



Extramural Official Duties and Conflicts of Interest

CASE STUDIES

January 2008

Note: The following case studies are not derived from actual cases but have been created to help guide NIH staff through similar situations that may arise. Any similarity to actual staff and/or situations is unintentional.

CASE STUDY # 1: An Extramural Scientist with Significant Intramural Responsibilities

Dr. Jones is a senior member of the extramural staff of the NIBIB. She reports to the Director of Extramural Activities, who signs her timecard and provides performance ratings. While Dr. Jones' responsibilities do not include managing a scientific portfolio, she attends meetings convened to discuss programs and funding decisions. She also has access to summary statements and grant applications. Dr. Jones provides information at these meetings based on her scientific expertise and the nature of her responsibilities. When she was hired, an established "firewall" restricted Dr. Jones from being involved in decisions related to funding or general program management because she also has an active intramural research program with a number of collaborations. She has a separate operating budget for this activity from the NIBIB intramural program and she reports secondarily to an intramural Lab Chief for this part of her job. Dr. Jones publishes widely and is now often invited to present her work at national and international meetings and at research institutions. The extramural programs of the NIBIB support many of the research institutions and programs to which she is invited. Because of limited travel dollars available to her through her laboratory budget, she requests approval of sponsored travel, which is reviewed by the Lab Chief.

Does the firewall established when Dr. Jones was hired sufficiently protect her and the NIBIB from conflicts of interest and the perception that Dr. Jones has an unfair advantage due to her knowledge of her colleagues' and potential competitors' research plans?

Perhaps, the most important key to managing this potential conflict is training Dr. Jones to ensure she has a clear understanding of the issues and is sensitive to their complexity. A variation of the conflict of interest/confidentiality agreement used for peer reviewers might be appropriate to document the issues and evidence that Dr. Jones is aware of them. This is a complex situation, since Dr. Jones, officially an extramural scientist administrator, is not just working in someone's intramural laboratory, but in fact is immersed in intramural research and has her own lab with intramural staff (technicians, post-docs) reporting to her. Yet, she needs access to confidential information to perform her extramural responsibilities. The established firewall may be sufficient but it would be advisable to make Dr. Jones aware of potential issues and to continue monitoring the situation.

What about her collaborators—is there a conflict when it comes to any discussion about them, and would this be personal or institutional?

It should be made clear to Dr. Jones and others on the staff that she has no role in allocating extramural funds or making administrative decisions after award. It would also be appropriate for her to refrain from any internal discussion related to her collaborators or their work within the extramural staff context. Her extramural supervisor should periodically review these collaborations with Dr. Jones. Under most circumstances, the conflicts would be with the individual collaborators. However, there may be some circumstances in which at least a perception of conflict may extend to the collaborator's laboratory or institution. These should be managed, as appropriate, with the DEA director.

What about sponsored travel? Is it appropriate for Dr. Jones to accept sponsored travel? Consider the issue in light of the following:

- 1. The differentiation between extramural and intramural staff and the practices the NIBIB has put in place regarding Dr. Jones are not apparent to extramural investigators.*
- 2. Extramural staff cannot accept sponsored travel from an institution that is or potentially is an applicant/grantee.*

The sponsored travel requires that the DEA Director, as the official supervisor:

1. Review and initial the request;

2. Remind Dr. Jones of the need to limit her presentation strictly to the research from her laboratory;
3. Avoid any discussion of grants or applications; and
4. Ensure that the sponsor of the travel is not a grantee institution within the NIBIB portfolio. Travel to grantee institutions should only be covered with intramural funds for sharing her research findings.

As a final note, different controls would be necessary if the extramural responsibilities were in programmatic management or in review. In that case, such extensive intramural involvement may not be permissible.

CASE Study # 2: Giving Scientific Advice to an IC Director on Extramural Activities

An IC director is interested in a special initiative to encourage the funding of innovative applications. He has asked for nominations of innovative applications that have been peer-reviewed and approved by Council, but are not within the payline. To sort through the large number of nominations received from IC staff, he has asked the IC's Review Chief to pull together a selection committee of IC extramural and intramural staff to identify the most innovative applications for his consideration.

Is this permissible?

It is generally permissible for intramural researchers and extramural program, review, and policy staff to serve on this committee.

What protections should be put in place regarding conflicts of interest and confidentiality?

