

NIH Manual 2300-308-4, Appendix 3A

Intellectual Property Policy Waiver Request for
U01 grant "Opportunities for Collaborative Research at the NIH Clinical Center"
<http://grants.nih.gov/grants/guide/notice-files/NOT-HD-12-02S.html>

Purpose

This memorandum seeks permission to waive, as part of the *Opportunities for Collaborative Research at the NIH Clinical Center* extramural grant program, the current NIH policy asking all investigators working under appointments at NIH to assign their invention rights to NIH. The Funding Opportunity Announcement (FOA) for this program is scheduled to be issued in early Fall 2012.

Review and consideration of this issue is required now so that 1) the FOA can be advertised in a timely manner and 2) the parameters for participation can be necessarily defined. Clarity and resolution of this issue is critical in moving this program forward.

Description of New U01 Program

In July 2012, NIH announced its intention to publish a FOA for a new grant, *Opportunities for Collaborative Research at the NIH Clinical Center (U01)*, to support collaborative translational research projects. This FOA is intended to provide extramural investigators funding and a process to establish collaborations with NIH intramural investigators, thereby allowing external investigators to take advantage of the unique research opportunities and resources available at the NIH Clinical Center. Applications submitted in response to this FOA must include at least one extramural PI and one intramural PI, and meet the stipulation that some portion of the project work take place at the Clinical Center in the form of a collaboration.

Intellectual Property Rights and the New U01 Program

While collaborations between intramural and extramural investigators at the Clinical Center ("on-campus") are not without precedent, this new program is unique in its large-scale and specific emphasis on fostering collaborations and promoting the utilization of the Clinical Center by outside investigators. To ensure the success of the program, it is important to reconsider the current practice of expecting external investigators who collaborate on campus to assign their invention rights to the NIH.

By way of background, 45 C.F.R. Part 7 directs that NIH employees assign rights in inventions made using Government resources to the Government. NIH also normally requires an assignment of invention rights from non-employees working at NIH or in NIH programs in exchange for the use of NIH facilities, equipment, materials, information, and/or time and assistance of NIH employees to conduct research. Chapter 203 of the United States Public Health Service Technology Transfer Manual makes provision for specifically defined programs to request a waiver or modification of the requirement to assign inventions developed by such non-employees. The NIH program official may seek approval from the Deputy Director for Intramural Research for the NIH in consultation with the DDER where appropriate, for NIH to obtain less than the entire right to an invention made by a non-employee working at NIH.

For the new U01 grant program, there is significant concern that the current policy of expecting collaborating investigators doing work on campus to assign their invention rights to the government like NIH employees, with waiver on a case-by-case basis only, may both hamper the success of the program and create undue consternation in the external community. First, NIH's practice stands in contrast to other research entities, which generally do not require automatic assignment of ownership rights when collaborators use their

facilities. Unfamiliar with NIH's requirements, or otherwise objecting to them, potential applicants may be deterred from applying for funding under the program. Time and resources may be diverted to help potential applicants understand, and agree, to a policy that will sound foreign to many of them. And, for many, they may simply decline to apply. As a result, some of the high-risk, high-reward basic and translational research that the Clinical Center is uniquely situated to support may not be done and public health advances may be slowed.

Second, as you are aware, the Bayh-Dole Act allows grantees to take title to their grant-funded inventions. The UO1 in this case is premised on the grantee conducting the activities of the grant in collaboration with the NIH Clinical Center to advance joint research goals. It is fundamental to the purpose and conditions of the award that investigators collaborate on campus. As a condition of the UO1, the Bayh-Dole Act will obligate the grantees to comply with its terms, including granting the Federal government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States an invention made by a grantee, whether such invention was made at NIH or at the grantee's institution. This is a unique program, in that the UO1 will provide funding and require grantees to collaborate with NIH at the NIH Clinical Center. For this program, therefore, it could be viewed as contrary to the intent and goals of the Program and the Act for NIH to require grantee investigators to assign their invention rights to the government. Any invention that is made jointly by NIH researchers and grantees will be jointly owned by the grantee investigator's institution and the NIH. Such a requirement may even require a Determination of Exceptional Circumstances to be legally supportable under the Act. As above, many investigators may consequently decline to apply or raise other objections, and public health may be adversely affected.

Based on this information, we request a waiver to allow non-employee investigators on this UO1 to be exempt from the requirement to assign their intellectual property rights to NIH for inventions made under the UO1 funded on-campus collaborations.

Approval Decision: (VALID FOR THE TERMS OF THE PILOT CYCLE ONLY)

(1) Non-employee investigators on this UO1 are exempt from the requirement to assign their intellectual property rights to NIH for inventions made under the UO1 funded on-campus collaborations based on the UO1's requirement that the grantee collaborate with NIH at NIH facilities, and in accordance with the Bayh-Dole Act the U.S. Government will be granted its standard statutory rights in grantees' inventions.

Yes	X
No	

Michael Gosses
SIGNATURE

11/2/12
DATE