

**Department of
Veterans Affairs**

Memorandum

Date: **FEB 21 2007**

From: General Counsel (023)

Subj: Decision Memorandum to Implement the Recommendations of the Review of the Office of Research (VHA) and OGC Working Relationship

To: Acting Under Secretary for Health (10)

1. Please find attached an informal decision memorandum documenting General Counsel's and VHA's decision to adopt the recommendations of the review conducted by Dr. Margaret Hammond and Renée L. Szybala of the working relationship between VHA's Technology Transfer Program (TTP) and PSG IV. As you know, the purpose of the review was to address communication and collaboration issues which allegedly negatively impacted VA's research program. On December 15, 2006, Margaret and Renée reported their findings and recommendations to you and VHA management. At that meeting OGC and VHA agreed to adopt their recommendations.

2. The decision memorandum would document VHA's/OGC's decision to implement the review recommendations. This would provide notice and clarification to TTP, Regional Counsels, and any other affected offices, of the significant changes VHA and OGC is making in connection with TTP operations and OGC's provision of legal services in the area of Technology Transfer. Further, the memorandum will memorialize VHA's/OGC's commitment to making TTP an important priority. We note that TTP and OGC are already meeting on a weekly basis to implement the recommendations. We further note that TTP concurs in the decision memorandum. We thus recommend that you sign and issue the memorandum, acknowledging that TTP has the lead as it is their program, and tasking PSG III as the lead within OGC to provide legal advice to TTP.


Paul J. Hutter

VHA/LEGATIVE
CORRESPONDENCE

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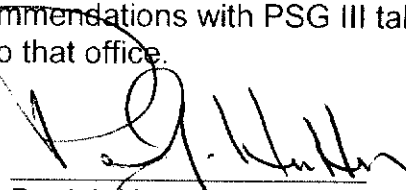
Decision Memorandum

Implementation of the Recommendations of the Review of the Office of Research (VHA) and OGC Working Relationship Regarding Technology Transfer

1. VA research and the Technology Transfer program constitute important VA priorities. They are vital for our health care mission and to the veterans for whom we care.
2. Last Fall, at our request, Margaret C. Hammond, M.D., Chief, Consultant, SCI & D SHG, Puget Sound Health Care System and Renée L. Szybala, J.D., Associate General Counsel, OGC (023) conducted a thorough and expeditious review of the facts and circumstances pertaining to certain roles and responsibilities of the Technology Transfer Program (Office of Research and Development) and OGC's Professional Staff Group, PSG IV, which handled legal matters in the areas of Information Law and Intellectual Property. Specifically, Dr. Hammond and Ms. Szybala were tasked with identifying the difficulties the two offices were having in collaborating concerning issues including, but not limited to, the timely creation and review of research agreements involving clinical trials of pharmaceuticals, other research agreements and licenses.
3. On December 15, 2006, this team reported their findings and recommendations to VHA and OGC management, which informally accepted them at that time. (Recommendations attached). Some of the recommendations regarding PSG IV have since been rendered moot by the reassignment of certain of their functions to PSG III. This memorandum formalizes our decision to implement all of the other recommendations. The Technology Transfer Program will have the lead in implementing the recommendations with PSG III taking the lead in OGC in providing legal assistance to that office.



Michael J. Kussman
Acting Under Secretary for Health


Paul J. Hutter
Acting General Counsel

IV. RECOMMENDATIONS

A. Personnel

1. PSG IV has informed us that they had been considering reassigning the lead for the tech transfer program within PSG IV to another attorney.
 - That decision should be made without delay. Such a reassignment should be to an attorney with some familiarity for this subject area.
 - If responsibility is not shifted, provide some leadership training to current attorney (decision making, timeliness, conflict resolution, style)
2. Provide leadership training for Director, TTP (decision making, timeliness, conflict resolution, style, project management, ORD data systems)
3. Engage in close supervisory monitoring at multiple levels.
 - Stay engaged until conflict resolved, stated results achieved and program back on track
 - Incorporate expectations in performance plans or other reviews
 - Require frequent (weekly) progress reports and briefings
 - TTP/OGC to report quarterly to joint meeting of senior managers until resolution of conflict and substantial productivity.
4. Add CRADA expertise to TTP staff.
 - Fill TTP vacancy ASAP

B. Communication

1. All parties (including PSG IV and TTP) must stop expressing negativity
 - Avoid assumptions, check-out opinions, resolve suspicions
2. Ensure clear communication to all participants in process (within OGC, between OGC/ORD)
3. Continue with written comments from OGC to promote clarity and as tool for reference
4. Change format of OGC comments to make them more client-friendly.
 - Make clear what changes are legally necessary to obtain OGC concurrence
 - Separate policy, format, and other observations and make clear they are suggestions only.
 - When possible, suggest alternatives for achieving client's goal when disapproving proposal
 - Provide tracked changes in document whenever possible.
 - Ensure OGC input during review process is consistent with final comments.