The Review Chief should discuss explicitly the confidential nature of the materials and group discussion, as well as issues pertaining to conflicts of interest. Members who are not accustomed to dealing routinely with such confidential materials, including intramural staff, should receive, review, and sign the conflict of interest forms used in peer review.

Are there any other concerns?

It should be made clear to all staff who will contact the PI about potential funding, based on IC determined procedures.

CASE STUDY # 3: Scientific Officers on Cooperative Agreements

An extramural Program Officer has been significantly involved with a cooperative agreement, attending monthly phone conferences and annual meetings with the PIs. The cooperative agreement includes three primary institutions (with six investigators in close collaboration) plus a network of more than 50 investigators who use the core facilities at the primary institutions from time to time. This Program Officer has been designated as the Scientific Officer (SO) for the grant.

A second extramural HSA has been selected to handle the Program Officer responsibilities.

Should the SO recuse herself from programmatic oversight of any application submitted by the six PIs?

By virtue of her assignment as SO, the extramural staff member has taken on the scientific role for this cooperative agreement, beyond the administrative responsibilities of a Program Officer. This implies that she has substantial scientific involvement that, among other things, could result in publishing with the group. Essentially, she now is considered a collaborator and she should recuse herself from handling grants from the six PIs and other coauthors on the papers. In some cases, it may be necessary for the SO to assume some programmatic responsibilities as well. In such cases, a waiver must be obtained (see Manual Chapter 54815 [draft]).

Should she recuse herself from any application submitted by the primary institutions?

Even if substantially involved, the SO could serve as Program Officer for other applications from the PIs' institutions, unless another conflict exists.

Should the SO recuse herself from any application submitted by the 50 other investigators or their institutions?

Unless there is another conflict, this would not be necessary.

What should the SO's role be for initial or second-level review of the cooperative agreement application?

The SO cannot attend the closed session of study section review for competing submissions, nor can she attend the Council discussion for that application; only the Program Officer can attend, however. The SO could attend an open session of the initial review meeting, if one is held. Inasmuch as the SO would not have had any involvement with the development of the initial (type 1) application, she could attend the initial review meeting.

Case Study # 4: Intramural and Extramural Scientific Research Collaboration within the Same IC

The Chief of the Chemistry intramural laboratory has indicated to an IC extramural Health Scientist Administrator (HSA) that he and his entire group would be delighted if the HSA spent some time in the Chemistry intramural laboratory at any time that is suitable to him. In his invitation, he stated that the HSA's expertise on agents that interact with DNA matches a major interest of his laboratory and it would be mutually beneficial to pool their intellectual resources in this effort. The HSA indicates that collaborating with this intramural group would be directly pertinent to the mission of his IC and that the interaction would enhance his ability to maintain the expertise and skills in his basic research area, which in turn will benefit his responsibilities within the IC as a Program Officer. He requests approval to consult with the intramural investigators in this capacity.

The HSA's immediate supervisor has no objections to the HSA's collaborating on this or other research activities with the intramural laboratory in the scope and form described above, if it does not impact his performance of his current duties. However, based on the posted descriptions of "outside activities", it is ambiguous to the supervisor whether this activity would constitute an "outside activity" and what steps, if any, are needed to obtain clearance for the activity.

Is this a permissible activity?

Yes, this is considered an official duty.

Since this is not a part of the HSA's official position or current assigned responsibilities, could participation occur during regular tour of duty hours?

Yes. The HSA could participate during his official duty hours unless his supervisor feels that the employee does not have sufficient time to do so in addition to his current assignments.

Would this activity present any level of conflict for the HSA in his position as a Program Officer? Are there other issues that must be considered, such as the potential impact of interactions that involve extramural collaborations with laboratories outside of NIH that are associated with the principal intramural laboratory? Would these issues be approached similarly if the HSA were an SRA?

Even though the collaboration is considered to be part of the HSA's official duties, conflict of interest must be managed with the investigators in the intramural laboratory and collaborating extramural investigators. The HSA would need to recuse himself from the review or program administration of any grant applications, contract proposals, or awards listing the intramural investigators as key personnel or collaborators. The HSA should not share with members of the intramural laboratory any confidential or privileged information (e.g., grant applications, contract proposals, progress reports, summary statements) to which he would have access in the regular performance of his duties. The HSA should not take unfair advantage of any ideas, hypotheses, approaches, results, conclusions, etc., that are gained through his access to confidential materials associated with the performance of his HSA duties. Similar considerations would be involved if the HSA were an SRA.

