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Effective Collaborations: How to Protect Yourself, Your Collaborators, and Your Data

Alan P. Kozikowski*[a] and Joseph H. Neale[b]

Introduction

The two authors, one being a medicinal chemist and the other a biologist, have worked together successfully for over a decade. We have both put teams of people together to work toward a common goal in a number of project areas. While not all of these collaborations have always worked out optimally, we have both acquired some ideas as to the best way to maximize the chances for a successful outcome. Here, we share some of our knowledge in the hope that these tips are of value to the research community. While the comments about grant funding pertain largely to the US, the situations described will likely be broadly applicable to other regions, such as the European community. Further reading materials and some useful websites are given at the end of this manuscript—we encourage all readers to do their homework prior to entering into any collaborative agreement.

The Complexities of Modern Day Science

Due in large part to the increased complexity of our knowledge base at both the chemical and biological levels, research has become much more collaborative. New discoveries come about through working at the borders between, or among, various disciplines.

New collaborations generally arise because two or more scientists find a topic of mutual interest, realize that they each have a complementary set of skills and expertise that can serve to advance our state of knowledge, and recognize that by working together their chances to obtain funding and eventual success in the project may well increase. The ability to work together relies firstly on their mutual respect for one another's scientific achievements. Perhaps equally important are the individual personalities and their ability to work out problems in a reasoned manner. Even then things may go wrong. One party may cross the line in terms of their contribution to the collaboration or the failure of interpersonal skills to such a degree that the situation cannot be salvaged.

[a] *A. P. Kozikowski*
Department of Medicinal Chemistry and Pharmacognosy
Drug Discovery Program, University of Illinois at Chicago
833 S. Wood Street (M/C 781), Chicago, Illinois 60612 (USA)
Fax: (+1) 312-996-7107
E-mail: kozikowa@uic.edu

[b] *J. H. Neale*
Department of Biology, Reiss Science Building, Georgetown University
Washington, D.C. 20057 (USA)

In order to ensure that the collaboration does not go off course, and to best manage expectations and goals, it is important to put some simple agreements in place at the very start of the collaborative effort. A well-structured consortium agreement should be established that will cover the exchange of information and ideas, patent issues, publications, grant applications, sharing of students, overseeing/monitoring management, and a means for equitably dealing with any matters of scientific or fiduciary concern that might arise. The creation of an outside review group to mediate potential problems from the inception of a new collaboration is also an important consideration.

Company Collaborations

In many ways, collaborating with commercial companies can be easier than working with members of academic institutions. Most companies will often use the academic group as a "work for hire" entity, with all ownership issues spelled out in their sponsored work agreement. The company will generally elect to own intellectual property (IP) and will control the ability of the principal investigator (PI) to publish the work once it is completed. This is rather standard, and most academic collaborators are often happy to use the resources that derive from such agreements. However, they should clearly understand the restrictions that they will be compelled to follow before signing off on a sponsored agreement, as this may limit their ability to use data in not only publications but any future grant applications. The PI on such an industry sponsored project should always seek advice from their grants and contracts office, and/or technology management group. However, they should also do their own investigations.

As is often said, "those who have the gold make the rules", and as such, it is often difficult to get around the requirements imposed by industrial collaborations. On the other hand, the US National Institutes of Health (NIH) and other funding agencies often encourage academics to work with industry. In some of these programs the industry partner will receive funding from the government sponsor. In such cases, the company can be more flexible, and a more suitable IP sharing arrangement can potentially be agreed upon.

Joint Publications

In terms of publications, most journals and websites provide considerable details on what ethically constitutes the right to claim authorship on a manuscript. In most cases, all authors

should have contributed in part to the creation of the ideas, the carrying out of the ideas in the laboratory, and the writing and proof-reading of the manuscripts. Someone who simply proofreads the manuscript alone does not qualify for authorship, but may be acknowledged. In general, however, the collaborators should have worked out some formula as to who will be the corresponding author, which likely is to be based on the extent of their individual contributions to the body of work. In other cases, both authors may serve as corresponding authors, and share credit equally, as in cases where a chemistry–biology project is performed, with one group doing the chemistry, and the other the biology with the newly synthesized compounds. First authorship (or who will serve as the corresponding author) should also be addressed early in the process. Again, by having signed off on a collaborative agreement upfront, both parties are made aware of the authorship rules they will operate under, thus hopefully avoiding future misunderstandings.

Getting Authorship Issues Right

No one wants to open up a journal or a web page and find their work published without having any prior knowledge that it was going to be used, without being listed as a co-author, the possibility to proof the manuscript prior to publication, or appropriate acknowledgement. Likewise, it can be rather disheartening to be doing patent searches, and to discover that your collaborator took some or all of your data and filed a patent application without the appropriate disclosures or inclusion of all appropriate inventors. These things do happen.

