DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

SEP 2 0 2013

Refer to: DPI Case #2013-146

Dr. Michael Carome
1600 20th St. NW
Washington, DC 20009

Dear Dr. Carome:

This is in response to the correspondence you submitted to Secretary Sebelius regarding concerns of human subject protection with the Transfusion of Prematures (TOP) Trial. Your complaint was forwarded to our office. We appreciate your concern in this matter and will make every effort to maintain the confidentiality of your communications with this office. We are currently assessing the information you provided to determine the next steps, and I would like to describe the process we use to conduct reviews and to protect the confidentiality of related information.

Our office is organizationally located within the Office of the Director at NIH and is responsible for reviewing non-criminal allegations related to NIH programs and activities. We review allegations that are sent directly to us or that are referred to us by the OIG or other NIH organizations. We have the authority to conduct reviews involving allegations of improper conduct by NIH employees under the Public Health Service Act, 42 U.S.C. 282(b)(1) which authorizes the Director of NIH to establish and implement general policies for the management and operation of programs and activities at NIH.

Please note that it is NIH policy to neither confirm nor deny that a review is being initiated or is under way. All information (for example, the status of a review or the nature of evidence) is confidential and therefore may not be provided to you or anyone other than officials with a need to know, subject matter experts, and legal counsel. Information, documents, and reports related to ongoing and completed reviews are subject to Freedom of Information Act exemptions related to pre-decisional documents, unwarranted invasion of personal privacy, and law enforcement purposes, and are therefore not releasable. Report recipients are asked to comply with confidentiality requirements.

We use a two-stage report clearance process that includes a draft report and a final advisory report. The final advisory report is a pre-decisional document prepared for NIH management officials. Therefore, it is sent to NIH officials with a need to know, with an information copy sent to the subject.

We thank you for your interest.

Sincerely yours,

Thomas V. Hartshorne
Supervisory Auditor
Division of Program Integrity
Office of Management Assessment, OM