

Department of
Veterans Affairs

Memorandum

Date: SEP 27 2007
From: Chief Research and Development Officer
Subj: Approval of Master CRADA with Novartis
To: Under Secretary for Health

1. As you know, obtaining agreement on our first "Master CRADA" with a major drug company is an important step in the effort to revitalize the clinical trials currently conducted within VA medical centers throughout the country. The master agreements are templates that will be used nationwide and to which the protocol for the particular study will be attached. Master CRADAs are not contracts, but the terms they contain are deemed agreed upon, and not subject to renegotiation, on a nationwide basis for both VA and the pharmaceutical company. This will both save the need for local negotiation of these contract terms and promote consistency nationally.
2. We seek your approval of the attached Master Agreement template between VA and Novartis, the first such Master CRADA on which agreement in principle between TTP and the drug company has been obtained. Its terms have been fully negotiated and meet legal and program requirements, including those required for patient safety and the protection of private health information. The Office of General Counsel has participated both in the drafting of the model and the negotiations with Novartis and has concurred in this agreement. We expect this Master to speed up negotiations of other master agreements by serving as a template for those negotiated in the future.
3. We are extremely pleased and excited that our efforts have come to fruition in this way and believe that quick implementation of this agreement will be beneficial to VA health care and VHA's research program. It will make participation in clinical trials more available to our veterans and ultimately will lead to the approval and availability of additional therapeutic drugs for the treatment of veterans and the public.

Joel Kupersmith
Joel Kupersmith

9/27/07
Date

Approved/Disapproved

Michael J. Kussman, M.D. SEP 28 2007
Michael J. Kussman Date
Under Secretary for Health