



STANFORD
UNIVERSITY
INDUSTRIAL
CONTRACTS
OFFICE

Researcher's Guide to Working with Industry

CONTENTS

PERSPECTIVES	2
SPONSORED RESEARCH AGREEMENTS	8
MATERIAL TRANSFER AGREEMENTS.....	15
OTHER INDUSTRY AGREEMENTS AND RELATIONSHIPS	19
Equipment Loan Agreements	
Data Use Agreements	
Affiliates Programs	
Gifts	
Confidentiality Agreements	
Corporate Visiting Scholars	
CONSULTING.....	23
CONFLICTS OF INTEREST AND COMMITMENT	25
KEY TERMS.....	27



At the Industrial Contracts Office at Stanford University, our mission is to foster and maintain mutually beneficial relationships with industrial sponsors and provide first rate and timely service to our constituents — Stanford faculty and staff — while maintaining a balance between Stanford and industry interests.

The Industrial Contracts Office (ICO) negotiates research agreements with industry on behalf of Stanford for our faculty researchers. Our goal is to bring funding and materials into university labs to support university/industry research relationships. Most industry-university collaborations are unique and they need to be treated this way — cookie cutter solutions do not work for all projects. ICO strives to be as flexible as possible in negotiating industry contracts while at the same time keeping paramount the university’s fundamental mission of research and education.

The first pages of the “Researcher’s Guide to Working with Industry” are designed to provide an overview of university and industry research contracting. Details on the agreements and the issues involved follow in later sections of this Guide. More information can be found at our website: <http://www.stanford.edu/group/ICO/>

Perspectives

While Stanford has a long record of working with industry, most research here has been and continues to be funded by the U.S. federal government. Research projects with industry are different from projects funded by federal agencies such as NIH or NSF. Stanford's research policies and processes center on managing research contracts and grants within a framework of extensive and well-defined federal regulations. By contrast, industry sponsored research requires more flexibility, and these contracts may need extensive negotiations to balance the parties' interests.

Industry research relationships differ from those with federal or state agencies, or nonprofit foundations. The federal government has traditionally supported long-term, fundamental university research, allowing investigators significant autonomy in conducting their research. On the other hand, companies frequently seek quick access to specific research results. They fund research with an eye to achieving a return on their "investment." Increasingly, companies are seeking collaborative relationships that will provide them with a commercial advantage, allowing them to better perform in a competitive, global environment.

In recent years, our negotiations with companies have been made more complicated by a number of federal compliance laws directed largely at industry but sometimes nonprofits too. These include laws against kickbacks paid by medical equipment companies, against corrupt activities overseas, and against bribery and certain other practices both within and outside the U.S., all of which can make negotiations more complicated.

WHY DO COMPANIES FUND RESEARCH AT STANFORD?

Companies large and small turn to Stanford for a wide range of needs, including access to new and emerging science, technologies and strategies; contact with students (who may become their employees); and access to specialized equipment and facilities. In addition, companies often wish to leverage federally funded research that could lead to commercial benefit.

Research projects with small companies, especially those that have not had experience working with university researchers, are often different from those with large, established corporations, who may employ staff dedicated to fostering and shepherding university relationships. A research project funded by a small company may be crucial to developing a product line or to securing investor funding. Large companies with multiple established businesses may explore emerging opportunities by funding research at Stanford, but these projects typically are not critical to the company's current core businesses.

HOW DO WE MEASURE SUCCESS?

The success of university/industry collaborations cannot be easily quantified in terms of metrics such as funding amounts. A relatively small project from a company may mean valuable lab experience and employment for students, top-quality publications or a promising, new research avenue for a faculty member. A small breakthrough today may mean a significant advance in the future, as the research continues.



A single research project may create intellectual property (IP) that is valuable to a company. But often, the most productive university/industry relationships are those created with an eye to a long-term relationship, rather than simply a one-off project. The long-term benefits of multi-year relationships extend far beyond access to results or potential intellectual property from a single project. Even though the cultures and missions of companies and universities may vary greatly, these research relationships enable the two parties to share resources they would not otherwise have access to. The university is exposed to real-world issues and projects; the company gains a window into the future.

HOW ARE UNIVERSITIES AND INDUSTRY DIFFERENT?

Universities and companies typically have disparate priorities and objectives, which can conflict. These differences influence ICO's negotiations. The university's goal is to educate students and advance knowledge. Companies seek to develop products and services to meet the needs of customers and create value for shareholders. Because of these different missions, universities and companies must take time to understand one another and recognize that company-university research relationships are different from those between two companies.

These diverse missions overlap at times. Research may lead to innovative products. Unique commercial resources can enable basic scientific discoveries. But at other times, these missions may conflict, for example, when a company wants the results of research at Stanford to remain secret. The most successful partnerships arise when universities and companies acknowledge and respect their distinct cultures and perspectives, and achieve a collaborative, peer-to-peer relationship despite their differences.

Familiarity with Stanford policies on publication, confidentiality agreements and intellectual property rights (described more fully below) are key to initiating a successful research relationship with industry. Later, university researchers can avoid problems by maintaining frequent communications with sponsors on research progress and sharing manuscripts and presentations in sufficient time before publication. Research projects with industry are increasingly collaborative in nature and require active management on both the university and the company sides to be successful.

