Contract Accords *Supplement*

Numbers 11 - 15

For University Industry Sponsored Agreements

University•Industry Demonstration Partnership

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These Contract Accords were approved by the UIDP Board of Directors at its regularly scheduled meetings in 2013.

Rationale for Creation of Contract Accords

ACKNOWLEDGMENTS AND RATIONALE FOR CREATION OF CONTRACT ACCORDS

When negotiating university-industry sponsored research agreements, there are common areas of disagreement that can delay or derail projects if not addressed. These common areas can be highly contentious, and the University-Industry Demonstration Partnership (UIDP) has approved the following Contract Accords to address five commonly recognized areas typically requiring additional time for resolution.

The following Contract Accords for University-Industry Sponsored Research Agreements were developed by a strategically assembled and dedicated team of research administration professionals from academia and industry with the goal of significantly adding to the current body of knowledge.

After several years of effort, the UIDP, its Contract Accords Working Group, and the general membership have strategically crafted Contract Accords 11-15 to facilitate these sponsored research negotiations and increase understanding on these subjects.

The objective of these Contract Accords is for each party to gain a greater understanding of how these topics can be adequately addressed and allow for mutual benefit to each party during the negotiation of sponsored research agreements.

The University-Industry Demonstration Partnership (UIDP) operates as a semi-autonomous activity convened by the National Academies and its Government-University-Industry Research Roundtable (GUIRR). The views expressed herein are not necessarily those of the UIDP member institutions, National Academies or GUIRR. Responsibility for the content of this publication rests entirely with the author and the members of the UIDP.

To Members of the University-Industry Demonstration Partnership (UIDP) Community

We are pleased to provide you this latest compilation of Contract Accords developed by UIDP members. This supplement contains Contract Accords 11-15 and should be used in conjunction with the 2012 Contract Accord booklet (available on the UIDP website (uidp.org)).

The development of these contract accords was the first UIDP project and these accords are widely used by academic and corporate researchers and negotiators who seek pragmatic approaches to grant and contract terms. As the project co-chairs, we are most thankful for all of the hard work and dedication displayed by the large number of people who volunteered their time and talents to help with the creation of these Contract Accords. An illustrative (albeit not exhaustive) list of individuals is given on page 3.

University-Industry Demonstration Partnership - October 2013

Project Contributors:

We would also like to thank two individuals who have provided outstanding project management support this initiative during the past few years. Dr. Johannes Dapprich served as project manager and is now dedicating his time and energy to make a success of his start-up, Generation Biotech. Ms. Elaine Brock had a distinguished career as a senior research administrator at the University of Michigan and possesses a wealth of experience negotiating contracts between the sectors. We are most fortunate to have these individuals playing such a critical role in the development of these accords.

Finally, we seek any suggestions or ideas for improving the value of these accords and welcome your participation in the development of future accords.

Connie Armentrout (Monsanto) Jilda Garton (Georgia Tech)

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Contract Accord 11:

Gifts

Definition

Gifts and donations to Universities and other academic institutions can take many forms but are often in the form of a monetary gift or tangible equipment for use in laboratory research.

For the purposes of this Contract Accord, "Gifts" are defined as something of value provided by an industry donor (Company) to a university donee (University) with no or few conditions on use, with no expectation of direct benefit to the Company, and with little accounting to the Company by the University for use of the Gift beyond stewardship. The essence of a Gift is the donative intent of the donor.

The following are some items often donated to Universities as Gifts: 1) financial support for University initiatives; 2) excess laboratory equipment; 3) financial support for graduate student poster sessions or seminar programs; 4) financial support for an endowed faculty chair position.

If the Company expects to receive a commercial benefit or has any material expectations in return for providing the 'Gift', then in almost every instance the University would define this as something other than a Gift. Different Universities have different views on the factors that would differentiate a Gift from something else, such as a research grant.

University perspective

Gifts are usually a small fraction of the total funding provided by a Company to a University. Primarily, this is because companies typically prefer to either place some conditions or restrictions on the funding they provide or, alternatively, expect some kind of benefit from the University in return for contributing this support. For example, a Company will often provide funding to support a particular research project and in turn expect to receive certain rights to use the results of that research (see e.g., Contract Accord 6: Foreground Intellectual Property.) These transactions are usually not Gifts and instead are considered research grants, sponsored research contracts, or collaborative research agreements.

When companies do make Gifts of money or laboratory equipment, they usually do so with no or minimal strings attached. In this way, the Company might request that the Gift be used to support research in a very broad area (e.g., diabetes, nanotechnology) and allow the University to use the money at their discretion in support of the general research area. The Company may ask the University to accept liability for use of the Gift (especially in the case of equipment, cell lines, genetically engineered animals, or other non-monetary gifts whose use may pose some inherent risks) but not to provide indemnification for such

use. The University should provide a receipt for the Gift (without describing its value) so that the Company can account properly for the donation.

When making Gifts, both parties prefer the associated paperwork to be minimal and straightforward. Internal policies and politics that may affect how the University processes and allocates Gift funds across different departments or colleges within the University should not affect the Company. However, the University reserves the right to decline to provide a Gift receipt if the transaction does meet the University's definition of a Gift. In some cases, the transfer of material goods with value from the Company to support University research even with no expectations of reciprocal benefit may best be managed using a material transfer agreement. (see Contract Accord 10: Material Transfer Agreements.) The conditions and restrictions included in the material transfer agreement and the policies of the receiving University may have an impact on whether the transaction is a Gift, or something else.

Universities typically cannot give reciprocal Gifts to Companies because they are non-profits. The University expects the Company donor to properly account for anything of value that the University provides to the Company, such as football tickets, parking passes, access to libraries, or courtesy titles.

Certain situations or conditions are in conflict with the treatment of a transaction as a Gift, such as: access by Company personnel to research labs or specialized equipment; Company oversight of the use of the Gift; required progress reports; detailed budgets or specific statements of work related to use of the Gift; Company access to commercial use of results; return to the Company of unexpended funds; review of draft publications based on use of the Gift; required protection of the Company's confidential information by the University; inclusion of boiler plate terms, such as in a purchase order; required cost-sharing or expenditures by the University.

