

Red Flags in Industry Research Documents

Industry/academic collaboration is important and ubiquitous. Be aware, however, that legal documents you receive from industry may be seriously flawed, and if you sign them will directly harm you, your research, and your academic career. They may create personal liabilities in unexpected ways. Contrary to what you may hear, these documents are negotiable, and listed below are Children's resources to help or do it for you. This document outlines some of the points that can harm you and your research.

Industry documents come with many names and functions: materials transfer agreements ("MTAs"), collaboration agreements, consulting agreements, confidentiality agreements, and research support or sponsored research agreements, to name just a few.

Problematic documents are not presented just to beginners. Companies routinely offer them to sophisticated and experienced scientists, believing that the scientists, impatient with "legal" issues, will overlook grossly unfair terms in order to proceed with their research. Often, documents come from the "business" side of industry, which is much more aggressive than the scientific side that is treating the scientist with respect.

Bitter experience proves that it's a mistake to overlook these terms. Companies will aggressively enforce these terms when they want to profit from a scientist's discovery, or control scientists' freedom to publish. In several widely publicized cases, company tactics have included charging the scientist with theft, fraud, or dishonesty; suing to prevent publication; and seeking huge monetary damages. Companies may also claim to own or control all your subsequent related research discoveries, and seek to hold you personally financially responsible for actions of your research staff.

The IPO and the Office of General Counsel frequently see documents which:

- require the Company's prior approval for you to publish.
- allow the Company to publish your research data and results without your permission.
- limit publication by students and fellows, in violation of Harvard policy.
- require you to get signed confidentiality statements from each student and fellow, and make you personally liable for damages if they do not strictly comply.
- assign ownership and control of all your discoveries to the company.
- require you to give the Company unlimited use of your work.
- prohibit you from using material or information in research in which any other commercial entity participates through sponsorship or supplying materials.

- require you to disclose your research results to the company first, under no promise of confidentiality. This means copies of your lab notebooks, and all your data.
- require you to write summaries and reports for the company without compensation .
- require you to assist the Company in pursuing its rights, on demand.
- make you personally liable for any unauthorized sharing or use of materials.
- directly conflict with your obligations to research sponsors including the NIH, and other suppliers of materials and information.
- violate Harvard conflict of interest rules, or Harvard faculty policy statements on relationships with industry.
- jeopardize not only your own research, but also the research of colleagues, by transferring these obligations to anyone who uses the results of your research.

You need to understand the key issues raised by these documents, and the resources available to help you at Children's. The rest of this document presents a few of the most important and frequent issues, and ends by referring you to various offices for help. Skip ahead to Section 3 on page 4 if you just want to know who to turn to for help, and what assistance is available.

1. Ownership or control of your methods and results

MOST Company first draft documents transfer exclusive rights or ownership of your methods and results to the Company. NEARLY ALWAYS the language says that you "assign" your rights to the company. This kind of language is often found in materials transfer agreements, consulting agreements, scientific advisory board agreements, and some collaboration agreements. Here is what those documents can mean for you:

Under U.S. law, **ownership generally means complete control**. If you give a company ownership of all rights related to your use of a reagent in your research -- or other research discoveries -- you have given them control over your research. Depending on the language, you may have also given away your future research.

If you invent something, the company will be interested in patenting it. A patent is a right to exclude others from practicing a discovery: there is no broad "research exception", and no automatic exception for the scientific discoverer or inventor. So: **If you assign your "rights to inventions" to a company, you cannot continue the research without the company's permission, even if you made the discovery** and the company had nothing to do with it except supplying its reagent.

These documents pose equal dangers to your collaborators, including colleagues within your lab at Children's. **Your signature on a flawed materials transfer agreement may give away not only your rights, but the rights of your colleagues in the same research, data and scientific discoveries.**

Similar points apply to copyrights - which are ownership rights in research documents, reports, manuscripts, publications, and software. If you agree to language "assigning" your rights, it is the company, not you, which has all rights to exercise them.

It doesn't matter whether a company's contribution is minimal (e.g. one reagent in a complex series of experiments): **if you have assigned all your rights, the company gets 100% of the rights.**

Watch for downstream effects: It is common to see language that asks for all your rights to any discoveries you made 'during' the research; or any "improvements"; or any discoveries you would not have made "but for" the fact that the company supplied you a reagent or materials you used in earlier research. Any of these versions can haunt your research for years to come.

