

## CASE STUDY # 10: Public-Private Partnerships

*Dr. Smith is an NIH intramural scientist. He is approached by a company whose management has been following his lab's work for several years. The company makes novel reagents and has a platform that is likely to be useful in Dr. Smith's work, but these resources are too expensive for him to use routinely. The company offers a partnership with Dr. Smith's lab and the NIH that would include providing reagents and analytical work for free. In return, the company asks that Dr. Smith acknowledge their contribution in his publications and that he speak at scientific meetings on their behalf.*

*Is this a partnership?*

Maybe. It depends to what degree this is merely a transfer of materials and specifically requested analyses, versus a collaborative design process involving initial and ongoing input from the company scientists. Alternatively, it could be structured in a number of ways:

1. as an MTA (if it only involves the transfer of reagents);
2. as a CRADA (depending on the intellectual property issues relating to inventions and licensing related to the projects outcomes); or
3. as a gift, if the reagents and/or analyses are donated as (in kind) gifts to the IC.
4. It would be considered a partnership, if there were ongoing interactions related to the design and conduct of the research by both parties (PPP-public-private partnerships manual chapter (MC) in development).

*Can the arrangement proceed?*

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

- Has Dr. Smith provided equal opportunity and fair access to other companies that have similar reagents and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of the participating IC and with Dr. Smith's lab?
- 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?

*Can he speak on the company's behalf at scientific meetings?*

Dr. Smith may present his data and results at scientific meetings and in the literature in accordance with his IC policies regarding presentation and publication of government produced science. He may acknowledge the contribution of reagents and analysis by the company, but may not speak on the company's behalf. Dr. Smith remains a government scientist and is obligated to present his results fairly and completely. The company cannot seek or obtain rights to influence or limit his presentations, as this would represent an unacceptable *quid pro quo*.

*Who can make the decision to enter into a partnership?*

If this is an MTA or a CRADA (not generally considered PPPs), the usual procedures arranged through the IC technology transfer office need to be completed.

If this is a partnership, the oversight will include the lab chief/branch chief, the SD and the IC Director, who ultimately needs to sign the MOU documenting the partnership. Guidance from the Office of the 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 authority would apply. 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 by 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 listed, affirm that they are consistent with U.S. laws and regulations and NIH policies, and define the outcomes of the partnership.

*What agreements need to be in place?*

Partnerships are generally documented in Memoranda of Understanding 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 arrangement is conducted as a CRADA or MTA, then the IC technology transfer office will initiate the process to establish these agreements.