Company perspective

Company researchers should work closely with University personnel when they are considering making either a Gift or a research grant because of the different views Universities have in this area. Some Universities may consider money directed to a professor to continue or advance work in a general research area a Gift. Other Universities will call that a research grant. The Company should consider the specificity with which it needs to define what the funds are to be used for. If the Company is comfortable with a general description of the research area without a defined statement of work, deliverables, or budget, a Gift may be appropriate.

The best course for Company researchers is to describe to the University what they want done with the support and what, if anything, they expect in return. They can then work with the University to determine how to classify the transaction and what paperwork is needed to go forward.

Company researchers should be aware that some professors may encourage a Company to fund or otherwise support research as a Gift because that may provide the professor more freedom in the use of the funds. It is important to talk with the appropriate office at the University that handles Gifts and grants to make sure they agree with the professor's assessment of how the funding should be handled. In instances when the Company has been advised by University faculty or staff members of the University's

affiliated or independent philanthropic or research foundation to direct their support though an entity other than the University, it is important for the Company to consult with the appropriate University personnel – typically in the office of sponsored programs or business and finance – before transferring funds or material to benefit the University to ensure proper consideration of the transaction by an authorized representative of the University.

Similarly, Companies should not view the making of a Gift as a potential way to avoid University facilities and administrative charges that would otherwise apply to a sponsored project (See Contract Accord 12: Budgeting). Use of Gifts to inappropriately curry favor with a researcher or secure other benefits or business from the University may prompt questions about the Company's donative intent or be viewed as unethical. Gifts to Universities that benefit faculty that have personal financial interest in the donor Company may raise questions of conflict of interest that require disclosure and management.

Principles

- Company researchers should describe to the University what they want done with the support they intend to provide and what, if anything, they expect in return and then work with appropriate University representatives to determine how to classify the transaction and what paperwork is needed to go forward.
- Gifts of money or laboratory equipment are to be provided with minimal, or no, strings or conditions attached.
- A Company may ask the University to accept liability for use of some kinds of non-monetary Gifts.
- A Gift is not an appropriate way to avoid University facilities and administrative charges that would otherwise apply to a sponsored project.
- Cash Gifts and 'unrestricted grants' that are directed to a particular professor, lab or research should be reviewed by both Company and the University administrators.
- Universities should acknowledge Gifts by providing a Gift receipt.
- Companies should properly value a Gift by taking into account anything of value received by the Company from the University in recognition of the Gift.
- A University may decline to provide a Gift receipt if the transaction does not meet the University's definition of a Gift.

Outliers

- Endowments - or gifts that are distributed over time
- Gifts from corporate foundations
- Funds for scholarships and individual student donations are also gifts but these are not considered here

Contract Accord 12:

Budgeting

Establishing the Budget is a key step in determining whether it is feasible to proceed with a sponsored project. The University's project Budget (Budget) must clearly articulate the funding required to successfully undertake the proposed project and allow the industry funder (Sponsor) to assess whether the Budget is consistent with the funds they have available (See Contract Accord 1: Statement of Work (SOW)). If the University's Budget exceeds the Sponsor's available funds the University and Sponsor should assess whether it is possible for either party to seek additional funds from other sources such as another company with complimentary goals, cost-sharing from the University's funds, or other third party sources such as the state or federal government. Alternatively, the parties should modify the SOW to fit within the available funds. The Budget should clearly identify the various cost components and give sufficient detail to ensure that the Sponsor can easily correlate the Budget with the SOW. The Budget should cover total costs of the project both direct and indirect costs (also called Facilities and Administrative or F&A costs) and, for cost-reimbursable projects, should identify both direct and indirect cost Budget components.

Direct Costs:

- Direct costs are the costs that can be readily and specifically identified with a particular sponsored project with a high degree of accuracy. The direct costs will vary widely depending on the type of project being proposed, e.g., animal research, clinical research, prototype development, literature review, routine testing. Other factors will affect the direct cost as well such as; the collaborative nature of the project, the level of expertise required, the need to purchase or pay to access equipment, the inclusion of student research assistants, and the duration of the project.
- For projects supported, in whole or in part,by the federal government, Universities must comply with Office of Management and Budget Circular A-21 (OMB A-21) which prescribes the allowability of certain costs and the assignment of those allowable costs as direct or indirect costs. By policy, and in order to assure consistency across financial systems, many Universities extend the principles in OMB A-21 to other sponsors, including industry Sponsors. With certain limitations, OMB A-21 is intended to enable the University to recover full costs on projects.
- Budgeting of personnel is very different between Universities and most industry Sponsors. Universities usually state the amount of time required for faculty and research staff to perform the work on a project as a percent of their overall effort rather than as an hourly rate. Related salary expenses may include fringe benefits though for some Universities these are considered indirect costs. Calculation of fringe benefits is often determined from past experience of the University and can be expressed as a percent of salary or as a line item with or without further details about each component of the benefits.

- Salary for other personnel including postdocs, students, technical staff and dedicated administrative support needed for the project should be included and calculated either as a percent of overall effort for academic staff or as an hourly rate. Note that salary costs for administrators require particular Budget justification if the funds are ultimately being charged by the Sponsor to the federal government since these costs are generally included in and recovered by the University as indirect costs.
- The Budget may include a line item for purchase of equipment. However, it should be noted that many Sponsors are attracted to certain Universities because they already have the type of equipment necessary to undertake the proposed project. Since the acquisition of equipment may be a big ticket item, the University and Sponsor should discuss the need to purchase new equipment versus alternatives such as; using less up to date equipment or providing the University with access to the Sponsor's or a third party's equipment, leasing, or borrowing equipment. Title to any Budgeted equipment is generally retained by the University after completion of the project though this should be discussed and clearly stated in the sponsored project agreement.
- The costs of travel associated with the project performance or presentation of results by University personnel or participating students may be included, such as travel to the Sponsor's site to collaborate, access equipment or provide updates, or travel to professional meetings.
- When graduate students are paid a salary to perform work on a sponsored project, tuition is often included as part of the student's overall compensation package. Depending on the University's policies tuition may be shown as a benefit or separate line item.
- Other direct costs, such as for software, subject reimbursement, materials and supplies required for performance of the project, may also be included.