CHALLENGES AND REWARDS

Industry sponsored research projects can expose academics to interesting, real-life problems. Companies may also provide access to specialized equipment not available in a university lab. However, negotiating industry sponsored research agreements can be time-consuming and sometimes challenging, particularly if the sponsor is not accustomed to working with universities or views the project as a customer-supplier relationship. Contract terms such as IP ownership, pre-negotiated licensing terms, confidentiality of results, publication review and approval, and indemnification provisions may be difficult to negotiate. Companies may have unrealistic expectations concerning IP and other results, if the researchers have not communicated sufficiently with the business people. Companies may also terminate research projects early when results don't meet their expectations or when their business plans change.

Differences between Stanford and its corporate partners



ENVIRONMENT

open vs. closed



MANAGEMENT

consensus vs. hierarchy



CONFIDENTIALITY

public vs. secret



TIME

flexibility vs. deadlines

UNIVERSITY

Stanford has an open environment that encourages the free exchange of information and ideas. Students and researchers come and go on campus; visitors from all countries are welcomed without regard to citizenship; and access to most facilities is open. Visitors are not controlled by signing in at a central reception desk.

Stanford's 1,500+ faculty members set the university's academic policies. The university is a consensus-driven, non-profit organization. Individual investigators pursue a research agenda based on their curiosity and have the academic freedom to pursue knowledge for the public benefit. The administration supports the faculty to enable the best research and education.

Stanford maintains a core policy of no secrecy in research. Stanford researchers publish their results to advance and disseminate knowledge. Publication is how faculty and students further their careers. University discoveries cannot be kept as trade secrets.

Academic research by nature is unpredictable and doesn't easily conform to a specific timeline. It is difficult to forecast when, or even if, a breakthrough will occur.

UNIVERSITY

versus

versus

versus

versus

INDUSTRY

Companies have closed environments. They need to control access to information that may be crucial for their business success. Outsiders cannot freely visit company facilities without permission and may need to sign non-disclosure agreements before entering a building or attending a meeting.

At for-profit companies, the board and CEO direct top management to drive the research agenda to pursue market opportunities, achieve strategic goals, and deliver goods and services. Employees support the company objectives of generating revenues from sales of products and creating value for investors.

In industry, maintaining trade secrets and proprietary information can mean a crucial competitive advantage. Companies must protect their secrets with many safeguards.

In companies, product and business cycles and changing markets make innovation time-critical. Companies may expect specific deliverables or intellectual property to result immediately from projects they fund. They fund research with an eye to achieving a return on their investment.

INDUSTRY

Sponsored Research Agreements

GETTING STARTED

When industrial sponsors fund research projects at Stanford the terms of the relationship are governed by contracts called industry Sponsored Research Agreements (SRAs). These projects have a specific research plan, a time frame and a budget. Generally, the process begins when a Stanford Principal Investigator (PI) and industry colleague identify a project of mutual interest. This idea is then formalized with a written description of the research plan.

After agreeing on the details of the project, the Stanford PI works with the appropriate university office to complete a budget and a proposal development routing form called a PDRF. The PI should also begin the process of obtaining compliance approvals for performing the research at the university. (See pages 12 and 14 for more information.)

Sponsored Research Agreement Process

Idea

Research idea: PI and company agree on project

Preparation

PI works with university offices* for a budget, internal forms, research compliance**

Negotiations

With PI input, ICO negotiates contract terms such as intellectual property, publication, payment, and confidential information

Award

Project awarded and account set up

Research

Research performed

Results

Results delivered, such as publications, reports to company, student training, intellectual property

The company provides funding to Stanford and in return receives research reports and certain defined intellectual property rights.

When ICO begins negotiations, ICO needs to know if any other funding or materials from outside parties will be used to support the project. This helps us ensure that the new SRA does not conflict with rights that have been granted in other agreements. ICO also needs to know of any potential or actual conflicts of interest; for example, if our researcher owns stock in, sits on the board of or receives a gift from the company that is funding the project. (See page 25 for more information about conflicts of interest.)

NEGOTIATIONS

Often Stanford's template SRA is the starting point for the contract. (It is available at <http://www.stanford.edu/group/ICO/industry/industrySRA>.) Whether we use the sponsor's agreement or our own, any agreement negotiated by ICO must comply with both federal law and Stanford policies.

The SRA governs all aspects of the project: the scope of the research program, overall cost and timing of payments, intellectual property ownership and licensing rights, publication review, termination, liability and other related terms. Initially, Stanford and the company may disagree on some of

* ERA (Engineering), RMG (Medicine), OSR (other schools)

** human/animal subjects, biosafety, radiation safety, stem cell approval, export controls, conflict of interest review

these terms. ICO's job is to efficiently negotiate through the differences. Our objective is to end with an agreement that both parties can live with and, with luck, reuse in the future.

Common issues that arise in sponsored research negotiations include:

Use of Results

Research projects generate data and results. A company sponsor may seek to own those results for its commercial advantage. However, Stanford typically owns the research results from its investigators, who may publish those results and use them in future research. The company may receive rights to use the results for its own purposes.

Confidential Information

Companies are concerned with protecting their trade secrets, intellectual property and other confidential information. Stanford understands and respects this perspective. But, due to the university's open environment and flow of researchers and students, we do not have the ability to monitor who has access to specific information.

