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DEC Use in Preclinical Drug Development Services Program for NcTT/NCATS

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May 17, 2012

Ms. Kelli T. Broda
Contracts Specialist
Office of Acquisitions
6701 Rockledge Dr. RKL2/6100 MSC 7902
Bethesda, MD 20892-7902

Re: Solicitation Number: NHLBI-CSB-RFC-TR-2013-19-KB
Preclinical Drug Development Services for the NIH Center for
Translational Therapeutics (NCTT/NCATS)

Dear Ms. Broda:

This is in response to the Special Notice Request for Comments on the Proposed Use of a Determination of Exceptional Circumstances (DEC) for the subject program.

The Council on Governmental Relations (COGR) is an association of more than 185 U.S. research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research and other sponsored activities conducted at its member institutions. We have had many discussions with NIH over the years with regard to the utilization of Determinations of Exceptional Circumstance (DECs) in NIH programs and activities, and appreciate the opportunity to provide comments on the subject DEC.

We do not disagree with the concept of and rationale for the DEC with regard to the NCATS Therapeutics for Rare and Neglected Diseases (TRND) and Bridging Interventional Development Gaps (BrIDGs) programs. A DEC approach, if done narrowly as here, may be appropriate. We understand that retention by contractors of patent and invention rights to subject inventions that are methods of manufacturing or synthesis of materials submitted by contributors and require the use of, improve, or incorporate such materials, might well be a deterrent to submission of the materials.

However, we have several concerns about the proposed DEC as stated. In addition, the DEC applies to two different programs. While neither involves NIH funding for investigators, we are uncertain whether they will operate in similar fashion.

The BrIDGES program is the successor to the former NIH RAID program. Under this program investigators submit new therapeutic agents to NIH contractors for preclinical developmental services. Presumably the DEC will apply to the contract service providers, since investigators are not funded under the program. We are concerned about the description of the DEC in the Notice. As worded, it is not clear where the rights actually reside under the proposed DEC. The DEC implies “Contributors” may request assignment of rights. Presumably in the case of BrIDGES this applies to investigators or their institutions. However, it also states that if the Contributor “declines offer of assignment” (query: from whom?), NCATS may dispose of the invention rights as it determines, such as allowing contractors to “retain” invention rights.

If the Contributor declines title, it is not clear why NCATS should dispose of the invention rights. In that circumstance, it appears appropriate and more consistent with Bayh-Dole for the contractor to retain normal Bayh-Dole rights. Should the contractor not be able or interested in pursuing commercialization, only then would rights revert to the government.

In addition, the DEC states in a separate paragraph that “Rights to all other Subject Inventions will be retained by the Contractor pursuant to the Bayh-Dole Act.” It is not clear whether or not this refers to “Class 2” inventions.

The DEC also would benefit from clear definitions. For example, “Contributors” are variously referred to as “Providers” or “Collaborators.” There is no definition of “Materials,” so it is unclear whether derivatives also are included. Including derivatives may raise other issues, so the DEC needs to address this clearly.

The BrIDGES FAQs indicate that some of the contractors have agreed to offer a first license option to the originating investigators, while others may be subject to the DEC. This appears confusing to potential contributors. Will it be clear at time of submission which contractors are covered by the DEC? There may be advantages to dealing with invention rights through license options in some cases, particularly if the scope and coverage of the DEC is uncertain. But in any event the terms governing rights to materials or technologies should be clear prior to submission of the new compound or agent.

The TRND program envisions owners of proprietary materials or technologies providing the materials for collaborative preclinical studies for development of therapeutics for rare and neglected tropical diseases. No grant funds will be provided for the collaborations, which will involve NIH and academic scientists as well as biotechnology and pharmaceutical companies, and will be supported by NIH intramural funds.

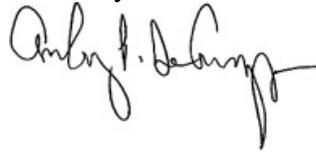
In this situation it is unclear where and to whom the DEC applies. The Bayh-Dole Act applies to funding agreements, which are defined as grants, contracts or cooperative agreements. If contract service providers are involved as in the BrIDGES program, the DEC would apply to them. However, according to the TRND website, the collaborations will be supported by CRADAs or Research Collaboration Agreements. Bayh-Dole is not applicable to such agreements, and Subject Inventions under Bayh-Dole are not involved. Since there are no Subject Inventions, a DEC may not be appropriate.

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Finally, we became aware of this DEC through the May 2 notice in *FedBizOpps*. It apparently did not appear in the NIH Guide or the Federal Register. While an important resource, *FedBizOpps* is not necessarily the best mechanism to reach the NIH constituent community. We have raised this concern with NIH before in connection with other proposed DEC's. We urge NIH to consider posting announcements of this sort in the NIH Guide and/or the Federal Register.

Again, we appreciate the opportunity to provide comments and would be glad to discuss our concerns further.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony DeCrappeo". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anthony DeCrappeo