What steps are needed for approval?

Approval is obtained by the intramural investigator preparing a memo inviting the HSA to participate in the planned activities and includes any relevant information, such as activities, meeting schedules, hours per week, and length of collaboration. The HSA's supervisor would need to approve the activity and counter-sign the memo. The memo would provide documentation for the employee's file.

CASE STUDY # 5: How Collaborative Relationships that Change over Time Can Impact Conflicts of Interests – Giving Lectures

Dr. Murray is the HSA who runs the Hepatitis Program in NIDDK. He is asked by Dr. Lee of Georgetown University to give a lecture on Recent Findings in Hepatitis Research in a graduate course that Dr. Lee is putting together. Dr. Murray feels that this will not interfere with his NIH duties and would help him maintain his professional standing. When he was a professor before coming to NIH, he had always enjoyed interacting with graduate students. Dr. Murray discusses this with his supervisor and it is agreed that this can be done as an "official duty" activity. There would be no compensation for this lecture.

Following the lecture, Dr. Lee and Dr. Murray go to the university cafeteria for lunch. Over lunch they discuss scientific issues of mutual interest. The next week Dr. Lee contacts Dr. Murray to tell him about the positive feedback he's heard from the students about Dr. Murray's lecture. He mentions that he is going to offer the course during the next semester and invites Dr. Murray back to give the same lecture. After again discussing this with his supervisor, Dr. Murray agrees.

Over the next couple of years, Dr. Murray's lecture becomes a regular part of the course. The post-lecture lunch becomes a tradition as well and Dr. Murray and Dr. Lee develop a friendship around their mutual scientific interests – they often e-mail each other when they see research articles that they think will interest the other.

One day Dr. Murray sees that Dr. Lee's new grant application has been referred to his program.

Does Dr. Murray have a personal conflict with Dr. Lee's application?

He certainly does. Dr. Murray now has a personal relationship with Dr. Lee, even though it began as a lecture and then discussions around scientific issues. POs have such scientific discussions with PIs frequently; however, this relationship is currently described as a "friendship" and most PIs are not friends with their POs. Dr. Murray therefore discusses this issue with his supervisor and the supervisor decides where to transfer the application and which HSA should serve as PO. Dr. Murray did not take the responsibility of reassignment upon himself, since he is in conflict on any actions related to this application.

Should Dr. Murray be considered in conflict with all applications from Georgetown University?

Dr. Murray should discuss this situation with his supervisor and may find it useful to include the Director of Extramural Activities in the discussions. Although he does not have the title of Adjunct Professor nor does he receive any compensation, his repeated lectures do provide an ongoing service to Georgetown University. It now appears that this activity would place him in conflict with the university, and his supervisor must consider the impact this conflict has on Dr. Murray's ability to perform his NIH job. The supervisor may decide that Dr. Murray will need to end this activity or perhaps the frequent nature of it.

CASE STUDY # 6: IC Directors and Mentorship

Dr. Smith, the Director of the NINDS, also has an intramural laboratory at the NIMH. One of the postdoctoral fellows in his lab, Dr. Chen, submits a K99/R00 to NINDS. As the Director of the NINDS, Dr. Smith will have final sign off on all K99/R00 funding decisions, will participate in discussions on the program, and will make final decisions on how many grants NINDS should fund and how much money should be expended on the program.

How should the application from Dr. Chen be handled?

Dr. Smith is recused from anything having to do with Dr. Chen's application. Unless the K99/R00 was submitted in response to an RFA, Dr. Smith may have oversight and final sign off on other applications competing with Dr. Chen, but Dr. Smith may not engage in any discussions of Dr. Chen's application, nor appear on any paperwork associated with this application.

Even with these precautions in place, there may remain a concern. Since the number of K99/R00 applications to be funded is limited, Dr. Smith's decision not to fund any one of these, in effect, increases the chances that Dr. Chen's application will be funded. But there needs to be a "reasonability" test. The precautions suggested seem reasonable and it seems highly unlikely that Dr. Smith would engage in elaborate and convoluted machinations to ensure the funding of Dr. Chen's application.

Who approves documentation for Dr. Chen?

