

**Department of
Veterans Affairs**

Memorandum

Date: June 25, 2004

From: Acting Chief Research and Development Officer (12)

Subj: Invention Ownership Rights and Royalties

To: NPC Executive Directors

1. VA affiliated non-profit research and education corporations (NPCs) must ensure that agreements with non-VA entities involving intellectual property (IP) and royalties be consistent with Department policies and regulations.
2. **Intellectual Property:** Where the VA has executed a Cooperative Technology Administration Agreement (CTAA) with an affiliated university, the NPC's agreements with sponsors and any other documents NPCs sign that may contain clauses pertaining to IP must reflect the terms of the CTAA. Regardless of whether a facility has a completed CTAA, NPC agreements may not conflict with VA policy regarding IP. Also, if an NPC enters into agreements such as material transfer agreements (MTAs) or other documents concerning IP, they must ensure that they are consistent with VA policy and/or the CTAA.
 - a. A CTAA allows VA and affiliated universities to be co-owners of IP while providing the universities with authority to patent and market any IP that may result from research studies. If a CTAA exists between your VAMC and its affiliated university, the rights to develop and market any new invention created by a VA employee (full or part-time) or a VA WOC appointee belong to the university. Exceptions are made if the type of study in question (e.g., a data collection study sponsored by a pharmaceutical company) has been exempted in the CTAA or if the university has reviewed the study agreement in accordance with the terms of Clause 3.1 of the CTAA section on licensing and any other local sub-agreement that may be in place. For example, unless there is a waiver in the CTAA or the university has given its approval, research agreements between a pharmaceutical company and NPCs may not promise a right of first refusal to license any inventions resulting from the research project. Under the terms of the CTAA, VA has already given to the university the right to develop intellectual property developed by VA personnel and/or using VA facility resources.

- b. NPC executive directors should be aware of the guidance on appropriate language for clinical research agreements between NPCs and pharmaceutical companies involving VA Medical Centers (VAMCs) with and without CTAAs. This guidance is available on the NAVREF web site at <http://www.navref.org/legal/main.htm>. Regional Counsel advice, or the assistance of a member of the OGC Corporations Panel, should be sought to negotiate language that differs substantively from the samples on the NAVREF web site or if there are any questions. NPCs found to sign agreements containing inappropriate terms may be required to obtain VA counsel approval of all future agreements (Handbook 1200.17. d.). Executive directors may also want to enlist VA attorney assistance with other types of documents that may contain clauses relevant to IP.
- c. A list of universities that have signed CTAAs with VA can be found at <http://www.vard.org/tts/iaa/partners.htm>. If the CTA with your affiliated university is one of the early ones that do not exempt NPC data collection studies, or if the university is not fully cooperating on expeditious processing of agreements for NPC-administered studies, please contact Nancy Maher, PhD, of the VA Nonprofit Program Office (202-254-0201).
3. **Royalties:** An NPC may not accept for administration royalties owed to VA that result from an invention in which the VA has asserted ownership. Such funds must be directed to the Department of Veterans Affairs Technology Transfer Program (TTP). See Handbook 1200.18 for details.
- a. NPCs must comply with applicable federal laws governing royalty payments and their distribution. Upon receipt at ORD, the TTP will distribute a portion of non-personal royalty funds to the VAMC where the intellectual property was invented. Facilities may use these funds for scientific research and development consistent with the VA research mission and objectives. However, because these funds are distributed as *appropriated* research and development dollars, they must be treated as such by the facility and may not be directed to an NPC for administration.
- b. VHA will soon amend Handbook 1200.18 to specifically address intellectual property ownership rights and management of invention royalties at the local level. In the meantime, please follow the guidance stated above.
4. If you have questions regarding this memorandum, please contact Nancy Maher, PhD, VA Non-Profit Office at (202-254-0201) or Nancy.Maher@hq.va.med.gov.



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