



MAY 09 2014

The Honorable Charles E. Grassley
Ranking Member
Committee on the Judiciary
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senator Grassley:

Thank you for your letter of April 1, 2014, about the recent research misconduct case at Iowa State University of Science and Technology (ISU) involving Dr. Dong-Pyou Han. Specifically, you asked a series of questions concerning the National Institutes of Health's (NIH's) efforts to recover grant funds spent in support of the project involving research misconduct.

As you know, the Department of Health and Human Services (HHS) Office of Research Integrity (ORI) and ISU found that Dr. Han engaged in research misconduct. Specifically, Dr. Han falsified results in research to develop a vaccine against human immunodeficiency virus-1 (HIV-1) by intentionally spiking samples of rabbit sera with antibodies to provide the desired results. Falsified neutralization assay results were widely reported in laboratory meetings, seven national and international symposia between 2010 and 2012, and in grant applications and progress reports submitted to the National Institute of Allergy and Infectious Diseases (NIAID).

Under the ORI's purview, Dr. Han entered into a Voluntary Exclusion Agreement and has voluntarily agreed for a period of three years, beginning on November 25, 2013:

- (1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS's Implementation (2 CFR Part 376 *et seq.*) of the Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180 (collectively the "Debarment Regulations"); and
- (2) To exclude himself voluntarily from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The NIH takes these matters very seriously. Dr. Han's three-year voluntary exclusion agreement is the maximum exclusion period available under OMB debarment guidelines, absent significant aggravating circumstances. Whether to pursue criminal action against Dr. Han is ultimately a matter for the U.S. Department of Justice to decide.

Currently, the NIH is in the process of assessing the effect of Dr. Han's actions on the research supported by the NIAID from an institutional perspective. ISU as grantee is legally responsible and accountable for the use of funds provided for the performance of the grant-supported project or activity. As provided by Section 8.5: Special Award Conditions and Enforcement Actions of the *NIH Grants Policy Statement*, a grantee's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause the NIH to take one or more actions, including enforcement actions, depending on the severity and duration of the noncompliance. The NIH undertakes any such action in accordance with applicable statutes, regulations, and policies.

The following are our responses to your questions:

- 1. Has NIH ever sought to recover funds spent in support of activities involving research misconduct? If no, why not? If yes, please provide the total amount recovered and describe each instance in which NIH attempted to use this authority, involving the outcome of those efforts.**

Although the NIH evaluates the need to take action against grantee institutions when there are confirmed cases of research misconduct, the NIH has not taken recent action to recover funds. In research misconduct cases, a finding of research misconduct is levied against an individual researcher(s), as are the remedial actions. In considering taking institutional actions related to research misconduct, the NIH takes into account the egregiousness of the case in the context of the effect of the misconduct on the value of the scientific research conducted, that is, whether the project yielded valid results that were not affected by the research misconduct.

- 2. Will NIH attempt to recover funds in the case involving ISU and Dr. Han? If no, why not? If yes, what is the status of the recovery process?**

The NIAID has engaged in active discussions with ISU regarding this matter and has determined that ISU must return \$496,832.17, the amount of grant funds used to support Dr. Han's salary over the award period, to the federal government.

- 3. What will be done with the \$4 million in unspent grant funds related to Dr. Han's research?**

The amount in unspent grant funds initially cited in press reports was not correct. The NIAID is currently working closely with ISU to ensure the appropriate and orderly closeout of all ISU projects identified in the ORI finding.

- 4. How does NIH make the decision on whether to seek recovery of funds spent in support of activities involved in research misconduct?**

Please refer to question 1 above.

- 5. Who makes the final determination at NIH on whether to seek recovery of funds spent in support of activities involved in research misconduct?**

Generally, the decision is made by the funding Institute or Center, in this case the NIAID.

MAY 09 2014

6. Does NIH work with ORI to recover funds? If yes, please describe NIH's collaboration with ORI. If no, please explain why not.

The NIH receives and reviews ORI's notices regarding findings of research misconduct against individual scientists to ascertain their potential impact on relevant funded projects in which the scientists were involved.

I trust that the information in this letter responds to your questions.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Francis S. Collins".

Francis S. Collins, M.D., Ph.D.
Director