Co-inventors each have a 100% right to use a discovery -- without being accountable to other inventors. **Unless a written agreement says otherwise, industry collaborators in your labs will have the ability to use and publish your collaborative results (even before you do) without paying you or sponsoring your research.**

The collaboration problem is even worse if labs equate "contribution" on a lab team with inventorship. **Inventorship is a legal term of art, and is based on a different standard than authorship or academic contribution.** Naming the wrong inventors, or failing to name the right ones, can invalidate a patent. Because patents are generally necessary to protect companies' investments during drug development, sloppiness or inaccuracy in naming inventors will cause companies to hesitate to sponsor clinical applications of your research -- even if the science is excellent. Also, a collaborator of yours may be a competitor of theirs; if the collaborator has advance rights you will have severely limited your options to translate your science into applications and further sponsored research. Talk to the Intellectual Property Office, or the Office of General Counsel, if you have questions about inventorship. **NEVER agree with an industry collaborator to make them a co-inventor on a discovery without having discussed it beforehand with either the IPO or the Office of General Counsel (see contact information below).**

Company documents that require you to "assign" all rights will nearly always conflict with your obligations to other sponsors and funding agencies -- including the NIH (which specifically prohibits assignment without the NIH's consent). They may also conflict with signed materials transfer agreements. If

your research is commercially sponsored, the ownership rights must be coordinated. If not, you will likely have violated grant conditions, as well as placed yourself in the middle of any lawsuit among your various research sponsors.

2. Ownership or control of data, and concerns with "confidential information"

Company ownership of data means a company controls its use, unless the agreement specifically says otherwise. There is no 'research use' or 'publication use' exception for data unless an agreement specifically preserves your rights.

Many documents define and protect "confidential information". When a company protects its own information this way, it is probably reasonable. But very often, companies define "confidential information" to include **your** research data, methods and results or anything you later produce -- even at Children's -- that uses information you obtained from the Company, or uses the **results** you obtained in earlier research uses of the information. Often, companies will try to include information that you supplied to the company before the study began. Then, an agreement not to disclose company information actually restricts your own use of your own pre-existing data, and also prevents publication.

Sometimes, even in a simple agreement to transfer a reagent, a company will impose obligations more appropriate for sponsored research. For example, a recent materials transfer agreement for a reagent required the investigator to write a full report to the company on all uses of the reagent in his research, and to provide access and the right to copy all his lab notebooks -- not just for research involving the reagent, but also for any subsequent research of a related subject matter.

HMS and Children's are concerned to protect the educational experience of trainees. **Confidentiality provisions that restrict the academic opportunities of trainees violate HMS policies.**

3. Resources

You should not sign documents without ensuring that they do not harm the research efforts of you or your colleagues. That does not mean that every document must be negotiated by Children's; instead, it means that you should always freely ask for help and advice, use the model documents Children's has available for you, and read and understand applicable policies. Children's has the following resources to help you, all available without any charge to you:

A. Education

If you wish further education in these issues, for yourself, or your lab, division or department, contact Patrick Taylor in the Office of General Counsel. He will coordinate

a presentation with the other offices based on the specific issues you wish to be addressed.

B. Model Agreements

Certain documents are available on the "Intellectual Properties" website (see Children's internal web page, section for "Research").

- "**Consulting Agreement Kit**" including an issues list, and a Model Consulting Agreement you can send to companies, or use to compare with what they send to you.
- "**Materials transfer agreement**" ("MTA") for receiving materials from companies or sharing them with academic and other collaborators.
- "**Confidentiality agreement**" for disclosures to Companies (e.g. for preliminary briefings concerning your research. REMEMBER TO DISCLOSE DISCOVERIES TO THE IPO BEFORE MAKING THEM PUBLIC.
- "**Industry-sponsored clinical trial agreement**" - you can download and send this to companies to accelerate the discussion process. Tell them to follow up with John Counts of the corporate sponsored research office (contact information below).

In the case of MTAs, the Intellectual Property Office will prepare an MTA for you, if you provide it certain information via its web link. The Consulting Agreement Kit is for your own use. Others are for reference.

All MTAs and confidentiality agreements must be approved and executed on behalf of the Hospital by the Intellectual Property Office, as well as executed by the Principal Investigator. All clinical trial agreements must be negotiated and approved by the Office of Sponsored programs, and executed by the Vice President for Research.

C. Policies

Children's and HMS have detailed written policies directly concerning intellectual property, conflicts of interest, conflicts of commitment, clinical research, and holding equity in research sponsors. There are also other more general policies which have important applications to research and biotechnology, such as Children's policy prohibiting insider trading. **The most frequently applicable policies may be downloaded from the Children's internal web page (click on *Clinical and Research - Intellectual Properties*, then *Policies*)**, and questions may be directed to the Vice President of Research or the Office of General Counsel.

D. Offices

1. The Intellectual Property Office - 5-7050. They IPO will generally handle industry materials transfer agreements, industry licenses and related industry collaborations. Each department and lab has liaisons. Contact your liaison by e-mail or telephone for a quick consult, and get their sense of whether fuller review under the circumstances would be useful. If you do know who your liaison is, e-mail Donald Lombardi, Chief Intellectual Property Officer, and he will help you.

2. The Office of Sponsored Research - 5-7044. OSP will handle agreements directly related to clinical and non-clinical sponsored research, whether commercial or federally funded. E-mail John.Counts@Childrens.Harvard.edu with questions.

3. The Vice President of Research - 5-7809. - contact concerning actual or potential conflicts of interest.

4. The Office of General Counsel - 5- 6108. We will help with any legal questions concerning any of these issues, including questions referred by the offices listed above. We will also help with consulting agreements, scientific advisory board memberships, and conflicts of interest questions. (E-mail Patrick.Taylor@Childrens.Harvard.edu with questions.)