

## **SETTLEMENT AGREEMENT**

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively the “United States”) and the Cleveland Clinic Foundation (“CCF”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### **RECITALS**

A. CCF and its affiliated entities, including the Lerner College of Medicine and the Lerner Research Institute, receive grant funding from the National Institutes of Health (“NIH”), a component of HHS.

B. The United States contends that it has certain civil claims against CCF arising from false statements and payment claims submitted to NIH between November 1, 2013 and May 31, 2020 in connection with grants designated as R01 HL121358 (Grant #1); R01 HL126729 (Grant #2); and R01 HL138465 (Grant #3), based on the following alleged conduct, which is referred to below as the Covered Conduct:

1. CCF failed to disclose in grant applications, “Just-In-Time” application updates, and Research Performance Progress Reports (collectively “grants submissions”) that its employee, who was identified by CCF as the Principal Investigator on Grants #1, #2, and #3, had pending and/or active other support from foreign sources.

2. The grants submissions in which CCF failed to disclose its employee’s other support were made through NIH’s eRA Commons system, a platform for grant applications and administration. Individual eRA Commons users are assigned unique passwords, and NIH

policies prohibit users from sharing their password with others or to allow others to use their password to make entries on their behalf. Despite this requirement, CCF employees shared eRA Commons passwords, and at least some of the false submissions failing to disclose the Principal Investigator's other support were made by other CCF employees using the Principal Investigator's username and password.

3. CCF falsely certified to NIH that the grants submissions omitting the Principal Investigator's other research support from foreign sources were true and accurate.

C. This Agreement is neither an admission of liability by CCF nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

### **TERMS AND CONDITIONS**

1. CCF shall pay to the United States \$7,600,000 ("Settlement Amount"), of which \$3,800,000 is restitution, by electronic funds transfer pursuant to written instructions to be provided the Office of the United States Attorney for the Northern District of Ohio no later than 14 (fourteen) days after the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and conditioned upon the United States' receipt of the Settlement Amount, the United States releases CCF from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§

3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other terms of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals.

4. CCF waives and shall not assert any defenses CCF may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. CCF fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of

every kind and however denominated) that CCF has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. CCF agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of CCF, and its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) CCF's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment CCF makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by CCF, and CCF shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Within 90 days of the Effective Date of this Agreement, CCF shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by CCF or any of its subsidiaries or affiliates from the United States. CCF agrees that the United States, at a minimum, shall be entitled to recoup from CCF any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine CCF's books and records and to disagree with any calculations submitted by CCF or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by CCF, or the effect of any such Unallowable Costs on the amount of such payments.

7. CCF agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, CCF shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. CCF further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

8. This Agreement is intended to be for the benefit of the Parties only.

9. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Northern District of Ohio. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

15. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on CCF's successors, transferees, heirs, and assigns.

17. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

18. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**



DATED: 5/17/24

BY: \_\_\_\_\_

MICHELLE HEYER  
ELIZABETH L. BERRY  
Assistant United States Attorneys  
Northern District of Ohio

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

SUSAN E. GILLEN  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
United States Department of Health and Human  
Services

**THE CLEVELAND CLINIC FOUNDATION**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Counsel for The Cleveland Clinic Foundation

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

MICHELLE HEYER  
ELIZABETH L. BERRY  
Assistant United States Attorneys  
Northern District of Ohio

DATED: 05/15/24

BY: \_\_\_\_\_

SUSAN  
GILLIN

Digitally signed by  
SUSAN GILLIN  
Date: 2024.05.15  
18:52:56 -04'00'

SUSAN E. GILLEN  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
United States Department of Health and Human  
Services

**THE CLEVELAND CLINIC FOUNDATION**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Counsel for The Cleveland Clinic Foundation



**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

MICHELLE HEYER  
ELIZABETH L. BERRY  
Assistant United States Attorneys  
Northern District of Ohio

DATED: \_\_\_\_\_

BY: \_\_\_\_\_


SUSAN E. GILLEN  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
United States Department of Health and Human  
Services

**THE CLEVELAND CLINIC FOUNDATION**

DATED: 5/17/2024

BY: 

DATED: 05/17/2024

BY: 

Counsel for The Cleveland Clinic Foundation