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U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research Oversight

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Washington, DC 20420
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August 20, 2018

Michael A. Carome, M.D., Director
Sidney M. Wolfe, M.D., Founder and Senior Adviser
Public Citizen Health Research Group
1600 20th Street, NW
Washington, DC 20009

Re: Public Citizen's Letter, dated July 5, 2018, regarding the Myocardial Ischemia and Transfusion (MINT) Trial

Dear Drs. Carome and Wolfe:

The Office of Research Oversight (ORO), Veterans Health Administration, Department of Veterans Affairs (VA) is in receipt of Public Citizen's letter, dated July 5, 2018, regarding concerns about the Myocardial Ischemia and Transfusion (MINT) Trial sponsored by the National Heart, Lung, and Blood Institute, National Institutes of Health (NIH), and coordinated through the Rutgers Robert Wood Johnson Medical School.

Public Citizen's letter acknowledges the substantive changes that were made to both the research protocol and associated informed consent document, and recommends additional actions for consideration. It should be noted that one of the recommendations in Public Citizen's letter is to "immediately [contact] all subjects (or surviving family members of subjects) who were enrolled in the MINT trial using the original seriously deficient sample consent form and provide those subjects with accurate information about the purpose and risks of the research." In the course of evaluating Public Citizen's initial concerns, which were outlined in its letter dated August 1, 2017, to ORO and the Office for Human Research Protections, Department of Health and Human Services, ORO did *not* identify any VA research sites that had enrolled subjects in the MINT trial at the time of receipt of the letter or that had obtained consent from subjects using the version of the consent form referenced in the letter.

Your organization's continued commitment to the protection of human research subjects is appreciated. If this office can be of any further assistance, please do not hesitate to contact me.

Sincerely,

DOUGLAS D BANNERMAN
109303

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BANNERMAN 109303
Date: 2018.08.20 17:57:01 -04'00'

Doug Bannerman, Ph.D.
Executive Director

cc: Lisa R. Buchanan, Division of Compliance Oversight, Office for Human Research Protections,
Department of Health and Human Services