

Department of
Veterans Affairs


Memorandum


Date: AUG 11 2004

From: Acting Chief Research and Development Officer (12)


Subj: Annual Facility Human Protections Program Report

To: VA Associate Chiefs of Staff for Research (151)

Thru: Acting Deputy Under Secretary for Health (10A) 

Deputy Under Secretary for Health for Operations and Management (10N) 

1. VHA Directive 2003-031, Establishment of a Facility Human Protections Program (FHPP), requires each facility Associate Chief of Staff for Research (ACOS/R) to report to the Office of Research and Development (ORD) on an annual basis:
 - The total amount of direct costs of industry-sponsored studies with human subjects conducted at their VA medical center (VAMC).
 - The total amount of funds that were made available by the study administration entity (NPC or university) in support of FHPP-related activities as defined in the directive, and
 - An accounting of costs incurred by their VAMC in support of FHPP-related activities.
2. The first requirement should only include funds collected in FY '04 for per patient direct costs, proportionate to the number of VA patients enrolled in a study. Funds collected for study administration, IRB review fees or any other indirect costs should **not** be included in this figure. The second requirement should reflect the total amount made available by the administration entity for FHPP support and may include direct payments and/or the value of "in-kind" contributions made to the VAMC in FY '04. This amount should be at least 10 percent of the first item. The third requirement should include facility costs (research and/or medical care appropriation) that can be attributed to human subjects research compliance-related activities associated with industry-sponsored studies.
3. The Office of Research and Development will send an electronic report template to each research office on August 31. This report will be due to ORD no later than October 31, 2004. If there are any questions regarding this memorandum, please contact Nancy Maher, PhD, of the VA Non Profit Program Office at (202) 254-0201.


Stephan D. Fihn, MD, MPH