Generally, we prefer that companies do not divulge confidential information to anyone at Stanford. Highly proprietary projects that involve a company's valuable secrets are not well-suited to the university environment. However, if sharing confidential information is necessary for a particular research project, the company may request that individual researchers personally enter a non-disclosure agreement. Generally, Stanford is not a party to these agreements. Stanford may also be able to accept certain confidentiality terms as part of an SRA, provided they are consistent with researcher interests. In either case, any confidentiality terms must comply with university policy. (See page 20.)

Publication

Academic researchers publish the results of their work to disseminate knowledge to the general public. Stanford rigorously protects the rights of its researchers to publish.

On the other hand, companies may be concerned that publishing could reveal their confidential information or cause a loss of intellectual property resulting from the research. In these cases, the SRA can provide for a publication review and delay period of up to 90 days so that the company can make sure that its confidential information is not inadvertently divulged and so it can identify inventions, if any, that may not have already been disclosed to it (<http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/openness-research>).

Intellectual Property

Although research may generate new IP, Stanford's mission is research, not development of IP. Stanford agrees that when a company funds research here, it should have access to resulting innovations. But sometimes we disagree on the scope of that access and further requirements for licensing.

Stanford's goal is for inventions generated at the university to be further developed and commercialized for the benefit of society. Like most U.S. research institutions, Stanford owns IP created through research here. Most SRAs grant the sponsor the right to use this IP for internal research. They typically also offer first rights to negotiate a non-exclusive or an exclusive license to commercialize the IP. Exclusive licenses will include payment and diligence requirements to ensure that the company will develop the invention.

Because it is difficult to place an accurate value on an invention that does not yet exist, Stanford generally does not pre-negotiate financial terms for commercialization licenses. It's difficult to place an accurate value on an invention that doesn't yet exist. Also, Stanford must comply with Internal Revenue Service regulations related to sponsored research. These regulations apply because Stanford funds construction of many of its research facilities through the sale of tax-exempt bonds. Under IRS regulations, Stanford cannot give a sponsor preferential treatment and must negotiate "fair market value" after an invention has been created (http://www.irs.gov/irb/2007-29_IRB/ar12.html).

SRA FAQs

How long will it take to negotiate my SRA?

This depends on how quickly Stanford and the company can agree on the contract terms. ICO handles about 150 new SRAs a year. These negotiations, especially intellectual property terms, can be complex.

Factors that influence the negotiation time include:

- A company's prior experiences working with academia – The more experience the company has with academic partners and our concerns, the more likely we will come to agreement quickly.
- Stanford's experience with the particular sponsor – Sometimes previous agreements can be quickly re-used.
- Conflicts of interest – If a researcher has multiple relationships with the company (such as sponsored research and consulting), ICO needs to know as early as possible so that COI review is timely. (See page 25.)
- Legal review at the company – Even when business and science colleagues negotiate terms in principle, many companies require legal review and approval, which can be extensive.

Is there anything the PI can do to help expedite the SRA?

PIs can help facilitate the process by:

- Completing the proposal development and routing form (PDRF), including a statement of work and university budget
- Making introductions and helping ICO establish a working relationship with the company
- Starting early to obtain university approvals for using certain materials, working with animal or human subjects and initiating conflict of interest review as needed
- Explaining sticking points to their scientific counterparts at the company, if negotiations stall
- Knowing their priorities and relaying that information to ICO
- Responding to ICO when input is requested

What should I include in the statement of work for my project?

Successful research projects are built on a solid foundation from the statement of work (SOW). While each SOW is unique, a useful description includes clear objectives, deliverables (most often a report) and sponsor obligations to provide materials or equipment. Some items for consideration include:

- Is the sponsor contributing anything to the research besides funding (such as personnel, intellectual property, materials or equipment)?
- How will you separate this work from other ongoing projects in the lab?
- What funding will be needed and when?
- What timelines are realistic? Is continued funding contingent on periodic reviews?
- Who is responsible for which parts if the work is collaborative?
- Since the goal is research (not development), project descriptions must not promise to produce inventions or achieve performance objectives.
- Keep in mind that highly proprietary projects are not suited to the open environment of Stanford.

Who prepares the budget for SRAs?

PIs and their administrative support staff negotiate and prepare the sponsored research budget according to school and department practices. ICO does not participate in this step.

Who can sign an SRA?

ICO has signature authority on behalf of the university's Board of Trustees to sign industry SRAs. PIs sign to acknowledge that they understand and will abide by the agreement. PIs are not parties to the agreement.

How can I build a good long-term relationship with my sponsor?

We find that our best company relationships have an active advocate both within the university and at the company. This enables both sides to take advantage of what the other has to offer, while troubleshooting when either side hits a snag.

After the project starts, you can be a good partner to the company by fulfilling your requirements under the terms of the contract. This may include promptly delivering reports or sharing of publications.

Indirect Costs (IDC)

Research at Stanford requires more than simply the researchers and supplies. Research operations run smoothly because they are supported by the infrastructure of the university: buildings, specialized equipment, research administration, and even utilities and waste removal. These indirect (or facilities and administration) costs allow our researchers to focus their time and energy on what they do best.

Stanford's IDC rates are negotiated every year with the U.S. government. Industry sponsors sometimes ask to negotiate the IDC rate. However, indirect cost rates are not negotiable and the university applies the same federal rate paid by U.S. taxpayers to industry.