5. Tasking of drafts from TTP to OGC for review must be clear, formal and in writing
 - Establish shared log of draft agreements under review and assignments in CO.
 - Establish expectations for phone or meeting resolution of minor issues.
 - Define standards for responsiveness
 - Two days for email; two days for comment during development of CRADA

6. Allow no dropped balls.

7. Complete each Master agreement within 14 days of its arrival in CO (exclusive of drug company review time)
 - Inform drug company of internal performance expectation in order to reflect VA's understanding of their business needs.
 - 30 days is absolute outside maximum time allowed for the agency to disapprove or require modification of any agreement submitted by the Laboratory Director. Strive for substantially less.

8. Establish weekly meetings of team (PSG IV and TTP) until program is back on track.
 - Discuss new and old business related to models, Masters, licenses and exceptions
 - Identify pending agreements and assign appropriately
 - Keep log of very difficult issues to ensure discussion.
 - Discuss concerns, questions; discuss process issues.

C. Process

1. Affirm OGC/TTP roles and boundaries
 - VHA (TTP) handles policy and programmatic issues
 - OGC handles questions of law
 - Nonoccurrence by OGC does not mean VHA must abandon its proposal or give OGC final authority

2. Prior to procedures being drafted or launched, OGC must complete its current reconsideration of the interpretation of tech transfer laws.

3. Institute a written SOP for review of draft CRADAs and licenses
 - Procedures must be in writing and understood by all.
 - Change of position could greatly alleviate current issues with drug companies
 - Any change must be clearly communicated to field
 - Change should be reflected in Models to the extent appropriate.

- Should maintain confidentiality of CRADA interpretation in order to negotiate
4. OGC procedures should not differ from usual procedures for handling legal aspects of VA programs.
 - OGC CO should be involved in resolution of legal issues of national scope
 - E.g. interpretation of Federal Technology Transfer and intellectual property laws (historically PSG IV)
 - E.g. interpretation of laws and authorities of VA non-profit corporations (historically PSG III).
 - Here, includes concurrence on Model and Master CRADAs, and substantive changes to them, due to national scope
 - CO participation in negotiations with collaborators would help inform and give context to legal advice.
 - Those at the table should have authority to speak for their organization on most issues discussed.
 - Other advice from OGC CO should come on as requested basis.
 - Regional Counsel should be involved in resolution of local legal issues
 - Provide advice and concurrence as requested on local (single site) CRADAs
 - Participate in local or early negotiations
 5. TTP personnel should lead development of model and Master CRADAs
 6. **Exceptions** to policy and legal models for single site CRADAs and licenses must be fully justified and tracked
 - Simple data base should be created by TTP for shared tracking
 - Changes to policy desired in field must come in as request to TTP (copy to OGC), properly justified and entered by TTP into data base.
 - Changes to legal model desired in field should come in as request to OGC (copy to TTP), properly justified and entered by OGC in data base.
 - Justification should be based on relevant criteria such as: risk of IP, current status and ownership of IP, needs of and importance to veterans and VA, collaborator views and needs, input from investigator.
 - CO review will ensure national consistency and that expectations are not so frequent as to overtake the rule.

7. Define review process
 - Masters: generating party to TTP to OGC
 - ~~Models: TTP to OGC~~
 - Other: field to TTP to OGC

D. Management of TTP

1. Require development of tracking system for CRADAs
 - TTP to report yearly on # of clinical trial agreements, # CRADAs, # waivers
 - Track outcomes
 - Timeliness of CRADA development
 - IP, licenses
2. TTP should write policy and procedure manual
 - TTP should define work products and timeline
 - TTP Director to lead small team (OGC/TTP)

E. Jump-Starting the Program

1. Finish and disseminate any change from OGC reconsideration of legal interpretation
2. Establish CRADA development process as important priority for VHA
3. Appoint Director of TTP as Lead
4. Appoint dedicated legal advisor who will give first priority to Lead's requests.
5. Require Lead to provide, within one week, prioritization of tasks and timeline for completion
 - Many believe completing the first master is most important
 - Novartis or Sanofi may be furthest along
 - Timeline may point to need for temporary infusion of resources
 - Include completion of PI initiated clinical trial model
6. Lead should reconstitute multi-office Work Group
 - For one-week of intense activity to complete work on models and negotiation of highest priority Masters
7. Develop and implement strategy for rehabilitating VA and its credibility with drug companies.