

**Department of
Veterans Affairs**

Memorandum

Date: **JUL 26 2010**

From: Chief Research & Development Officer (12) and
Chief Officer, Office of Research Oversight (ORO)(10R)

Subj: Roles and authority of the VISN and Medical Center Research Compliance
Officer (RCO) and Office of Research Oversight (ORO) with regard to a VA-
affiliated Nonprofit Research and Education Corporation (NPC)

To: Medical Center Directors

Recently, there have been discussions regarding the roles and authority of the VISN and Medical Center Research Compliance Officer (RCO) and Office of Research Oversight (ORO) with regard to a VA-affiliated Nonprofit Research and Education Corporation (NPC).

The RCO, who reports to the VA Medical Center Director, is tasked with informed consent and regulatory audits of research required by VHA, as well as education functions. Additionally, the RCO may be tasked by the VA Medical Center Director with additional jobs and responsibilities. ORO is responsible for the oversight of VHA research in areas of human subject protections, laboratory animal welfare, research safety, research laboratory security, research information protection, research misconduct, and research-related debarment or suspension. While most documents requiring review for oversight purposes are available from VA sources, in certain instances a RCO or ORO Reviewer may need to seek documents from the NPC.

NPCs are created through Federal law to be flexible funding mechanisms for approved VA research at VA Medical Centers, but they are also nonprofit corporations under state law. They are neither an agency nor an instrumentality of the United States, 38 U.S.C. § 7361(d)(2)(b). However, under section 7366(a) of title 38, United States Code, "The records of the Corporation shall be available to the Secretary." Both the RCO and ORO are manifestations of the Secretary. They are the research oversight tools employed by VHA management, under which VA research is conducted and administered in the name of the Secretary. This section provides the statutory authority for review of a NPC's records by either or both ORO and the RCO, when appropriate. Certainly such authority must be used sparingly so that it does not create untoward distractions from the mission of the NPC and must be used only when it can be justified by a stated, valid oversight purpose.

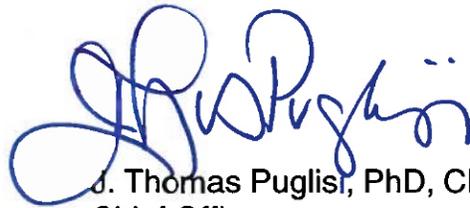
Should the situation arise where a RCO or ORO Reviewer seeks review of an NPC's documents, has communicated a valid oversight purpose to the NPC and the NPC

refuses to provide the records, the RCO or ORO Reviewer should contact the Administrator of VA's Nonprofit Program Office (NPPO), currently Kim Collins. The Administrator will work with the RCO or ORO Reviewer and the NPC to find a solution. In some instances, the situation will necessitate going up the chain in VHA and ultimately to the Secretary. At each step, the reasonableness of the request will be weighed against the need for the records requested. During this process, it is expected that an accommodation and agreement will be reached. If an agreement cannot be reached, the Secretary will request the necessary records, at which point the NPC cannot legitimately refuse.

Any questions or inquiries should be addressed to the Office of Research and Development, Nonprofit Program Office at 816.922.2043 or via e-mail to Kim Collins, NPPO Administrator at Kimberly.collins@va.gov.



Joel Kupersmith, M.D.
Chief Research & Development Officer
Office of Research & Development



J. Thomas Puglisi, PhD, CIP
Chief Officer
Office of Research Oversight