Although ICO handles research agreements with companies, a specialized clinical trials group called CT-RMG handles industry-funded trial agreements (http://med.stanford.edu/rmg/clinical_trial.html).

Compliance

Stanford must comply with applicable federal, state and university policies regarding human subjects and the use of animals, human tissue, human stem cells, hazardous materials, radiological hazards, and export-controlled material. ICO checks to make sure that the proposed research has received all approvals regarding use of these materials before signing an SRA or other research agreement.

MASTER AGREEMENTS

Master Agreements, sometimes called “blanket” or “umbrella” agreements, are used when a company expects to fund multiple projects at Stanford over a period of time. In these cases, ICO pre-negotiates the legal terms and conditions of the agreement. When a new project is proposed, only a new statement of work, time period and budget are needed; the rest of the terms from the Master Agreement apply. This expedites the process of finalizing individual projects.

Material Transfer Agreements



Material Transfer Agreements (MTAs) are used for the transfer of research materials from one entity to another. These materials range from biological samples to chemical compounds to specialized laboratory animals. ICO negotiates MTAs with companies and with other research institutions. “Incoming” MTAs are used when Stanford researchers receive materials from another entity. “Outgoing” MTAs are used when Stanford researchers send materials to an outside entity.

When Stanford researchers send materials to another nonprofit research institution, Stanford encourages them to do so without an MTA whenever possible. However, 1) outgoing human tissue samples, 2) stem cells, and 3) materials generated with funding from the California Institute for Regenerative Medicine (CIRM) each require specialized MTAs.

Incoming MTAs

Incoming MTAs must be reviewed and signed by ICO. To get started, a PI submits the completed and signed routing or eRouting form (<http://otlportal.stanford.edu>). After ICO reviews the form, we will contact the PI to let him or her know if the MTA can be signed as is. Many MTAs are only intended to track possession and do not require further negotiation. Other MTAs contain conditions and restrictions because the provider wants to control use of the material; for example, when creating the material required a significant investment of resources.

Researchers must tell ICO what funding will be used to support the research using the material. This information enables us to avoid conflicts between rights the university may grant to the funder and rights the university may grant to the provider of the material.

Most, but not all, materials from other nonprofit research institutions are received under either the Uniform Biological Material Transfer Agreement

(UBMTA) or the Simple Letter Agreement (SLA) recommended by the NIH. ICO can sign these agreements without further negotiation. However, other incoming MTAs (often those from companies) may initially contain provisions that must be negotiated based on Stanford policy. Issues are often similar to those found in SRA negotiations; others such as ownership of derivatives of the original material apply mostly to MTAs.

One area that may require further discussion is ownership of intellectual property developed from the materials. Companies may ask to own these inventions, particularly when they feel the material is valuable. However, the research is usually funded by a different party, most often a federal agency. The U.S. government prohibits giving ownership of inventions to anyone other than the funded university. When the funding for the research project is internal, such as individual or departmental/school unrestricted funds, doing the work still relies on more than incidental use of Stanford's resources, and generally the university will own any IP that is generated (<http://doresearch.stanford.edu/policies/research-policy-handbook/intellectual-property/inventions-patents-and-licensing>).

While Stanford does not grant title to inventions developed using incoming materials, ICO can agree to offer certain licensing options: either an exclusive, royalty-bearing license or a non-exclusive, royalty-free license to inventions developed as a direct result of the use of the material.

Occasionally companies seek terms (such as publication restrictions or rights to future intellectual property) that conflict with Stanford's policies. We cannot accept onerous terms that may prevent our researchers from pursuing their research objectives or publishing their work.

Outgoing MTAs

MTAs are generally not required when Stanford researchers send their lab materials to colleagues for research purposes. Stanford encourages its faculty to share their laboratory materials without an agreement whenever possible, and a number of other universities support this policy.

However, if a PI has special considerations and would like to use an MTA for outgoing materials, ICO can assist. For nonhuman material being sent to a company, our standard outgoing MTA template for industry is suitable. For nonhuman material for colleagues at non-profits, we recommend using one of two standard academic agreements, the SLA or the UBMTA. These documents

are available on ICO's website (<http://www.stanford.edu/group/ICO/researcher/reMTA.html#mta3>).

If these templates do not fit the situation, ICO can help create an outgoing MTA. In addition, the Office of Technology Licensing (OTL) will assist with agreements for materials that may have commercial value.

Human Tissue

Companies sometimes request human tissues for research purposes. These samples are valuable and may be difficult to obtain. They require specialized agreements and extra oversight from the university. These special agreements, called Human Tissue Agreements (HTAs), protect the privacy of human subjects and ensure the tissues are used in bona fide research.

Stanford reviews tissue transfers on a case-by-case basis and requires Institutional Review Board (IRB) approval (<http://www.stanford.edu/group/ICO/researchAdmins/raMTA.html#hta>). In most cases, PIs can share human tissues with colleagues for a project of mutual interest as long as the PI has no conflicts of interest, is collaborating on the research and will receive access to the resulting data. PIs may not give companies access to human tissue in return for gifts.

ICO negotiates and signs HTAs, except for transfers related to clinical trials, which are handled by the office handling the trial agreement. If the tissues must be collected for the transfer, ICO handles this arrangement with an SRA that covers PI time, indirect costs and the costs of obtaining and sending the tissues. In both cases the PI must provide ICO with a copy of the IRB approval or exemption letter.

