



October 29, 2018

The Honorable Charles E. Grassley
Chairman, Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your August 27, 2018 letter about the Moderate Alcohol and Cardiovascular Health (MACH) Trial. As you know, I directed the National Institutes of Health (NIH) Office of Management Assessment (OMA) to conduct a review of the MACH Trial to identify any indication of misconduct by NIH employees or irregularities in the process of grant development and funding mechanisms for the study. I also engaged NIH's Advisory Committee to the Director (ACD) to review concerns with the study and, after receiving their recommendations, I directed that the study be terminated. Thank you also for recognizing the value of the steps already taken to address this situation and for your additional questions about our activities.

The MACH Trial will end formally on January 31, 2019, following completion of an orderly closeout, which is underway. The total amount of NIH funds expected to be spent on the trial, including closeout, is \$4 million. This represents funding provided in Fiscal Year (FY) 2016 and FY 2017. No additional funding has been provided.

OMA has completed its review and issued a report, which was provided to the NIH Office of Human Resources (OHR) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) management for appropriate disciplinary action. As a result, three individuals are no longer employed at NIH or anywhere within the Department of Health and Human Services. While NIH has a longstanding commitment to keep administrative personnel action information confidential, we certainly understand the concerns that you have raised.

The integrity of the NIH grants administrative process, peer review, and the quality of NIH-supported research must always be above reproach. I am determined to make sure that violations of policies are not happening in other parts of the agency. Some of the additional actions NIH has initiated include:

- (1) identifying issues of concern raised about the MACH Trial and reviewing processes in support of public-private partnerships and program development;
- (2) reviewing the training needs of NIH staff and developing case studies that describe appropriate program staff interactions with applicants;
- (3) developing additional questions and documentation requests for establishing public-private partnerships;

- (4) identifying further considerations for risk analysis when evaluating potential public-private partnerships; and
- (5) identifying and reviewing awards greater than \$5 million in cases where only one application was received.

NIH will report on these activities at the ACD's December meeting, which will include public discussion. We will provide more information to you at that time.

Thank you for your sharing your concern about this matter. NIH remains committed to safeguarding the public's trust in federally supported research.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins". The signature is fluid and cursive, with a long horizontal stroke at the end.

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