



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

May 16, 2019

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

RE: Project Title: Crystalloid Liberal or Vasopressors Early Resuscitation in Sepsis Trial
Sponsor: National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)
Principal Investigator: David A. Schoenfeld, Ph.D., Massachusetts General Hospital, Clinical Coordinating Center for the NHLBI-funded Clinical Trials Network for the Prevention and Early Treatment of Acute Lung Injury (PETAL Network)
ClinicalTrials.gov Identifier: NCT03434028

Dear Drs. Carome and Wolfe:

Thank you for contacting the Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS) (letter dated May 1, 2019) regarding NIH officials' forbiddance of two senior scientists at the NIH Clinical Center from communicating with the Office for Human Research Protections (OHRP) about the CLOVERS trial.

We agree that NIH employees who have concerns about ethical or regulatory violations related to the protection of human subjects in any clinical trial should be free to communicate with the OHRP about those concerns without fear of reprisal.

OHRP Response to Public Citizen – CLOVERS Trial
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OHRP is continuing its evaluation of Public Citizen's original complaint letter (dated August 28, 2018). We appreciate Public Citizen's additional comments and will certainly take them into consideration as we move forward.

Thank you for your organization's continued commitment to the protection of human research subjects.

Sincerely,

Lisa Buchanan

Lisa Buchanan, MAOM
Operationally in Charge
Division of Compliance Oversight

cc:

Dr. Amy Patterson, NHLBI, National Institutes of Health (NIH)
Dr. Nakela Cook, NHLBI, NIH
Dr. Simone Glynn, NHLBI, NIH
Dr. Michelle Bulls, Director, OPERA, Office of Extramural Research, NIH
Dr. Pamela Kearney, Director, Division of Human Subjects Research, Office of Extramural Research, NIH
Dr. Adam Berger, Director, Division of Clinical and Healthcare Research Policy, Office of Science Policy (OSP), NIH
Mr. Taunton Paine, OSP, NIH
Dr. Joanne Less, Food and Drug Administration