CIRM-Funded Materials

The California Institute for Regenerative Medicine (CIRM) requires an MTA to send or receive research materials created using CIRM funds. These transfers are reported to CIRM.

Master MTAs

Master MTAs govern the ongoing transfer of materials between Stanford and other organizations. The terms and conditions remain the same for each material transferred under the master. The specifics of each transfer are documented in an exhibit to the master.

MTA FAQs

How many MTAs does ICO handle?

ICO receives over 450 MTAs per year – that’s nearly 2 per business day.

Who can sign an MTA?

ICO has signature authority on behalf of Stanford to sign MTAs. PIs also sign incoming MTAs to acknowledge that they have read, understood and will uphold their obligations under the agreement. When PIs choose to use an outgoing MTA, the PI may personally sign the outgoing agreement and ICO does not need to sign it.

The company wants a non-exclusive, royalty-free license to intellectual property resulting from my MTA. What does this mean to me?

A non-exclusive, royalty-free (NERF) license allows the company to use and commercialize intellectual property (typically an invention) resulting from your research, without payment to Stanford. Granting a NERF license under an MTA can diminish the prospects for translating innovations discovered under the agreement into products for the public because no one other than the material provider can obtain an exclusive license to that invention.

This may be a problem because some companies (particularly start-ups and therapeutic companies) require exclusive licenses to justify their development costs. The company with the NERF license may have little incentive to invest in commercializing the invention if it is not core to the company mission. Considering this, Stanford is unlikely to pursue patent protection for inventions encumbered by non-exclusive, royalty-free licenses.

Other Industry Agreements and Relationships

EQUIPMENT LOAN AGREEMENTS

Companies often lend equipment to Stanford researchers at no cost for research purposes. In return, the company receives data or a report from the project where the equipment was used. No intellectual property rights are provided to a company under an equipment loan agreement.

DATA USE AGREEMENTS

Some companies have data that Stanford researchers would like to use in their research. Data use agreements allow our researchers to use company data for research purposes only. No intellectual property rights are provided to a company under a data use agreement.

AFFILIATES PROGRAMS

Stanford has a wide range of active Industrial Affiliates programs, focusing on topics ranging from space navigation systems to reducing earthquake risks. These programs are designed to facilitate dialogue between industry and Stanford researchers working in the same field of interest. Affiliates programs are headed by two or more faculty members and supported by membership fees from a group of companies.

In return for contributing to and helping sustain research in Stanford programs of interest, the companies receive facilitated access to research programs. Members attend meetings, receive copies of reports and publications, and have opportunities to recruit students. However, affiliates programs do not provide intellectual property rights in return for membership fees.

A typical affiliates program supports several projects focused on an area of pre-competitive research. This is different from a sponsored project where a single company funds research in one faculty member's lab with a statement of work and budget for a defined period of time. Affiliate funds are subject to the university infrastructure charge for gifts.

The structure and administration of affiliates programs vary. Some programs provide full information on their websites and simply send invoices to members. Other programs use more formal agreements that are reviewed and signed by ICO and a company official. The cognizant dean from the Stanford school and the program director may also sign. Sample agreements can be found at <http://www.stanford.edu/group/ICO/industry/industryAffiliate.html>.

Membership in these programs is available to all interested companies. The full list of affiliates programs can be found at http://corporate.stanford.edu/affiliate_programs.html.

GIFTS

Companies sometimes give gifts to particular Stanford faculty or labs. These gifts are handled by the university's Office of Development. Gifts differ from sponsored research in that they are given with no strings attached. Although they may be directed to a particular line of research, gift agreements do not include budgets and statements of work. IP rights are not granted to a company in exchange for a gift (<http://doresearch.stanford.edu/policies/research-policy-handbook/definitions-and-types-agreements/definition-sponsored-projects-and#anchor-1102>).

CONFIDENTIALITY AGREEMENTS (NDAS)

Stanford researchers and a company may wish to share confidential information, often in conjunction with preliminary discussions related to a potential research project or sharing materials. Access to this information can be facilitated under a confidentiality agreement (sometimes called an NDA or CDA). ICO may review company confidentiality agreements related to university research as a courtesy and for compliance with university policies.

A Stanford researcher may personally sign a confidentiality agreement on his or her own behalf provided he or she: reviews the terms; follows university policy; and complies with federal export control laws (which apply to certain non-public technologies). Confidentiality agreements should not create obligations that restrict or redirect research. A researcher may not sign an agreement that could affect the IP rights of Stanford or its other researchers. Stanford researchers should keep in mind that complying with confidentiality restrictions might create conflicts with their long-term research objectives and publication interests.

Stanford generally does not sign confidentiality agreements on behalf of the university because we have an open environment and lack mechanisms to ensure that information received by individual researchers can be kept confidential. Unlike a company, Stanford does not require employees to sign confidentiality agreements as part of their employment. University researchers only have the authority to sign for themselves and may not sign for Stanford, its schools or its departments (<http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/openness-research>).

Standard confidentiality agreements are available online at <http://www.stanford.edu/group/ICO/researchAdmins/raFAQ.html#cAgreement>. These may be used without further review if no changes are made.

CORPORATE VISITING SCHOLARS

Faculty may invite qualified company employees to Stanford for an extended period to collaborate on research activities. These visitors are not paid by the university and remain employees of their companies. Faculty or program hosts must make sure that the Visiting Scholar does not do proprietary work for his or her employer using Stanford facilities. Although funding is not required for these visitors, the visitor's employer may give a gift to the faculty's department.

