



**DEPARTMENT OF VETERANS AFFAIRS
UNDER SECRETARY FOR HEALTH
WASHINGTON DC 20420**

JUL 28 2003

The Honorable Steve Buyer
Chairman
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Buyer:

Enclosed are the Department of Veterans Affairs' responses to the 18 post-hearing questions you submitted as a follow up to the Subcommittee on Oversight and Investigations' hearing on Human Subject Protections held on June 18, 2003. A complete set of responses (redacted and unredacted number 4) were provided electronically to your staff on July 21, 2003.

If you have further questions, or need additional information, please have a member of your staff contact Doug Dembling, in the Office of Congressional and Legislative Affairs. He may be reached at 202-273-5615.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert H. Roswell". The signature is fluid and cursive.

Robert H. Roswell, M.D.

Enclosures

**Post-Hearing Questions for
Robert H. Roswell, M.D.
From Chairman Steve Buyer
Regarding the June 18, 2003, Hearing
On Human Subject Protections**

1. The GAO's testimony is highly critical of VA's efforts to implement the recommendations made in its September 2000 report on human subjects protections. It does, however, praise ORCA for the actions its staff took during the same period of time. In light of this, please explain VA's rationale to abolish ORCA?

Response: The Office of Research Compliance and Assurance (ORCA) contributed in many ways to the improvement of VA's protection of human subjects participating in research. However, despite ORCA's contributions, recurrent issues related to human research conduct compelled VA to make changes to both ORCA and ORD. VA's experiences led to the establishment of mechanisms for more rapid, broad and effective development and dissemination of policy and education. These actions go beyond assurance of compliance, and are directed to assure the adequacy and integrity of research programs. The changes modify and strengthen the principles that brought ORCA forth. All personnel in the former ORCA are now exclusively devoted to oversight in the new Office of Research Oversight (ORO), expanding VA's capacity for research oversight.

2. Dr. Wray recently held a training seminar for senior VHA officials in Ann Arbor, MI. Before that training seminar, how many similar seminars were held since 1999?

Response: Veterans Health Administration (VHA) officials from ORCA conducted eleven one-day regional leadership seminars since 1999. No national research training seminars were previously held for senior leadership. Additional information is included in the response to number 12.

3. Does the VA believe it is essential to give the Office of Research Oversight the authority not only to monitor situations where there may be problems, but also to give it the authority to initiate random checks?

Response: Yes. ORO will visit some facilities even when there is no evidence to suggest there are compliance problems. In the past, ORCA visited at the invitation of leadership in the facilities and the Networks and performed multi-assessment visits to review compliance at the facilities.

4. For researchers who violate either the Common Rule or VA's internal policy on human subject protections, but do not actually commit a crime, does the Department have a set procedure concerning disciplinary actions? Does VA have a minimum level of discipline? What disciplinary actions were taken against the researchers at West LA in 1999?

Response: 4. For researchers who violate either the Common Rule or VA's internal policy on human subject protections, but do not actually commit a crime, does the Department have a set procedure concerning disciplinary actions? Does VA have a minimum level of discipline? What disciplinary actions were taken against the researchers at West LA in 1999?

Response: The facility director determines disciplinary action on a case-by-case basis. Sanctions can include termination. ORD can bar individuals from receiving VA funding, and ORO can suspend the assurance of a facility (but not individual) until the site is in compliance.

Several individuals received disciplinary action at West LA in 1999. The Chief of Staff received a reprimand - this action has expired. The _____ received a reprimand; this action has expired and was purged from the individual's personnel file. The _____ received a demotion, but the action was overturned upon review of the Merit Systems Protection Board. One _____ was suspended. However, the grievance process overturned the suspension. The _____ resigned in August 2001 and is not currently a VA employee.

5. Did the VA consult with [the] Office of Human Research Protection (OHRP) when it moved to create a new organizational structure within the Office of Research and Development?

Response: No. VHA had access to the policies of OHRP and other organizations involved in research protections.

6. Is the VA familiar with the *Report to the Advisory Committee to the Director, NIH from the Office for Protection from Research Risks Review Panel*, published in 1999? Was this gold plate standard utilized during VHA's reorganization of ORD and ORCA?

Response: VHA is familiar with the report and has consulted closely with one of its authors. While some analogies can be drawn between the relationship of the former Office for Protection from Research Risks (OPRR) to the National Institutes of Health and that of ORCA to ORD, the scope of oversight of OPRR and its successor, the Office for Human Research Protections differ greatly from ORCA. Unlike the NIH, VA conducts an intramural research program. In addition to funding grants, VA employs its principal investigators and maintains responsibility for ensuring that its patients get the highest quality care. Therefore, ORD's first moral obligation is to preserve and ensure the health of our veterans—in short, to ensure the protection of human subjects.

7. Secretary Principi issued a memo on April 15, 2003 expressing great concern about the lack of training in ten crucial areas. Did the training session conducted by Dr. Wray address all ten of his concerns? Please provide the Subcommittee with VA's written plan that responds to this mandate.