What recourse do you have to rectify this type of unethical behavior? In the case of publications, many journals now require that all authors acknowledge that they were involved in the manuscript preparation, and that they have reviewed it for accuracy prior to its submission. This is standard for most high-quality journals; however, this may not be the case for all. The existence of online access to the journals and ahead-of-print publication does allow researchers some ability to keep a lookout for publication of material with which they may not want to have their name associated, as the author can always contact the journal editor to request their name be removed. The obvious point of concern here is that one bad publication, including the plagiarism of work from others, or a paper that is filled with scientific errors can harm one's reputation.

Data Sharing

All good collaborative relationships require that data be completely transparent to the participating groups. Without this, and in the face of today's competitive pressures to garner research funding, some are tempted to retain data for future research applications outside of the collaboration. The best way to handle collaborations that generate data from multiple investigators is to set up and maintain a protected online data sharing site where all data can be stored. While the share-site will not ensure proper ethical behavior, it does help in many ways. The share-site becomes a very handy vehicle for keeping track of a large body of experimental data, including time dating of all information that is entered. These electronic records become an important point of reference in patent filings, as one can easily determine who has entered the data, and when, thus providing a handy documentation source of discoveries that may constitute new inventions. It also goes without saying that the failure of a collaborator to enter any data speaks volumes about his/her efforts in conducting the promised work.

Who Legally Owns the Data?

Generally, those who create a new idea or product own the output of their labors. However, in the case of both companies and academic institutions, the ultimate ownership of the research product lies with the university or the company, as one does, in most cases, assign all of their ownership rights to these entities in exchange for employment.

These issues of ownership among scientists and their institutions can become intertwined in complex research collaborations, especially in those cases where multiple scientists and institutions, both for profit and non-profits are involved. Documentation regarding how the collaboration is to be managed is thus needed from the very beginning.

Some of the more complicated issues to handle often relate to protection of intellectual property. For example, when new chemicals are made for targeting a specific biological target, these chemicals are just physical matter without biological assay data to go along with the chemistry. Thus, the biologists are adding value to a chemical structure by evaluating whether the addition of these compounds to enzymes, receptors, cells, or animals leads to a desirable biological outcome. The chemical substance is key to achieving a certain biological effect; however, the biologist may claim to own the data they have generated, while the chemist would claim to own the substances. This can get messy if there is no agreement upfront as to how the work/results are shared—the two go together, and it is hard to publish a coherent paper, let alone produce a patent application, without the two data sets.

Clearly, the compound itself and the use of that compound are intertwined. Thus, these ownership issues need to be hammered out and understood upfront to avoid future confrontations or litigation. Moreover, the use of data can become especially controversial in cases where a collaboration has ended, but one or more members of the consortium decides to submit a new grant application using data generated from the collaboration. In such cases, it is best to obtain permission from the other party before using data generated jointly, prior to one of the parties applying for a new grant application alone. The key point here is that one should define at the outset how data will be shared upon termination of a formal collaboration.

Inventorship issues can be most complicated, given the possible link of patents to financial reward, and this is where a lawyer may be needed. In reality, inventorship issues are best handled by an unbiased attorney, as patent laws require that a

legal determination of who the proper inventors are be made, as detailed below.

Patent Issues

Patenting can be a problem, as all scientists who work on a project may not be deemed inventors, as inventorship is legally defined (albeit quite loosely at times). In cases where new chemical entities are created by a chemist, and these then tested in what may be considered a routine assay by a biologist, it is unlikely (although far from unheard of) that the biologist will be named an inventor. This depends on the extent to which the biologist contributed to the design of the new compounds. If the biologist provides guidance or suggestions in the compound design, then they are likely inventors. Similarly, if the biologist created the rationale for the development of the new compounds, for example by identifying for the collaborating chemist the drug target as one that has a significant therapeutic goal and subsequently confirms this rationale with biological testing, then the intellectual contribution of the biologist should be recognized in the patent application. What the biologist should not do is apply for his or her own patent, as it is unlikely to be a valid patent, and, if done at the wrong time, could invalidate the "composition of matter" patent as well.

Issues like this should again be anticipated in any new collaboration. Perhaps the easiest way to handle IP issues, while minimizing any friction, and the connection between inventorship and royalty payments, is to have an agreement in place wherein the collaborating parties who contribute to the work are allowed some share of any possible royalties—slim as this may be, since most patents result in little or no payoffs—that may accrue from the work, even if they are not legally named inventors on the patent. One should remember that the naming of gratuitous inventors can lead to patent invalidation, and therefore such matters should be dealt with in a technically accurate manner. In most cases where there is wrongdoing, little can be done unless one is willing to report this type of activity to the university ethics committee, and if need be, to the university or company attorney to deal with any legal ramifications. The attorney should also notify the patent office that the inventors might have been named improperly and that the patent might therefore be invalid. It also is the university's responsibility to conduct investigations and to issue sanctions if necessary. While we have seen many patent battles take place over the years in research, one should always take a step back before engaging in legal warfare, as this is best done only if there is something substantive to be gained. Since most patents lead to no tangible financial gain, one should analyze each case carefully.