Facilities and Administrative (Indirect) Costs

- In addition to the direct costs, University Budgets will include facilities and administrative (F&A) costs (commonly referred to as indirect costs.) These are real costs to the University but cannot be easily associated with a specific project. Some common examples of University indirect costs include; facility operation and maintenance costs, central administrative office costs, general office supplies, and library operation expenses.
- Generally the F&A cost will be calculated as a percentage of the modified total direct costs (MTDC.) This MTDC base excludes some direct costs, i.e., equipment, capital expenditures, charges for patient care and tuition remission, scholarships, and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000.
- Universities are obligated to treat like costs consistently and are governed by the principles in OMB Circular A-21 when determining what costs are direct versus those that are part of their F&A (indirect cost) rate.
- To better understand the calculation of a particular University's indirect costs charged to a project, the Sponsor can ask for a copy of the University's negotiated rate agreement. The negotiated rate agreement is a written document mutually agreed between a University and its cognizant federal agency that records the F&A rate that the University can charge to the federal government over the period defined by the rate agreement. This agreement is re-negotiated periodically. The negotiated rate does not necessarily reflect all allowable costs and is generally several percentage points below the University's actual F&A rate.

- Some Universities have higher rates for iIndustry Sponsors than for federal sponsors that include any allowable costs that the government does not agree to cover in the negotiation of the F&A rate.
- Using an F&A rate to allocate indirect costs to projects enables the University to recover these indirect costs in a consistent manner that distributes the recovery of these costs across projects and reflects the University's total cost of doing business.

Principles:

- Payment terms can be negotiated and may be tied to milestones and deliverables that are defined in the SOW or in the contract terms as agreed between the parties.
- The University's proposed Budget should be the best estimate of the component costs needed to successfully perform a project.
- Budgets may be renegotiated if there are significant modifications to the proposed project but the changes should be agreed to in an amendment or formal modification of the sponsored project agreement.
- The Sponsor should have a clear understanding of what funds are being requested for each Budget item but may not be entitled to non-public information.
- When negotiating the Budget, the Sponsor should focus on the potential value of the research and compare this value to the requested cost.
- The Industry Sponsor should not rely on the principal investigator (PI) to provide Budget information or approval unless properly authorized to do so by the University.
- The University and its personnel should not rely on the Sponsor's scientists or unauthorized individuals to approve funding on behalf of the Sponsor.
- Universities should be given appropriate flexibility to make changes among the line items of a Budget during the proposed project period as necessary in order to increase the likelihood of success.
- Since research possesses significant uncertainty, the University's principal investigator should regularly communicate with the Sponsor on the project's progress and explain any significant modifications to the SOW that may be requested as well as ay significant deviations to the Budget if the project agreement requires compliance with a detailed Budget. Periodic project review meetings between the parties should be scheduled throughout the project period.
- Internal funding from the University as cost sharing is unusual for industry-sponsored projects and must be documented and approved by an authorized individual of the University.
- Sponsors and Universities should agree in advance on how payment will affect ongoing performance, e.g., will the University require cash in reserve in order to proceed or continue to perform in the event that the Sponsor's payment is delayed.
- Universities and Sponsors should determine in advance and formalize in the agreement whether the project costs will be recovered based on invoices for actual expenditures (i.e., cost reimbursement) or as a fixed price based on milestones, dates or other basis unrelated to expenditures.
- University researchers frequently request an extension of the project period without asking for additional funds. These no cost time extensions must be agreed to by authorized representatives of the Sponsor and the University.

Outliers:

- Consulting arrangements with individual researchers
- Dedicated user facilities that have an established cost structure (menu) for services (See Contract Accord 13: Specialized Services/Testing Agreements)
- Projects that are funded by a third party and incorporate terms that set conditions on the Budget
- Costs that are regulated by the government, e.g., Stark Law, Medicare Secondary Payer regulations, Office of Foreign Asset Control

Contract Accord 13
Specialized Services/Testing Agreements

This contract accord addresses agreements that fall outside traditional industry sponsored research agreements and go by various titles depending on the institution or organization involved.

Specialized services agreements, testing agreements, fee for service agreements, no IP agreements all refer to contracts for projects whereby a special capability exists within the University (University) and a company (Sponsor) seeks to access this capability (Testing Projects). These special capabilities of the University may include specialized equipment, facilities, or expertise that the Sponsor may not possess or have the expertise or ability to operate. Frequently, the Sponsor provides the materials and a protocol that the University uses to conduct the testing using its specialized equipment, personnel, or facilities. Another common situation requires the University to provide direct access to its specialized facilities or equipment for the Sponsor to conduct their own testing with limited technical assistance from the University. A third situation involves the Sponsor providing materials for the University to use with its specialized techniques, methods, or parameters to provide results to the Sponsor. One common factor of Testing Projects is that they do not generally produce results that the University intends to publish.

These projects frequently involve the Sponsor's existing background intellectual property (IP) and the University's role is routine testing of a sample of materials or data without requiring any analysis by University research faculty or staff, i.e., the University performs the tests and provides the results to the Sponsor. Since the testing does not involve methods unique to the particular Testing Project and the test materials belong to the Sponsor the likelihood of the University making an inventive contribution during conduct of the project is quite limited. Therefore, IP can be addressed using pre-determined terms that require a limited amount of negotiation or not addressed at all.

