



July 17, 2018

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

Dear Mr. Chairman:

Thank you for your May 16, 2018 letter concerning the "Multi-Site Randomized Control Trial of Health Effects of Moderate Drinking," also known as the Moderate Alcohol and Cardiovascular Health (MACH) trial. I fully appreciate your concern and interest in this study. As you know from the initial response I sent on May 23, 2018, I initiated two reviews of the study and its origin. I write now to update you on the findings of the reviews and my subsequent implementation of the recommendations made to me.

First, I want to reiterate my assurance to you that the National Institutes of Health (NIH) Institute and Center Directors share my strong commitment to safeguarding the public's trust in federally-supported research. NIH leadership strives to ensure that all the projects we fund have a solid scientific foundation and are administered in compliance with the applicable laws, regulations, and policies. NIH policy prohibits employees from soliciting donations of funds to NIH or any of its components.

Second, following recommendations from the independent Advisory Committee to the Director (ACD) on June 15, 2018, I announced that NIH will end funding to the trial. This decision was based on concerns about the study design that cast doubt on its credibility. These concerns included whether the study would effectively address other significant consequences of moderate alcohol intake, such as cancer. Additionally, the ACD noted significant process irregularities in the development of the funding opportunities, which undermined the integrity of the research process.

A preliminary report from the NIH Office of Management Assessment (OMA) has determined that a small number of National Institute of Alcohol Abuse and Alcoholism (NIAAA) employees violated NIH policies by soliciting gift funding and circumvented standard operating procedures designed to ensure fair competition for NIH research funding. These policy violations were committed by NIAAA employees prior to the involvement of the Foundation for the National Institutes of Health (FNIH). The FNIH manages the solicitation of funds from private donors for NIH research projects with appropriate firewalls. The OMA review found that the FNIH conducted its role appropriately.

Funding for the MACH trial will end within the next few months following completion of an orderly closeout. Additionally, NIH is taking appropriate personnel actions, but cannot comment on specific personnel matters.

In closing, let me say again how seriously I take this matter and assure you that NIH leadership is committed to ensuring the public's trust through strong stewardship of taxpayer dollars and a sustained focus on scientific excellence.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins", with a stylized flourish at the end.

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