All Visiting Scholars who remain employed elsewhere sign a patent and copyright agreement called the SU-18A (<http://doresearch.stanford.edu/policies/research-policy-handbook/non-faculty-research-appointments/visiting-scholars>). The agreement says that all patent rights and copyrights in

what the visitor develops while doing research here will be jointly owned by Stanford and the visitor's employer. We advise faculty hosts and departments to share the SU-18A agreement in advance to avoid misunderstandings about intellectual property.

Before inviting a Corporate Visiting Scholar, the faculty host should consider the visitor's role in the laboratory or office and the likely use of space, materials, and faculty and student time. If the visitor participates in research funded by a different company, the terms of that funding could potentially conflict with the visitor's status, especially if patents or copyrighted works result from the visitor's research.

Consulting



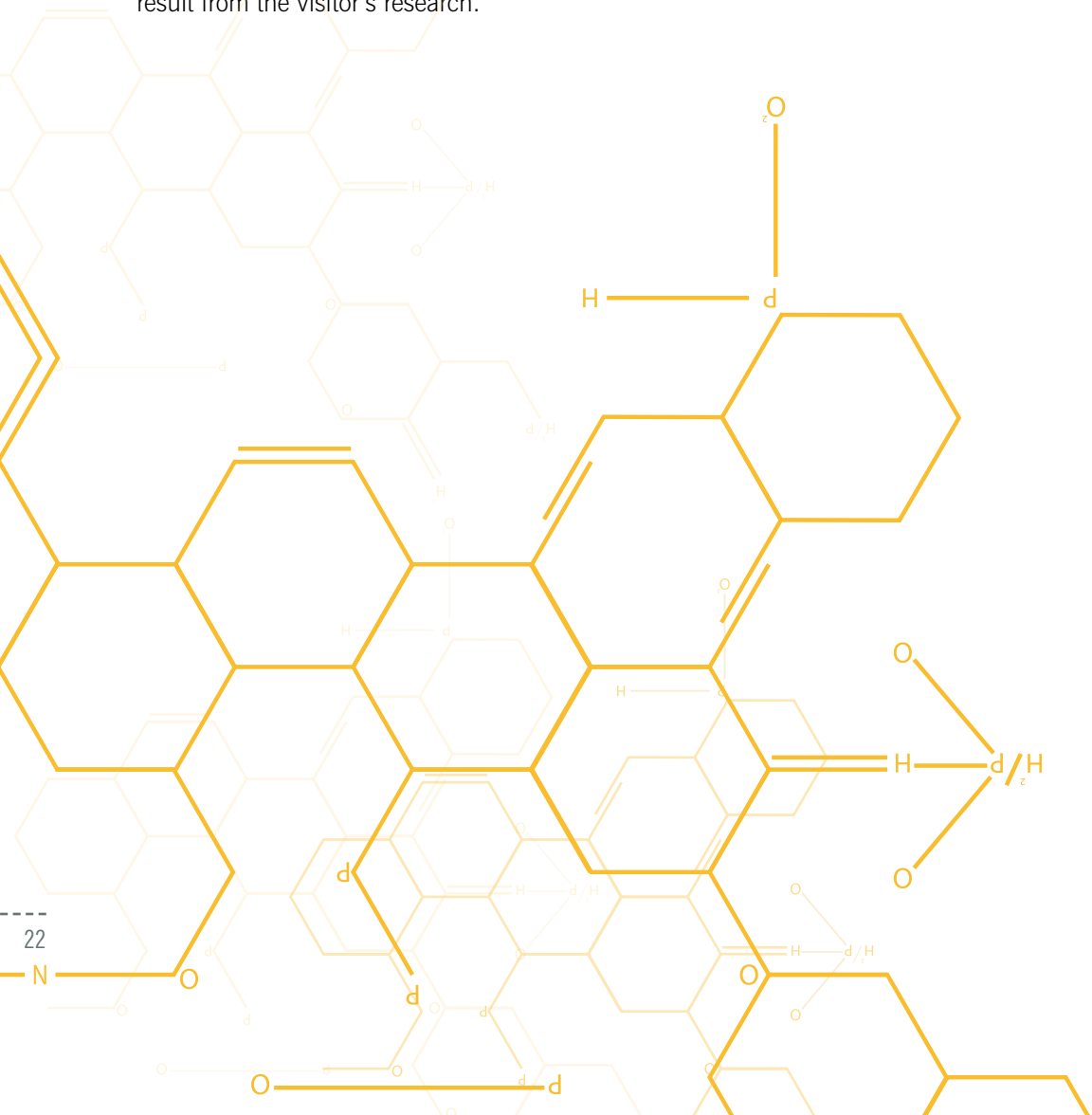
Stanford faculty or students sometimes work with companies as consultants. If a Stanford researcher decides to enter into a consulting agreement, the contract is between the company and that researcher; in other words, it's a personal agreement. The contract must be consistent with university policies and the researcher's primary obligations to Stanford. These policies are available on Stanford's DoResearch website, with separate policies for faculty, staff and students. Points to keep in mind when reviewing a consulting agreement include:

COMMITMENT TO STANFORD

Your primary commitment is to Stanford. The consulting agreement should not conflict with that obligation or other university rules or regulations. Stanford faculty should also provide the company with the Stanford University Requirements for Faculty Consulting Activities and Agreements (http://doresearch.stanford.edu/sites/default/files/documents/consulting_requirements_3.pdf).

