

## Report on Research Compliance Volume 16, Number 6. May 22, 2019 OHRP Watchdog: CLOVERS Trial Reflects Poorly on NIH Leaders, IRBs

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By Theresa Defino

In the nearly 10 years since Michael Carome retired from the HHS Office for Human Research Protections (OHRP) and joined the watch dog organization Public Citizen, he has been a frequent and vocal critic of his former employer. As director of Public Citizen's Health Research Group, Carome has long complained of lax and essentially non-existent enforcement by OHRP of human subject regulations, patterns RRC began documenting in 2011.

Carome even used to pen a column on the *Huffington Post* called "Outrage of the Month."

But Carome recently reached a level of ire that was new for him. On April 29, he called on NIH Director Francis Collins to resign along with Larry Tabak, principal deputy director, after *The Wall Street Journal* (WSJ) reported NIH had prohibited two NIH physician/researchers from talking to OHRP about a study known as the CLOVERS trial.

Senior NIH Investigators Drs. Charles Natanson, chief of the anesthesia section, and Peter Eichacker, M.D., head of the critical care medicine section at the NIH Clinical Center, brought their concerns about the Crystalloid Liberal or Vasopressors Early Resuscitation in Sepsis (CLOVERS) study to Carome, and Public Citizen forwarded a detailed analysis to OHRP. They contend the trial, which aims to enroll 2,300 patients, is too risky and lacks a control group receiving standard of care for sepsis.

"The reported actions by senior NIH officials constitute gross misconduct and corruption at the highest levels of the NIH, tantamount to an obstruction of ethical justice for the subjects of the trial," Carome said. "To avoid blatant conflicts of interest as the funder of the trial, NIH must have no role in determining with whom OHRP staff speak when investigating the research. These actions of the NIH leadership undermine the protections for human subjects who are enrolled in NIH-funded research and, ultimately, erode public trust in NIH."

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