An Inability to Agree

There often comes a time when the key people involved in the collaboration cannot come to a harmonious settlement in cases of a dispute. Thus, another key portion of the collaborative agreement should embrace a simple statement to the effect that when the two parties cannot agree, they will bring in an unbiased external party to make a binding recommendation as to how to proceed. This external group would thus serve as mediators in settling a dispute, bringing about a harmonious outcome or alternatively suggesting that it might be best to terminate the collaboration. The collaborative agreement would thus incorporate a statement that specific individuals will be consulted and asked to settle dispute in cases where the collaborators cannot come to an agreement on their own. This strategy can help to repair a collaboration, while saving on one's emotional energy.

Lifting Work from Others

It is entirely possible that your work could end up in someone else's "new" grant or publication after collaboration has ended, and without proper attribution to the source of the data. In the end, this apparent ethical dilemma comes down to the ownership of data; an issue which ultimately is best managed through a working collaboration contract. Of course, proper ethical conduct demands that anyone using jointly owned data should get *prior* clearance before using it in any fashion. In cases where the ownership of the work is clearly obvious, and the work is used inappropriately, the offended party should first alert the collaborator in order to attempt to work out a solution, which may mean asking a journal to make a correction. If this is not possible, one should then turn the concerns over to an ethical review committee within the university or company. However, as many who have experience in this arena know, universities are often not equipped to handle such disputes. At the same time, depending on the extent of the offense committed, the offended party may be forced to take legal action, especially in cases where IP rights that could affect the validity of a patent may have been violated. Moreover, it could be necessary to alert the funding agency as well, in order to prevent repetition of this behavior.

Failure to Follow Government Rules

In the US, there exist a fairly robust set of rules/guidelines that govern how federal grant dollars can be spent, and the reader is advised to pay close attention to these regulations which can be found at the NIH website. As stated by an NIH officer: "the NIH language is very explicit in defining the different roles and responsibilities of grantees and the NIH on grants, cooperative agreements, and contracts". Most importantly, these regulations may prohibit the PI from making any significant changes to a grant in terms of *key* personnel and budgets unless preapproval from the NIH has been obtained. Any changes that significantly alter the scope of work of a grant generally require preapproval.

While some individuals have come to think of the use of NIH funds as somewhat discretionary, this is simply not so. The NIH now oversees grants more closely, in order to ensure the maximum return from the support provided. An NIH grant, and the application that was submitted to obtain the money is now viewed much like a contract.

Another possibility as to where collaborations can go wrong is when the PI of a grant feels that they are not getting what was promised by a co-investigator. The PI can alert the co-investigator to problems, and if need be, then simply replace the co-investigator on the grant by another individual, once preapprovals are obtained. In such cases the co-investigator may have little recourse to take when being cut off from the grant, even if they believe this has been done inappropriately. This is one reason to try to opt for a multiple-PI grant in collaborations if at all possible. Of course, if someone is not properly carrying out their component of the research, it is their ethical responsibility to address the deficiency or bow out.

In other cases, a PI may use the work of others to obtain funding, and then channel those funds elsewhere. If this is done in the case where an individual has been listed as one of the key personnel, and if this is done without obtaining the required preapprovals, this may well constitute fraud. Again, the co-investigator(s) should be aware of rules regarding the award of grants, and pursue appropriate remedies when misdeeds are perceived or uncovered. In the US, the federal grant holder is ethically obligated to report any misrepresentations, waste, or fraud that is committed using federal moneys.

Concluding Remarks

We hope the reader finds this simple missive of value. Most of this information is common sense, and can be summarized in three words: documentation, Documentation, DOCUMENTATION.

Keywords: Collaborations · Collaborators · Funding · Regulations · Scientific agreements

[1] *Collaborations: with all good intentions*; H. Ledford, *Nature* **2008**, *452*, 682 – 684.
[2] Inventorship guidelines are often available from your institution. If not, we recommend a simple google search to find a plethora of documents openly available to assist you.
[3] Matters involving fraud, waste and mismanagement in any Department of Health and Human Services program(s), including NIH-funded grants or cooperative agreements, should be reported to the Office of Inspector General (OIG). The OIG maintains a hotline that offers a confidential means for reporting vital information. For more information visit the HHS OIG homepage (http://oig.hhs.gov/) or contact their hotline: (http://oig.hhs.gov/fraud/hotline/).
[4] NIH Office of Management Assessment, Division of Program Integrity: http://oma.od.nih.gov/pi/dpi.html.
[5] NIH regulations on how federal grants can/should be spent can be found here: http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm.
[6] For a sample collaborative research agreement, see: http://www.hhmi.org/pdf/gc300.pdf.

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