. Bulls -S Bulls -S Date: 2022.01.25 17:58:49 -05'00'

Michelle G. Bulls, Director Office of Policy for Extramural Research Administration Office of Extramural Research National Institutes of Health 301-594-6739

cc: Crystal Wolfrey, Chief Grants Management Officer (CGMO), National Cancer Institute Ki-Cha Flash-Zapata, Deputy Director, Division of Grants Compliance and Oversight, OPERA