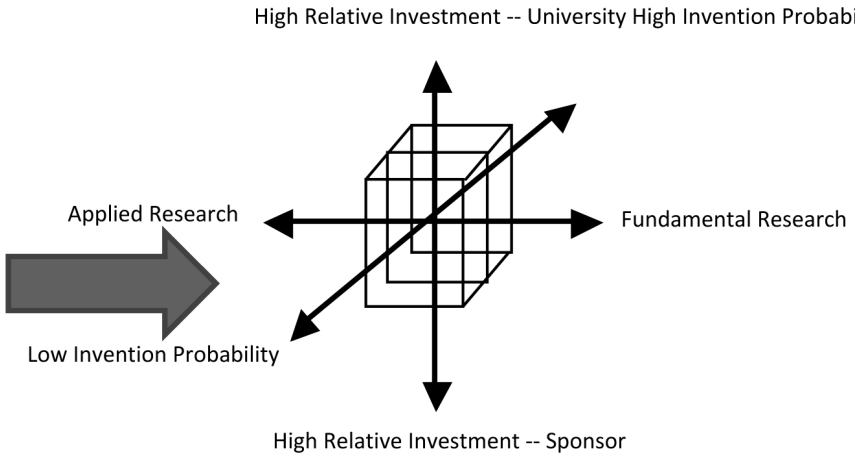
If IP provisions commonly contained in Testing Project agreements say that title to rights in any project foreground IP associated with the Sponsor's existing background IP or test materials will be assigned to the Sponsor even if University personnel are determined to be inventors[1]. Should there be a serendipitous invention made by the University during the project that is unrelated to the Sponsor's background IP, then rights to such project foreground IP will belong to the University unless otherwise specified. These serendipitous inventions may be more likely if the University's role goes beyond routine testing and involves other budgeted services such as evaluation and assessment of test results or data.

Facilities and administrative (F & A) costs for these projects may be different from on-campus research rates that Universities negotiate with their federal cognizant agency. The direct costs of these services may be a standard industry rate based on a fixed rate per unit of activity and may not be negotiable depending upon the University's policies. (See Contract Accord 12: Budgeting) [1]

[1]If the Sponsor is using federal funds to support the Testing Project assignment of Foreground IP may not be allowed. See Contract Accord 6: Foreground Intellectual Property for a general discussion of IP rights in sponsored research agreements. Also see, the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) http://www.law.cornell.edu/uscode/text/35/part-II/chapter-18

Because timing of these projects is often critical to the Sponsor's on-going research, pre-determined contracting vehicles are used in order to "fast track" the negotiation and execution of the agreement.

These projects fall closest to the area of applied research on a continuum of basic, theoretical research to applied and product testing research since there is a low investment for both parties, a low probability of invention



SPONSOR PERSPECTIVE:

- An industry research and development program often needs testing expertise, equipment, or facilities that are not available within its organization.
- Ongoing internal projects frequently depend on the results of externally sponsored testing in order to be validated and to continue (i.e., feedback from 'beta test sites' and then 'early adopters').
- Testing Projects often need to be initiated quickly which requires a contracting vehicle that is easy to negotiate and an expedited process.
- Master agreements for these Testing Projects are desirable.
- Testing Projects are usually low dollar investments with no expectations of patentable IP.
- Testing Projects are normally conducted in a short (3-9 months) period of time.
- Sponsors expect to own all foreground IP developed by University personnel that is associated with any of their existing background IP involved in the Testing Project.
- In addition to owning the results of the Testing Project, the Sponsor may need University expertise to evaluate and assess the data and results that are produced during such projects and these extension activities may be subject to different terms than those contained in the Testing Project agreement.
- The Sponsor expects confidential treatment of all the information and materials it provides as well as for the testing results.

UNIVERSITY PERSPECTIVE:

- Universities have developed unique equipment, facilities, methods, and techniques using funds from various sources that they can make available to others outside the University who would not otherwise have access to these capacities.
- Universities offer the excess capacity they have in these unique facilities, equipment, and expertise in methods and techniques to support these capacities when they are not being use for the University's core missions of education and research.
- University sponsored programs offices prefer to offer access to specialized services/testing efforts with agreements that require little or no negotiations.
- Universities often have fixed rates for use of these capacities.
- Universities participate in Testing Projects to create relationships with Sponsors that may then fund additional research projects at the University, recruit students, or provide other benefits to the University.
- Universities do not normally expect to produce publishable results from Testing Projects. Since publishable material is not likely to be generated in Testing Projects the agreement may be silent on publication, may expressly prohibit publication, or may subject publication to Sponsor approval. At a minimum any publications should be reviewed by the Sponsor for the purpose of removing any confidential or proprietary information from the publication. Proper credit would be given to the Sponsor for its support.
- The University will provide a final report to the Sponsor and often exclusive rights to use the report and data for any purpose. The University retains the right to use the data contained in the report for internal teaching and education purposes but does not retain the Sponsor's actual proprietary information or data for its own uses.
- Universities may retain the right to utilize results of Testing Projects for educational and teaching purposes.
- University cannot endorse any products or services tested for Sponsors.
- Generally Universities will not agree to warrant services performed or to re-perform services at no cost should the Sponsor not be pleased with the results. Most academic institutions (especially state Universities) do not have the resources or reserves to provide warranties or to perform services without reimbursement.
- To comply with applicable Internal Revenue Service procedures, the University is not supposed to provide any services that are in competition with such services that are offered by commercial laboratories.
- Net income generated from Testing Projects may be taxable to the University as unrelated business income.

PRINCIPLES:

- It is unusual for intellectual property to be developed under these agreements and the Testing Project agreement may be silent on IP. However, if IP is developed:
- he Sponsor maintains ownership of any IP related to its protocols, materials, or background IP used as the basis for the Testing Project, and foreground IP that may be developed by the University in relation to the intended solution that is the purpose of the testing.
- The University maintains ownership of anything related to its protocols, methods, or otherwise related to the unique services or capabilities being provided, or that is unrelated to the Sponsor's protocols, materials, or background IP.
- The Sponsor maintains ownership of the data and results of Testing Projects.
- Time -to-contract should be as short as possible and streamlined to facilitate quick initiation of Testing Projects.
- Deliverables vary depending on the nature of the special services but generally include a report of the results, data, and/or a processed material sample. Testing Projects are frequently carried out using proprietary protocols or materials provided by the Sponsor.
- The data produced by the University in performance of a Testing Project is not intended to be published, but may be by mutual agreement of both parties.
- The Sponsor is expected to pay the full cost of the Testing Project, including applicable F&A costs.
- The University is not permitted to use the samples or protocols for anything other than the intended purpose under the Testing Project agreement. Reverse engineering may be expressly prohibited.
- The University has to keep faculty and researchers performing under the agreements appraised of the terms, including confidentiality, non-use and avoidance of potential conflict of interest in case of multiple projects that are similar in scope.
- Liability of the University is usually limited under Testing Project agreements but liability of each party should be addressed in the agreement.
- Results are not guaranteed, warranted or endorsed by the University conducting the Testing Project.