Response: Yes, additional details are presented in the reply to question 12 below.

8. VA's written testimony discussed the "stand down" which was completed on June 6th with the submittal by each VAMC of a written report to central office. Since you have established the new Office of Research Oversight to check on research compliance, what is ORO's role in evaluating the reports for their adequacy? When will ORO provide the Under Secretary for Health with an assessment of the adequacy concerning actions taken by the VAMCs during the "stand down?"

Response: Directors of 107 of 109 facilities have attested "that their active Institutional Review Boards (IRBs) and Research and Development Committees are functioning effectively, are appropriately constituted, and meet regularly to provide timely review and oversight of new and continuing protocols as well as review adverse events and serious adverse events." ORO is discussing with ORD activities at the two facilities where additional work may be needed.

The remainder of the report focuses on areas within the purview of ORD. ORD briefed the Under Secretary for Health through the Deputy Under Secretary for Health on June 26. ORD briefed the Secretary on June 26, and the Deputy Secretary on June 27.

9. When GAO submitted its report in September 2000, entitled "Protection for Human Subjects Need to Be Strengthened," the VA agreed to promptly fulfill the five recommendations. The VA agreed to issue current, comprehensive and clear guidance, including a new Handbook on Human Subjects Protections. Despite commitments made by VA at three previous hearings before this committee, the Handbook has not yet been published. Why has it not been published? When will it be published?

Response: VHA has been preparing a handbook that accurately reflects Federal human research protection policies. Changing standards and varying interpretations complicated and lengthened the concurrence process. VHA delayed publication of the handbook and two others dealing with research protections this winter to incorporate the provisions of the Health Insurance Portability and Accountability Act. This has been accomplished and the handbook was published on July 15 (copy enclosed).

10. VA also agreed to determine the funding levels needed to support human subjects protection and ensure the appropriate allocation of funds. When was this assessment made? What funds are now allocated to adequately support the resources needed at VAMCs to support a robust human subject protection program?

Response: Health services researchers from VA, the University of Rochester, and the University of California at Los Angeles completed the study in June 2002. However, they restricted their assessment to institutional review boards (IRBs). The study found that a biomedical institutional review board is an expensive operation. Changes in regulations and the push to accredit IRBs and to certify IRB administrators have increased board costs. Over time this will place greater burden on small IRBs,

particularly those at academic medical centers where administrative reimbursement from the National Institutes of Health is capped at 26 percent.

IRB costs throughout the VA are estimated to be nearly \$20 million per year. In addition, annual research participant oversight and compliance costs have risen to over \$3 million. VHA provides partial funding for IRBs through VERA. ORD has funded the oversight and compliance costs (\$5 million has been transferred from the FY '03 Medical and Prosthetic Research budget to cover anticipated costs) and invested more than \$3 million per year in other research participant costs such as National Committee for Quality Assurance (NCQA) accreditation, researcher training and education, and computer equipment and software. ORD funding will increase with the full implementation of the Program for Research Integrity Development and Education (PRIDE). Implementation of VHA Directive 2003-031, Establishment of a Facility Human Protections Program (FHPP), will increase the funds available for this program. When accepting this type of grant/gift, VA officials will be required to ensure that the funds provided through such grants include an amount equal to 10 percent of the direct cost of study, or a flat fee of \$1200, whichever is greater. The purpose of this policy is to assist VA facilities in fully covering the costs associated with protecting human subjects who participate in such research studies. The policy applies to all newly funded and VA-approved industry-funded studies conducted at VA facilities

11. VA's testimony briefly discussed the status of the external accreditation program for the Human Research Protection Programs at VAMCs through a contract with the National Committee for Quality Assurance (NCQA). At the September Hearing last year, VA testified that it had directed the former ORCA to complete an evaluation of this accreditation program. The Subcommittee was provided with a copy of the program evaluation last December with one overall recommendation and eight general recommendations. Did VA endorse the recommendations and what has been done to implement them? How is the NCQA Certification process progressing?

Response: ORD endorsed the recommendations and has been implementing them by working very closely with NCQA since January 2003, through contract changes, and by Research and Development Accreditation Consulting Team (ReDACT) training. ReDACT training for six VA facilities was held June 25, 2003. The revised standards (Version 2.1) were posted on the NCQA website in April 2003, and the revised policies and procedures were posted in June 2003. VHA will work with each site individually to ensure that it is capable of being fully accredited.

NCQA accreditation activities will resume by early September 2003, when two sites (Memphis and Hines) will submit their required paperwork. On-site surveys will begin in October, and NCQA will speed up the process so that by spring 2004, approximately four facilities per month will begin the accreditation process. All VA facilities will have gone through the accreditation process by August 2005.