INTELLECTUAL PROPERTY

The SU-18 Patent and Copyright agreement is signed by all faculty, staff, student employees, graduate students and postdoctoral fellows. It states that title to all potentially patentable inventions created in whole or in part in the course of university responsibilities or with more than incidental use of university resources must be assigned to the university. Accordingly, a consulting agreement must not grant the company access to ideas that arise outside of consulting activities or related to university activities. Companies



should be given a copy of the SU-18 form (<http://www.stanford.edu/group/ICO/researcher/rePolicy.html>) to clarify that any assignment of intellectual property to the company is subject to the university's pre-existing rights.

ACCESS TO INFORMATION

The company university researchers consult for may not have early or exclusive access to the results of Stanford research.

SEPARATING ACTIVITIES

Consulting activities should be as separate from Stanford work as much as possible. In particular, consulting agreements must not involve or address Stanford University, or its resources and people, including students, postdoctoral scholars and staff. Correspondence and agreements related to consulting activities must not appear to be Stanford documents. Facilities and services of the university may not be used in connection with consulting.

SCOPE

The scope of consulting responsibilities should be very specific so that it does not grant the company access to work done outside the consulting agreement or interfere with publications resulting from academic work.

CONTRACT

The consulting agreement is a legal document drawn up by the company's lawyers. Researchers may wish to have their own attorney review the document before signing.

Conflicts of Interest and Commitment

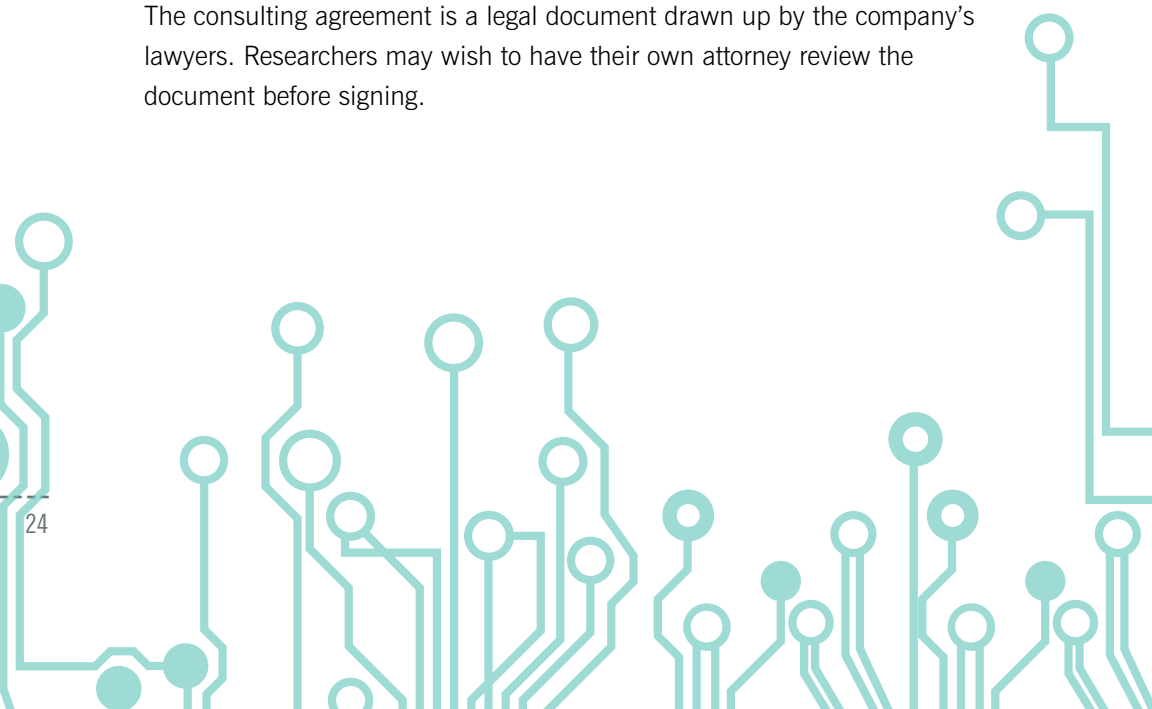
CONFLICTS OF INTEREST (COI)

A company may be interested in supporting a Stanford lab in a variety of ways. However, multiple relationships can create a conflict of interest for the researcher. COI occurs when there is a divergence between an individual's private interests and his or her professional obligations to the university and an independent observer might reasonably question whether the individual's professional actions or decisions are affected by considerations of personal gain, financial or otherwise. COI depends on the situation, and not on the character or actions of the individual. Stanford must ensure that a relationship with a company does not influence or appear to influence the research and education at the university or adversely impact students (<http://doresearch.stanford.edu/research-scholarship/conflicts-interest/overview-conflicts-interest-coi>).

Certain situations require "ad hoc" COI disclosure and review. This can happen when a researcher or lab has a financial relationship with a company. Examples of these financial relationships are combinations of sponsored research agreements, equity holdings, consulting arrangements, or licenses or options to patents. The researcher is responsible for documenting and disclosing these outside arrangements. These disclosures are reviewed by the dean or associate dean of the school and the Dean of Research to determine if there is an appropriate management plan for the conflict.