OUTLIERS:

Situations where equipment or expertise may be so exotic/expensive that only a company is able to provide it and the University wants to access that capacity. This type of work is not discussed here, although many of its characteristics would be closely related to collaborative research efforts which have been discussed under previous contract accords.

- Field trials are specific arrangements where one party grows regulated materials for another
- Clinical trials in human subjects
- Animal studies
- Testing done under capstone or undergraduate coursesFaculty consulting agreements
- Work for hire not involving unique capacities of Universities

Contract Accord 14:
Data Use Agreements

Data is often a necessary component or the result of a research project. For purposes of this Contract Accord, "Data" means a proprietary set of recorded information that is provided by one party to another party for use under defined conditions.[1] Data can take many forms, originate from various sources, and have different levels of sensitivity due to a variety of factors. A "Data Use Agreement" or "DUA" refers to a legally binding agreement, separate from a sponsored research or Material Transfer Agreement, which at least defines the Data, the terms and conditions of use of the Data, and the rights and obligations of the parties related to the use of the Data. The DUA is both a means of informing the User of requirements regarding the Data and a means of obtaining the User's agreement to abide by these requirements. Virtually any organization can be a provider or user of Data depending on the situational context. This Contract Accord will call the parties to a DUA "Provider" and "User".

Data is often proprietary to the Provider so many of the same elements and concerns that are present in Confidential Disclosure Agreements are also commonly addressed in DUAs.[2] Unlike Confidential Disclosure Agreements, however, where the Provider claims ownership or exclusive control of the Confidential Information, Data ownership may be difficult to ascertain particularly if the Data is in the form of a database that contains raw or source data obtained from different sources.[3] In those cases DUAs often do not contain Data ownership provisions though the Provider of the Data takes on a stewardship role that assumes control of the Data and the right to enter into DUAs regarding its use.

To determine whether Data can be shared, the Provider needs to know:

- Where the Data came from, e.g., derived from laboratory tests, results of interviews with human study participants; provided by others;
- Who needs or wants the Data, e.g., students, foreign nationals, clinicians; academic researchers;
- What does the User want to do with the Data, e.g., comparative research, validation, marketing, patient support;
- What institutional, legal or regulatory requirements related to the provision of the Data, e.g., HIPAA, Common Rule, Export Controls, are applicable;
- What is the proprietary value of the Data to the Provider, e.g., a database that would be costly to replicate.
- What other contractual conditions restrict the Provider from sharing the Data with User; e.g.,

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[1]Data may be unstructured or structured. Examples include: technical data pertaining to the operation of a motor, device, system, etc.; financial data; economic data; proprietary business information; records from governmental agencies or corporations; student record information; human research subject data and healthcare data. Data could refer to the source data, a set of data, or compilations of data (databases) .

[2]Some of the provisions of DUAs are similar to confidentiality agreements, and, in some cases, a Confidential Disclosure Agreement format may be used to transfer data. Another alternative may be the use a Proprietary Information Agreement. See Contract Accord 9: Confidential Disclosure Agreements.

[3]The Data may be facts or ideas that are or may be unprotectable under copyright law., Databases are generally protected by copyright law as compilations (a collection and assembling of preexisting materials or of data that are selected in such a way that the resulting work as a whole constitutes an original work of authorship).

developed under a sponsored research agreement in which the sponsor controls third party use of the resulting data.

The Data User also needs to answer some questions to determine if they can receive and use the Data:

- What Data is needed to accomplish a desired purpose, e.g., aggregate data or source data, personally identifiable or de-identified data;
- What is the scope of the intended use, e.g., research only, commercial use, redistribution;
- Who will need access to the Data, e.g., requestor only, students, other researchers, subcontractors;
- What legal or regulatory requirements related to use of the Data are in place, e.g., Institutional Review Board (IRB) approval, Privacy Board approval under HIPAA, license under export control regulations;
- Which portions of the Data will need to be disclosed if the User publishes results of their use of the Data.

Once the Provider and User have converged on what Data is being shared and the scope of the use they can address questions about terms that protect the sensitivity of the Data. Data security provisions fall into four general categories:

- Authorization or privilege management – identification of individual Users who are allowed to use the Data;
- Authentication or identity management - confirmation that the authorized User is really the authorized User; and
- Monitoring and enforcement – validation and assurance that use of the Data is consistent with authorized use and conditions of use such as keeping the Data separate from other Data, in a secure location, or not on a linked computer.
- Data Protection – instructions regarding any special infrastructure required to store and restrict access to the Data (dedicated and isolated servers and lock-cabinets)[4]; special control processes to protect the integrity of the Data, track the location(s) of the Data, track the release of the Data and the reasons for its release; archiving and/or disposing the Data at the prescribed times.

Principles:

- The Provider of Data is responsible for analyzing the source, sensitivity, legal and regulatory aspects of the Data to determine what provisions are needed in the DUA.
- The Data User should clearly explain the intended use of the Data to the Provider.
- The Provider and User are responsible for complying with regulatory requirements related to Data and their respective rights and obligations under the DUA.
- A DUA that involves performance of research by a university should include a process to allow the Provider to preview publications before public disclosure, to identify and modify or remove any

[4]The National Institutes of Standards and Technology describes requirements for implementation of different levels of information security. See http://csrc.nist.gov/publications/CSD_DocsGuide.pdf, Guide to NIST Information Security Documents.

confidential information or personally identifiable information that has not been properly de-identified so that the author can adjust the publication appropriately (see Contract Accord 3: Publications).
- The Provider and User should clearly describe any special requirements, e.g., privacy, confidentiality, information security standards, that the User is expected to meet.

