

CASE STUDY # 11: Another Public-Private Partnership

Dr. Wilson is the Program Officer in the keratin program, and a nail polish company approaches her to co-fund a program for research and training in fingernail biology. They want to give money to the institute to fund research on very specific projects and to meet with institute officials to help identify candidates for well-paid and highly publicized fellowships. They'd like the fellowship to be identified as the "keratin/company name" fellowships in fingernail biology. How should Dr. Wilson proceed?

Is this a partnership?

NIH program priorities can be promoted by relationships with outside organizations in a variety of ways. Two possibilities include:

1. funds are contributed by the outside organization to the NIH as a gift, thereby increasing the funds available to the NIH to make awards; and
2. awards made by the outside organization for applications that had been submitted to and were reviewed by the NIH, but were not funded by the NIH. If the NIH is making the awards, decisions must be made according to relevant peer review regulations and according to institute policies and practices related to program priorities. Additional funds received as gifts are awarded and managed in the same manner as appropriated funds. Funds awarded by outside organizations, whether based on NIH review results or according to any other criteria, are not NIH awards. In these cases, practices and procedures of the awarding organization are followed. NIH can partner in many capacities in grant awards made by other organizations, including providing advice on the design of an RFA, and serving in a review or advisory capacity. NIH staff cannot assume fiduciary or financial decision-making or oversight for an outside organization. This applies to both research awards and training awards (see Guidance for Partnerships for Extramural Funding Initiatives for more information).

Can the arrangement proceed?

Possibly, but only after considering several important issues. Among them:

- Has she provided equal opportunity and fair access to other companies and/or organizations with similar interests and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of her IC and program?
- Does the conduct of this research represent an NIH program priority?
- Can this science be accomplished better, more cheaply and/or more rapidly by entering into a partnership?
- Does the design of the relationship ensure that no outside parties unduly influence the allocation of government funds?
- Will there be open and public access to the results of the activity?
- Does the donor/partner receive a *quid pro quo* as a result of the donation/partnership?

If these are to be NIH awards the company's or organization's name attached to the awards. The donor can, however, be acknowledged in the RFA and in other documents describing the award as contributing to the NIH ability to support this award.

Who can make the decision to enter into a partnership?

Extramural program leadership would determine the advisability of entering into this research/training program and develop the necessary agreements and terms. Guidance from the Office of the NIH General Counsel and the Public-Private Partnership Program should be sought

to ensure the agreements are consistent with regulations and NIH policies. If a gift is made to the institute, the agency gift acceptance policy regulations would apply and the IC gift officer should be consulted.

What factors enter into this decision?

The decision to enter into a partnership is, first of all, scientifically driven: ensuring that scientific rigor in the interest of the public health is served in this arrangement. Once that has been determined, the details of the arrangement need to describe explicitly so that the roles and contributions of all the partners are fully explained, affirm that they are consistent with U.S. laws and regulations and NIH policies, and define the outcomes of the partnership. If the partnership is limited to a gift to the institute, an MOU may not be needed. If the donor or outside funding agency works with the institute or program to set up scientific meetings that examine the scientific basis of program decisions in this subject area, access to the discussion/meeting needs to be open to all appropriate parties (i.e., those with scientific interests in the area and expertise to contribute to the discussion). The science-based decision about whether to proceed will take into consideration the input from outside parties, including but not limited to that provided by the potential partner. This ensures that the process of government decision-making is not unduly influenced by parties who have special or unfair access to the decision-making process.

Can the contributing company or organization receive copies of the applications and/or summary statements from the NIH?

The applicant can convey the application and/or the summary statement to the outside entity at his or her discretion. This should be stated in the RFA. The NIH will not, however, transmit that information.

Can representatives from the outside company or organization participate in or observe the review of applications?

To maintain the rigor, confidentiality, and integrity of the peer review process, only individuals who are members of the review panel and certain NIH staff are permitted to attend the review.

Can the outside organization help the NIH decide which applications to fund and the level of funding?

The government cannot cede or share the responsibility of deciding how to allocate government funds. Therefore, an outside entity cannot participate in making initial funding decisions or in making annual decisions regarding continued funding based on progress.

Can Dr. Wilson speak on the company's behalf at scientific meetings?

The RFA can acknowledge that additional support for work in this area (or, specifically, support to extend the funding for this RFA) has been provided by (company name), but Dr. Wilson may not speak on the company's behalf.

What agreements need to be in place?

Partnerships are generally documented in Memoranda of Understanding (MOU MC in development) entered into by the parties involved (i.e., the company and the institute). PPP program staff and OGC should be consulted in the development of a partnership and in the drafting and execution of MOUs. If the support is in the form of a gift to the NIH gift fund, the agency gift acceptance authority would apply. The IC gift officer should be consulted.