ICO cannot conclude any agreements until the appropriate COI reviews and approvals are complete. Typically, reviewers are concerned with whether or not an individual can separate university research from company research; provide unbiased and appropriate guidance and support to students; maintain academic integrity in research and education; and adhere to government-mandated policies.

A resource page for COI is available at www.stanford.edu/group/ICO/researcher/rePolicy.html.



Key Terms

APB – The Administrative Panel on Biosafety provides training and oversees research and teaching activities involving the use of biohazardous agents and recombinant DNA molecules.

APLAC – The Administrative Panel on Laboratory Animal Care oversees and evaluates all research and teaching activities involving live or dead vertebrate animal use in compliance with federal regulations and university policy.

BIP – Background Intellectual Property refers to inventions or software created before — or outside of — a specific research project.

Compliance – Stanford research must conform to federal, state and local laws as well as university policies. Stanford's administrative offices such as IRB, APLAC, Environmental Health & Safety, and Radiation Safety train researchers and review campus research activities to ensure that applicable safety rules and ethical guidelines are followed.

CT-RMG – The Clinical Trials Research Management Group handles industry sponsored clinical trial agreements and related agreements.

ERA – The Engineering Research Administration approves grant proposals and prepares budgets for externally funded projects in the School of Engineering.

Export controls – These are federal regulations that impose access, sharing, or participation restrictions on the transfer and use of certain technology, software and information that are regulated because of national security, trade sanctions policy, anti-terrorism or nuclear non-proliferation concerns.

HTA – A Human Tissue Agreement is a type of MTA used for transfers of human samples and derivative materials for research purposes.

Start-up companies often present COI issues. Stanford does not allow a faculty member's start-up company to sponsor research in that faculty member's laboratory. The university is concerned with the difficulty of separating the faculty member's Stanford research from the company's development work and potential adverse effects on the students and the research group. In addition, if intellectual property resulting from the research is then optioned to the faculty-associated company, this could be considered "pipelining." The university cannot serve as a contract research facility for a faculty's company.

If a question or uncertainty arises, researchers should seek guidance from the school dean. Also, Stanford's Dean of Research provides a guide to ad hoc COI disclosures (<https://doresearch.stanford.edu/research-scholarship/conflicts-interest/coi-disclosure-and-review-procedures>).

CONFLICT OF COMMITMENT

Stanford also has related policies for conflicts of commitment, which usually involve issues of time allocation. A conflict of commitment exists whenever an individual's outside consulting activities (as defined in Stanford's Policy on Outside Consulting) exceed the permitted limits (normally thirteen days per quarter for faculty), or whenever a full-time faculty member's primary professional loyalty is not to Stanford. The best approach is to fully disclose the situation to the appropriate person (such as a faculty advisor or school dean) and discuss the implications.

ICO'S ROLE

Stanford and its investigators have a long history of productive research relationships with industry. The university's approach to working with industry mirrors our culture: It is diverse and flexible, yet maintains our core values of independence and openness in research. No two industry research relationships are identical and ICO works with each PI and company to craft an agreement both sides can accept. Created in 1997, ICO is dedicated to company relationships and bridges the sponsored research and technology transfer organizations, which are traditionally separate. This allows ICO to provide a unique resource within Stanford for supporting industry research interactions.

ICO – The Industrial Contracts Office negotiates industry sponsored research agreements, all material transfer agreements and related research agreements.

IDCs or F&A – Federally negotiated Indirect Cost Rates/Facilities & Administrative Rates apply to all externally sponsored projects (grants, contracts, cooperative agreements, subgrants and subcontracts) funded by federal, state or private sponsors and allow the university to recover certain costs (such as facilities, utilities, libraries, administration, student services) associated with training and research.

IP – Intellectual Property includes patentable inventions, copyrighted works and software. IP generated from Stanford research is managed by OTL.

IRB – The Institutional Review Board is a federally mandated panel comprised of faculty members, students and community members that oversees the protection of human participants in research at Stanford.

MTA – A Material Transfer Agreement is a contract under which one party provides another with lab research compounds, materials or biological organisms.

NDA/CDA – A Non-Disclosure or Confidential Disclosure Agreement is a contract requiring one or both parties receiving information or materials to keep confidential certain information (as defined in the agreement) and limiting use of the information to a specified purpose.

OSR – The Office of Sponsored Research handles grants and contracts funded by the federal government and other non-industry research sponsors.

OTL – The Office of Technology Licensing is responsible for administering the university's invention reporting and licensing program, evaluating inventions, deciding whether to file patents, and negotiating licensing agreements with industry.

PI – The Principal Investigator is the faculty member with authority delegated by Stanford to manage, control and guide externally funded research projects.

RMG – The Research Management Group approves and submits grant proposals and prepares budgets for externally funded projects in the School of Medicine.

SCRO – The Stem Cell Research Oversight panel oversees the conduct of research with human stem cells and human stem cell lines at Stanford.

SOW – A Statement of Work is a document describing the research activities to be performed under an SRA or other research agreement.

SPO # – A Sponsored Projects Office Number is the identifier Stanford uses for externally funded research projects.

SRA – A Sponsored Research Agreement is a contract providing the terms for an externally funded research project and typically includes a statement of work, budget, and time frame. SRAs also address IP rights, deliverables, publications and payment.



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