A DUA generally addresses at least the following points. The DUA Provider should consider these provisions in the context of the anticipated Data transfer and include the relevant terms in a DUA:

- A clear description of Data to be provided
- The permitted uses for the Data and any regulatory requirements that the Provider needs to have in place
- The names or general descriptions of individuals who can access or receive the Data
- Conditions under which the User can provide the Data to other Users and under what conditions
- The length of time the Data may be retained or used
- The method of Data disposal at the end of the DUA period (returned or destroyed)
- The User's obligations regarding new data generated based on the Data originally provided
- The management of new intellectual property created using the Data
- Instructions on how the Data should be aggregated, encrypted, anonymized, or de-identified.
- Safeguards required to protect confidential, private, sensitive information
- The process for review by the Provider of publications resulting from use of the Data
- Practical aspects of the Data transfer.
- Statement of ownership of the Data if it is proprietary, and the provenance and authenticity of the Data if that require confirmation.

A Data Use Agreement may NOT be required in some circumstances:

When Data is publically accessible and in the public domain, i.e., the Provider has dedicated any copyrights that may exist in the compilation of the Data to the public, it may be downloaded from the internet or received from a Provider without restrictions on use or redistribution.[5] It should be noted that public accessibility is not equivalent to being in the public domain and Users should be careful to read the copyright and other information about potential use restrictions that may be described on a website before using or redistributing such Data. Data that is not subject to legal, regulatory, or other restrictions of use may be made available by the Provider without a DUA.

Additional Considerations in DUAs involving Data derived from humans:

A DUA is required in some cases involving the use of Data derived from human subjects.[6]The DUA assures that the use of the Data is consistent with the informed consent obtained from the human participants or the confidentiality assurances provided to non-clinical human participants. The DUA helps

[5]Acknowledging the source of the copyrighted material does not substitute for obtaining permission. The safest course is to get permission from the copyright owner before using copyrighted material regardless of the form of the Data.

[6]Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104–191, 110 Stat. 1936, enacted August 21, 1996); HIPAA overview: http//www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html

to prevent the inappropriate use of protected or confidential information that could cause harm to the research subjects providing the data.

Data about students may be subject to federal law that protects a student's right to privacy about grades, behavior and other factors. Student or parental consent may be required prior to disclosure of such information by a Provider even if the User's intended purpose was non-profit research.[7]

Data Consortia:

Providers and Users with shared interests may enter into consortium membership agreements that describe the conditions under which members may deposit, access, use , store, and share Data. Membership in a Data consortium may be free or have a charge for membership or services. Various Data consortia are maintained by for-profit and non-profit organizations as well as by the federal and some state governments.[8]Data consortia provide an expedited way to provide and receive Data among a limited group of trusted colleagues. The Data consortia often also describe conditions for review of publications resulting from use of the Data and occasionally address rights in intellectual property resulting from use of the Data. The consortium may be subject to bylaws or other use provisions that are referenced but not fully contained in the DUA. Providers intending to join a Data consortium should read all relevant conditions of membership before making a commitment to both understand how membership facilitates their objectives as well as to avoid conflicting obligations regarding the Data.

Outliers:

- Classified Data, Technical Data and export restrictions on Data (See Contract Accord 7: Export Controls)
- Residual information (information retained in unaided memory)
- Fair Use of copyrighted databases
- Data Management Plans, federal agency requirements
- Registration of clinical trials and reporting of clinical Data, (FDAAA)
- Data registries
- Free licenses to use Data (See also Contract Accord 8: Copyrights and Software)
- Data Storage and information security requirements
- Implications for university Facilities and Administrative costs
- Tangible material or samples, e.g., geological samples (See also Contract Accord 10: Material Transfer Agreements).

[7]The Family Educational Rights and Privacy Act (FERPA) requires a written agreement to disclose Personally Identifiable Information (PII) from educational records without consent. These written requirements must meet DFR 99.31(1)(6)(iii)(C) or 99.35(a)(3).

[8]Examples of Data consortia include: IXI Services database; Higher Education Data Sharing Consortium; Linguistic Data Consortium; Inter-university Consortium for Political and Social Research (ICPSR); The Public Health Data Standards Consortium (PHDSC); The Encyclopedia of DNA Elements (ENCODE) Project Consortium; The International Cancer Genome Consortium (ICGC); The Material Data Management Consortium (MDMC); National Institute on Drug Abuse Genetics Consortium.

Contract Accord 15: Conflict of Interest

Overarching Principle: Objectivity in Research

Financial Conflict of Interest ("COI") is a fact of life that arises from the many and varied roles and relationships between University researchers and industry Sponsors. These relationships often promote mutual understanding of each other's needs and culture and lead to other kinds of beneficial relationships such as collaborative or sponsored research, student placements, material transfers, and data exchanges, and institutional gifts (note, however, that recent focus on perceived negative effects of conflict of interest stemming from donations in some areas such as medical research have decreased the likelihood of institutional gifts). In the medical device and pharmaceutical industry, direct clinical evaluation of new technologies by conflicted inventors may present a COI challenge but expert opinion, feedback, and involvement of inventors may be indispensable to the efficient and ultimately successful development of medical technologies. However, personal financial gain may be a motivator for "bad" behavior as well and if left unchecked, for instance, could cause a researcher to bias research results to promote their personal interests. What situations are covered by University COI policies may not be well understood by industry Sponsors. Similarly, University researchers may not understand the kinds of relationships that their industry Sponsors or collaborators would like to know about. This Contract Accord helps to provide a mutual understanding of the University's and Sponsor's perspectives about COI as it relates to sponsored research and intellectual property (IP) to help ensure a research environment that promotes faithful attention to high ethical standards and provides the Sponsor with a clear path to commercialization of any existing or newly created IP.

Examples of Federal Regulations

Both Universities and Sponsors are subject to federal regulations that govern disclosure and management of personal financial conflict of interest including who must disclose what to whom and when, as well as, where disclosed information will be maintained and whether it will be made publicly available.