12. Secretary Principi issued a memo on April 15, 2003 expressing great concern about the lack of training for the senior level in management of VA research training in ten

crucial areas. Has ORD's training addressed all ten of his concerns? Please provide the Subcommittee with its written plan that responds to the Secretary's memo.

Response: The training plan (see attached course outline) addresses each of the Secretary's concerns. One hundred thirty-six medical center directors received one day of training on May 29, 2003 in Ann Arbor. They will receive another half day on July 31. Other senior management will also attend the July 31 session, and the May 29 program will be repeated for them on August 1.

13. During Dr. Wray's teleconference on March 10, 2003 she stated that "the Office of Human Research Oversight will be a much, much smaller office and have responsibility only to do focus reviews for cause when I report to them for cause." Is this still the Department's position about ORO's role?

Response: No. ORO will have a broader role than implied during early discussions of the transition for the office. ORO will retain the responsibilities of the former ORCA for matters related to research compliance and oversight involving protection of human research subjects, research misconduct, animal welfare, and research safety.

14. When the VA established the former ORCA, now ORO, it was stated to the Committee during the April 21, 1999, hearing that "ORCA will be an independent, objective and unbiased entity in its compliance and oversight activities." In particular, ORCA would not be a part of the Office of Research and Development (ORD) to ensure that there would be no jeopardy to its impartiality and credibility. In January 2003, VA's original plan was to incorporate ORCA as a component of ORD. What precisely were the reasons for this change of direction?

Response: In January 2003, as issues continued despite the creation of ORCA, VHA began to carefully explore a range of possible organizational structures to more effectively achieve compliance at all research sites. In particular, there was concern that the effectiveness of ORCA was being undermined by the fact that sites were reluctant to seek consultation from ORCA for fear of triggering an investigation. One option that was considered was to incorporate ORCA into ORD.

After reviewing different possible structures, and in consultation with VA's congressional oversight committees, VHA determined that the compliance and oversight functions should remain outside of ORD to ensure complete faith in the independence, objectivity and lack of bias. Further VHA deemed it essential to the effectiveness of the human protection program that all policy and education functions be removed from the office responsible for oversight and compliance, and placed in ORD so that there could be undivided focus on developing policy, guidance, training and prevention of human protection problems before they occur.

15. During the four hearings this committee has held since 1999, including the two that the current VA Under Secretary for Health testified at last year, there was unequivocal support for the former ORCA. Without consulting with Congress, VA decided to

eliminate ORCA and incorporate it in the Office of Research and Development (ORD). Now we have a new organization the Office of Research Oversight. What assurances can you give the Subcommittee that ORO will be able to conduct its work with the independence needed to ensure that it is a credible entity, beyond reproach and of the highest integrity.

Response: I am committed to keeping the Office of Research Oversight independent from the Office of Research and Development. ORO has retained all of the authorities of the former ORCA, with the exception of education and training activities. A Chief Officer reporting to the Office of the Under Secretary for Health heads the office. The new directive for ORO will reflect its independence from ORD.

16. H.R. 1585 would require the entity, and I presume it will be ORO, to provide regular counsel to the Under Secretary for Health on all matters within its scope of responsibility. In order to avoid any conflict in this role vis-à-vis ORD, should it state that ORO is the primary advisor to the USH in these matters?

Response: ORO should be the primary advisor to the USH on research subject protection issues involving compliance and Federal-Wide Assurances. ORD should be the primary advisor the USH on research subject protection issues involving education and policy development.

17. H.R. 1585 would require that ORO conduct periodic inspections and evaluations of research integrity at VAMCs. Is ORO able to immediately conduct such prospective investigations and evaluations?

Response: ORO is prepared immediately to conduct prospective investigations and evaluations of research integrity at VAMCs. The Office has a comprehensive protocol that provides for the inspection and evaluation of human research protection, animal welfare, research misconduct, and research safety programs.

18. H.R. 1585 would require the Director of ORO to suspend, restrict, or modify research as determined to be appropriate. The Subcommittee understands that the former ORCA did make such determinations in consultation with OHRP/DHHS. How did that process work and do you think that the Director of ORO can appropriately discharge this responsibility.

Response: In ORCA, any suspensions or restrictions on the assurances for the protection of human subjects were discussed in advance with OHRP to assure consistency with their policies. OHRP is a cosignatory on the Federal Wide Assurances that ORCA/ORO negotiate with the VA facilities. The Chief Officer also discussed the actions with the Under Secretary for Health and/or the Deputy Under Secretary of Health. This was done by telephone or in person prior to the facility and the Network offices being notified that these actions would be taken. ORCA/ORO does not require "modifications" in the research in a broad sense, but may require or recommend that additional protections for human subjects be included in the research being carried out

or to be carried out. Depending on the nature of these modifications, ORO staff may consult with OHRP in advance and keep the office of the Under Secretary informed. Under the authority of the Assurance required by regulation and signed by both the ORO Chief Officer and a representative of OHRP, ORO will retain the responsibility for discharging any suspension or restriction of the Assurance.