All documentation associated with Dr. Chen's application should be sent to the DDER for signature.

CASE STUDY # 7: IC Directors with Intramural Laboratories Collaborating with Extramural Organizations

The Director of the NHLBI, Dr. Ford, has an intramural laboratory in the NIA. In her intramural capacity, Dr. Ford is collaborating with scientists at Johns Hopkins University. Dr. Grant, an investigator from Hopkins with whom Dr. Ford collaborates, submits an application in response to an NHLBI RFA.

Can Dr. Ford be involved in the review or funding of Dr. Grant's application?

Dr. Ford is recused from any matters related to Dr. Grant's application. In this particular situation, Dr. Ford is in conflict with the entire RFA and must be recused from any matters related to the RFA, including signing off on any funding decisions for any of the applications in response to this particular RFA.

For official documentation, who approves in cases where Dr. Ford is recused?

As with any IC Director conflicts, all signature and actions for grants resulting from this RFA must be sent to the DDER for action.

What about other applications that Hopkins submits that are assigned to the NHLBI? Is Dr. Ford in conflict with these applications?

Dr. Ford should discuss the collaboration with the NIH Director, NIH Deputy Director and/or NIH Deputy Ethics Counselor. Typically, the conflict is person-specific and limited to all of the individual collaborator(s). Dr. Ford provides a benefit to the collaborators, and not a direct substantial benefit to Hopkins. Therefore, Dr. Ford is not in conflict with other applications from Hopkins in which Dr. Grant is not a named participant.

Should Dr. Ford continue to establish research collaborations with PIs that are supported by or will submit applications to NHLBI?

Clearly, as an IC Director, Dr. Ford should carefully consider all collaborations into which she enters in her intramural capacity because of how these may impact her extramural responsibilities. Should her collaborations expand, more recusals may be necessary.

CASE STUDY # 8: Extramural Science Administrators Reviewing Manuscripts

Dr. Adams is an SRA in NINDS. His scientific area is visual neuroscience; his present responsibilities are to administer the review of fellowship applications. He receives a request from the editor of The Journal of Neuroscience to review a paper submitted by Dr. Jackson on signal transduction in the retina. He thinks that this activity will enhance his professional standing and his supervisor agrees that he can do this as an "official duty" activity. When he reviews the manuscript, it is clear to him that there are fundamental problems in the experimental design and that the work is not of the quality normally expected for that journal. He writes a very negative review. A couple of months later as he is going through the fellowship applications he is to review, he notices that Dr. Martin's application has a supporting letter from his Ph.D. mentor, Dr. Jackson. He discusses the situation with his supervisor.

Should Dr. Adams have turned down the opportunity to review the manuscript from Dr. Jackson in the first place? Should he recuse himself from administration of the review or can he simply alert the review panel to this potential conflict?

Reviewing scientific manuscripts submitted for publication is an activity that can enhance the professional standing and scientific credibility of NIH scientific staff, which should be allowed when it does not interfere with the employee's NIH duties. However, occasionally, as in this situation, this activity will result in a conflict that must be managed. Since Dr. Adams has reviewed Dr. Jackson's recent manuscript, he should not administer the review of an application submitted by Dr. Jackson or an application in which Dr. Jackson is named. It is not sufficient for Dr. Adams to explain the potential conflict to the review panel. He must alert his supervisor to the conflict/appearance of conflict and recuse himself from administering the review.

If this kind of situation occurs with some frequency, it may affect the supervisor's willingness to approve Dr. Adams' request to perform manuscript reviews. The supervisor needs to balance Dr. Adams' professional development, etc., with his ability to perform his job. In this situation, it may be difficult, but Dr. Adams' supervisor should work with Dr. Adams to monitor his official duty activities and to try to identify potential conflicts as they arise. For example, if Dr. Jackson had submitted an application that normally would go to Dr. Adams for review, Dr. Adams' supervisor should either prevent the assignment of that application to Dr. Adams or, when the conflict is called to his attention, immediately arrange to transfer it to another HSA's portfolio.

Does reviewing a manuscript always put an SRA in conflict; and if so, for how long?

A number of considerations impact the seriousness of the conflict or perceived conflict. Note that, in the situation described, the review of the manuscript occurred recently. Had this review occurred much earlier, there probably would be no need for a recusal. Indeed, Dr. Adams might not even remember that he reviewed the manuscript. In all similar cases, common sense and professional judgment should be brought to bear. However, it is always useful for an employee to discuss a potential concern with the supervisor.