In August of 2012 revised regulations went into effect on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) impacting organizations that receive grants or contracts from the United States Public Health Service (PHS). i.e., virtually all Universities as well as their subrecipients. Several foundations and other non-profit organizations have also adopted compliance with these regulations as part of their grant policies. Since the consequences of bias in research involving or intended to benefit humans is significant, many University COI policies use these PHS regulations and the related implementing guidelines published by the National Institutes of Health (NIH) as the basis for their own internal policies. NIH Director, Dr. Francis Collins describes the need for such regulations: "The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the re-

search process."(http://grants.nih.gov/grants/policy/coi/). Other federal agencies also have COI policies that grantees and contractors should be aware of when accepting funds.

For Sponsors, federal regulations include Section 6002 of the Affordable Care Act (42 CFR Parts 402, 403) which creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals by requiring that information be reported annually to the Centers for Medicare & Medicaid Services (CMS). Information required to be reported by applicable manufacturers of covered drugs, devices, biologicals, and medical supplies for which payment is available under Medicare includes payments or other transfers of value manufacturers make to physicians and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations (GPOs) must report certain ownership or investment interests held by physicians or their immediate family members. Applicable GPOs must also report payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year. CMS intends to collect, aggregate and publish the data they receive on a public website. CMS explains the motivation for this legislation, "Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration is beneficial, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests." (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html).

Industry Perspective

Sponsors need to know that the project that they are sponsoring or the intellectual property that may result or that they are licensing is not complicated by relationships that a PI may have with the Sponsor's competitors. Sponsors expect that a University's policies require disclosure and mitigation of risks that may result from a researcher's personal financial interests and that the University has processes in place to implement the policies. Sponsors would like access to information obtained from these policies and related processes before they commit to supporting a sponsored or collaborative project or licensing a technology.

Researchers who enter into consulting or other agreements in exchange for a personal financial benefit generally are asked to perform services within the same area of expertise that was developed and is used in their University employment. Consulting agreements usually prohibit disclosure of information, including results, that the researcher generates or obtains in performance of the consulting activities and often require the researcher to assign any Intellectual Property ("IP") resulting from the consulting activity to the Sponsor or company they are consulting to. Therefore, statements of work or descriptions of services in consulting agreements entered into by researchers should be sufficient to distinguish the consulting activities from those of the researcher acting within the scope of his/her employment. Overbroad statements of services in consulting agreements are more likely to overlap with employment obligations or activities of a researcher inside the University making it difficult to sort out the circumstances under which an invention is made in order to provide the Sponsor or company that hired the consultant with clean title to the invention. Sponsors and companies engaging University researchers as consultants expect that the

researchers are aware of this issue and that they structure both their sponsored project activity as well as their obligations to competitor companies to avoid overlap and that they seek appropriate counsel from their relevant COI, sponsored projects office, technology transfer office or personal legal counsel before entering into agreements. Sponsors and other companies typically make it clear in a consulting agreement that the contracted party should not disclose any information to the Sponsor that the consultant has no right to disclose or that the Sponsor/company cannot use freely.

In some situations the participation of experts who have a financial interest is deemed essential to meaningful deliberations that relate directly to the subject of their financial interest. For example, a Food and Drug Administration review panel may require the expertise and insight of an inventor with a financial interest in a drug or device being reviewed. Key to the participation of such conflicted experts is full disclosure of the financial interests and careful assessment of the potential bias that may be inherent in their participation.

Sponsors expect that they can develop strategies together with their University collaborators that provide the Sponsor with the expertise it needs from University faculty but also address the potential risks posed by personal, financially beneficial relationships between the Sponsor and the faculty researcher who is also conducting related projects in their University employment capacity. For example a risk-reducing and transparent mitigation strategy might include preservation of the researcher's or inventor's personal role in technical evaluation research but under the direct observation of a mutually acceptable independent "chaperone" to monitor in key phases of product research and assessment such as appropriate patient enrollment, appropriate use of students, conduct of research procedures, recording of events and outcomes, and preparation and presentation of academic manuscripts and lectures.

Sponsors expect that the University's policies extend to all personnel involved in a sponsored project or license including trainees, students, technicians, and University personnel responsible for reviewing and approving sponsored projects and licenses.

Breach of a fiduciary duty that a researcher acting as an officer, director, or manager owes to the Sponsor that they are associated with could cause serious damage to the Sponsor's intellectual property, competitive position, or good will. Sponsors expect that a researcher understands the significance of this fiduciary duty and that these obligations are consistent with their University employment as well as with any other consulting agreements the researcher might have. Sponsors expect that researchers engaged in projects are held to at least as high a standard of ethical conduct as that to which the Sponsor's employees are held. Companies often wish to include a provision in a sponsored project agreement requiring that the University employees engaged in the sponsored project abide by the Sponsor's COI (or Code of Business Conduct) and ethics policies.

University Perspective

The activities of University researchers are subject to a myriad of federal, state, and local government laws and regulations as well as the policies or their employing University, and the guidelines, ethics and norms of their individual professional associations These regulations and laws describe who and what situations are to be disclosed, when and to whom the disclosure are made, how and when disclosed situ-

ations must be managed, public availability of certain disclosed information, and consequences of failure to comply with the regulations and laws. . In addition, it is increasingly common for Universities to encourage their faculty to participate in entrepreneurial activities both through their employment as well through external relationships with companies.

Many Universities have developed COI policies that incorporate a presumption of innocence and integrity of the researcher while participating in entrepreneurial activities that require disclosure by the researcher. Disclosure of an outside activity is not equivalent to admission that the activity constitutes a COI. Education of faculty is a key component of University COI management to avoid discouraging industry-sponsored or collaborative research, consulting, or other beneficial relationships with industry Sponsors and licensees. Violation of University COI policies is generally handled as an employment issue and does not automatically rise to the level of research misconduct, i.e., plagiarism, misrepresentation, fraud.

The goal of a University conflict of interest review and management system is to ensure that the personal interests of an individual do not unduly influence their primary obligations to science, Sponsor, University, colleagues, patients, or students. University conflict of interest committees are charged with reviewing disclosures submitted to them and rendering reasonable judgments as to whether the financial interests disclosed could directly and significantly affect the design, conduct, or reporting of the proposed project [or other projects]. If an inapproproate conflict is deemed to exist, the committee, with suitable consultation and notification, attempts to design an administrative oversight or other mechanism needed to manage the specific conflict situation.

Universities require disclosure of external activities of their faculty and staff if the activity is related to their University employment. Universities also require disclosure of personal financial interests in conjunction with the University's processes for review and approval of proposals to conduct sponsored research, prior to acceptance of an award, issuance of a subaward, or granting of a license to University owned technology. University policies and practices vary on these points both across Universities as well as within Universities. For instance, many Universities hold research using human subjects to a more stringent COI standard than other research.

Timing of the researcher's consulting relationship with a Sponsor may affect whether or how the potential COI is managed. For instance, a researcher may be asked to provide advice to a Sponsor about how the theoretical aspects of their University research might be applied to a particular problem that the Sponsor is facing. Provided that the researcher does not violate confidentiality obligations to his/her University employer or to other sponsors of the theoretical research, and that they do not disclose details of unprotected IP or IP licensed to a third party that belongs to the University, the researcher would likely be able to engage in this consulting activity .

Participation of the researcher who developed the invention that serves as the base of a new company poses unique challenges for the new company as well as for the University and the researcher. The success of the new company may be dependent on the ongoing participation of the researcher in the further development of the technologies as well as in the promotion of the company to investors and other participants. The University should carefully assess and manage any COI related to the researcher's participation, the researcher's financial and fiduciary interests in the company particularly with respect

to ongoing use of University facilities, the company's employment of students, and the time commitment of the researcher. Many Universities have developed policies and procedures for handling COI stemming from personal financial interest as well as institutional interests in these start-up companies.

Universities do not generally ask about how a particular industry sponsored project might affect or benefit the competitors of the Sponsor. Similarly most University COI policies ask for disclosures of outside activity related to the Sponsor of the research and subcontractors engaged on the project by the University and may not ask for disclosure of relationships that the researcher may have with competitors of the Sponsor. Universities would not necessarily know who a Sponsor's competitors are. However, the statement of work, the intellectual property license or option provisions, and the publication review clauses, if strategically prepared, allow a Sponsor to assess the affect of publication of results, for instance, on their competitors.

Most University COI policies recognize and enforce some set of general principles that define "good citizenship" for their employees and provide a basis for assessing the affect and scope of a conflict of interest. A typical set of these principles might be:

- Full-time employees owe their primary loyalty and effort to the University.
- Employees should not use their position to benefit self, family, or business associates or to the detriment of the University.
- Use of University resources requires explicit agreement and payment.
- Intellectual property generated in the performance of an employee's duties is owned by the University and appropriate disclosure to the University is expected.
- Faculty members are expected to abide by the rules of their own units or departments in addition to University policies, state and federal laws.
- Disclosure to supervisors, colleagues, trainees of outside interests related to one's work is expected.
- A University employee should not disclose or use the University's confidential information for the benefit of outside entities or interests.
- A University employee should not disclose an outside entity's confidential information to other University employees without appropriate formal agreements.

Universities use a variety of mechanisms to manage COI including requiring:

- Disclosure of financial interest to the public, other research participants, and subjects.
- Disqualification from participation in all or part of the research.
- Divestiture of all or part of the significant financial interest.
- Limiting participation of students or human subjects; and monitoring or verification of research by independent reviewers.

Universities will generally not agree to comply with a Sponsor's internal COI, Code of Business Conduct or ethical programs. To do this University research staff would be subject to widely varying standards and processes in addition to the policies and practices of their University employer. It would be extremely difficult for the University to become sufficiently familiar with such standards for each Sponsor and to monitor select faculty for compliance with the particular standards of the particular Sponsors. Faculty with multiple industry sponsored projects would be potentially subject to conflicting standards.

Principles:

- COI disclosure and management helps to preserve the public trust in the knowledge discovered and disseminated by the University and also to protect the University, the researchers, and their research sponsors from the appearance of bias or other forms of undue influence affecting the research results.
- University researcher's and industry sponsor's employees' dual roles with the other party must be dis closed and managed (i.e., a researcher consulting to the Sponsor of his/her research project.)
- Faculty support both from sponsored projects inside the University and personal agreements with the Sponsor or competitors designated by the Sponsor should be disclosed to a Sponsor upon request
- Personal relationships of a person's spouse, significant other, dependent children, and business partners are presumed to affect that person in the same way that their own personal relationships do.
- Decisions made by Universities to spend funds, e.g., to subcontract part of a sponsored project to another University or other external entity, should be unbiased, e.g., competitively bid or justified under University procedures for sole source purchases, subcontracts, consultants.
- Conflicted persons both in Industry and Universities should disclose their personal financial interests and may be required to recuse themselves from deliberations or decisions that may promote their personal financial benefit
- Review and finalization of agreements should be done by objective representatives of both parties as an arm's length negotiation .
- Researchers' financial and management interests in their own companies, should be disclosed to their Sponsors.
- Universities should be clear about management of COI involving University employees acting as consultants particularly recognizing the timing of the consulting with the Sponsor, i.e., before, during, or after the conduct of the sponsored project.
- Agreements should clarify applicability of University or Sponsor policies, including COI policies, when using faculty on sabbatical; scientific visitors from companies (see Contract Accord 5: Background Intellectual Property, Contract Accord 6: Foreground Intellectual Property)
- Sponsor and University researchers should be aware of potential delays and considerations of COI committees that may affect their project.
- The Sponsor should respect that University interactions with companies are not all centrally recorded so that the sponsored projects or tech transfer offices or the research team may not know all the relationships a University has with a Sponsor or its competitors.

Outliers

- Institutional or Organizational COI
- Roles of Students/Trainees in Faculty owned businesses

Notes
http://grants.nih.gov/grants/policy/coi/
http://grants.nih.gov/grants/policy/coifaq.htm

University • Industry Demonstration Partnership

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