Would the matter be handled differently were Dr. Adams a Program Officer, rather than an SRA?

Similar considerations come into play were Dr. Adams a Program Officer. In fact, since Program Officers are in a position to make a recommendation regarding funding, the potential for an appearance of conflict may even be greater. Finally, there are some extramural scientists who have no responsibilities for specific applications (for example, scientists in policy offices). For these individuals, it may be appropriate for the supervisor to issue a blanket waiver allowing them to review manuscripts without seeking separate approval for each, but this would apply to only a small number of extramural scientists.

CASE STUDY # 9: SRAs and Conflicts – Managing a Workshop

An SRA arranges a workshop on analytic methods to familiarize reviewers in her standing committee and interested staff with the uses and limitations of new techniques. She works in conjunction with the committee chairperson to invite noted authorities as speakers. The review group members come in for the workshop the day prior to the review meeting.. The workshop is a huge success, and, with the encouragement of the attendees, the chairperson and SRA decide to publish the meeting's proceedings.

Is an SRA allowed to hold a workshop?

Such initiative is encouraged, but it requires supervisor approval due to additional costs, as well as ensuring that the SRA has the time for the endeavor.

May an SRA publish with her chairperson?

If the SRA has made a significant intellectual contribution to the publication and received all clearances for the publication, this activity is encouraged.

Does the workshop create a conflict of interest between the SRA and the invited speakers?

The workshop itself does not create a conflict between the SRA and invited speakers. It is possible that events or discussions could occur at the workshop that may place a speaker's application in conflict with the SRA or the committee. In which case, a different review committee would be assigned or assembled for the review.

Does the publication create conflicts between the SRA and the chairperson?

Yes, the publication creates conflicts if the chairperson and SRA are coauthors and/or serve as editors together. In both cases, the SRA is not able to review the chairperson's applications, but may review applications from the chairperson's department or institution.

If a publication of proceedings results from the workshop, are attendees in conflict with each other?

No.

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.

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.

CASE STUDY # 12: Conflicts Emerging from Collaborations with For-Profit Organizations (Does size and structure matter?)

Dr. Wright has both extramural and intramural responsibilities at the NIH. She is party to a material transfer agreement (MTA) with a large pharmaceutical company called Gentour. Her counterpart on the agreement is Dr. Stevens who works within Gentour's CNS development division. While inspecting her applications for the upcoming review round, Dr. Wright notices an application from Gentour with Dr. Douglas as principal investigator.

Must Dr. Wright recuse herself from serving as the Program Officer on Dr. Douglas' application or grant?

Because large companies may have component divisions that are often quite separate from one another, individual conflicts with company employees are recognized, but usually do not pose conflict issues, as a whole, for a company as large as Gentour.¹ Nonetheless, Dr. Wright will need to ask a few questions to determine if she is in specific conflict with this application. Dr. Wright should confirm that neither she nor Dr. Stevens has personal or financial ties with Dr. Douglas.

Would any of this be different if Dr. Wright only had intramural responsibilities?

Intramural investigators may be invited to review applications. If Dr. Wright were asked to review Dr. Douglas' application, this would be acceptable so long as there are no other conflicts.

What if Gentour were a small business with Dr. Stevens as the major owner or an employee?

Small companies tend to have closer personal and professional relationships among their employees, making clear distinctions regarding individuals' interests within the company difficult to ascertain. Small businesses are essentially single entities, whereas a large business may have separate components that have little, if anything, to do with one another.¹ Therefore, there may be a conflict at the institutional level with a small company in a collaborative setting between an NIH employee and a company staff person. Anything submitted by a Gentour employee would present a conflict and Dr. Wright should be recused from all matters concerning the application. As above, Dr. Wright's conflict is at the individual level with Dr. Stevens.

Dr. Wright is expecting joint publications with Dr. Stevens. How might this influence the conflict situation with Dr. Stevens?

The MTA may be finished long before the findings are published. Dr. Wright's conflict with Dr. Stevens would last another three years after the last publication date or three years after any continuing collaboration ends.

¹ Making the determination of whether two individuals are far enough apart within a big company may prove challenging in and of itself.