These Contract Accords were approved by the UIDP Board of Directors at its regularly scheduled meetings in December 2008 and April 2012.
Rationale for Creation of Contract Accords

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.

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 ten commonly recognized areas typically requiring additional time for resolution.

After several years of effort, the UIDP’s Contract Accords Working Group, and the general membership have strategically crafted these Contract Accords 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.

<table>
<thead>
<tr>
<th>Contract Accord</th>
<th>University Champion</th>
<th>Industry Champion</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Preamble</td>
<td>Jilda Garton, Georgia tech &amp; Jennifer Murphy, George Mason University</td>
</tr>
<tr>
<td>1</td>
<td>Statement of Work</td>
<td>Jennifer Murphy, George Mason University</td>
</tr>
<tr>
<td>2</td>
<td>Indemnification</td>
<td>Kathleen Irwin, University of Wisconsin</td>
</tr>
<tr>
<td>3</td>
<td>Publications</td>
<td>Jilda Garton, Georgia Tech</td>
</tr>
<tr>
<td>4</td>
<td>Other Research Results</td>
<td>Kathleen Irwin, University of Wisconsin</td>
</tr>
<tr>
<td>5</td>
<td>Background Intellectual Property</td>
<td>Jilda Garton, Georgia Tech</td>
</tr>
<tr>
<td>6</td>
<td>Foreground Intellectual Property</td>
<td>Jilda Garton, Georgia Tech</td>
</tr>
<tr>
<td>7</td>
<td>Export Control</td>
<td>Susan Burket, Carnegie Mellon</td>
</tr>
<tr>
<td>8</td>
<td>Copyrights and Software</td>
<td>Cathy Innes, UNC Chapel Hill &amp; Jennifer Murphy, George Mason University</td>
</tr>
<tr>
<td>9</td>
<td>Confidential Disclosure Agreements</td>
<td>Bill Catlett, University of Austin</td>
</tr>
<tr>
<td>10</td>
<td>Material Transfer Agreements</td>
<td>Steve Harzy, University of Wisconsin</td>
</tr>
</tbody>
</table>

Acknowledgements

CONTRACT ACCORDS WORKING GROUP MEMBERS

The UIDP would like to thank all of the Working Group champions and members who wrote and reviewed these Contract Accords and provided feedback to the Working Groups.

The Board gives special thanks and recognition to Jilda Diehl Garton from Georgia Tech and Connie Armentrout, Monsanto for their leadership, and to Johannes Dapprich, who has served admirably for the past few years as the Contract Accords Project Manager.

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We also thank all other working group participants who are not explicitly listed here.

Beth Judson - Beth will be remembered as the person who helped get the Contract Accord and TurboNegotiator working groups started and for her constructive and tireless contributions to the initial accords. Beth died with her husband in a small plane crash in October 2010.
About UIDP

MISSION
The UIDP supports mutually beneficial U.S. University-Industry collaborations encouraging U.S. competitiveness by developing and disseminating strategies for addressing common issues between the two sectors.

VALUES
The UIDP values an honest and open culture that is characterized by:

RESPECT:
The development of a deep understanding and respect of the diverse goals, missions, and cultures among our universities and companies, and appreciation of the synergy that they can afford.

OPEN COMMUNICATION:
An environment where mutual respect fosters candor and communication.

COMMITMENT TO MAKING A DIFFERENCE:
Innovation for the public good, maximizing to the greatest extent possible, the information and products that will ultimately be available to the public.

Mutual commitment to shared scholarship, diversity, expertise, training and professional development.

Alignment of the varied goals and cultures of university and industry in pursuit of innovation and research.

Strategic, result-oriented thinking and the development of practical, active demonstrations. Recognition of the benefits of university-industry collaborations and the opportunity lost when mutually beneficial agreements cannot be reached.

INTEGRITY:
A commitment to principled and transparent negotiations.

STRATEGIC GOALS
- Promote education and research between companies, universities, and other research organizations to improve U.S. competitiveness, advance the U.S. scientific knowledge base and create an educated workforce by creating a forum to discuss collaborations in an environment of respect, open communication and integrity.
- Provide professional development opportunities for contracting and research-performing practitioners.
- Serve as a test bed and undertake demonstrations to experiment and model innovative approaches to university-industry collaborative efforts.

OPERATIONAL GOALS
- Support organizations committed to high value, high return university-industry partnerships.
- Promote principled, transparent and timely negotiations.
- Collaborative efforts to accelerate cooperative, multi-dimensional, long-term partnerships.
- Pursue efficiency and effectiveness, seeking to streamline transactions.
- Maintain and grow a cross functional set of UIDP projects and demonstrations that serve the needs of the members and other interested parties who sponsor and perform research.
- Provide timely communications (both internally and externally) on relevant issues.
Contract Accord 0:
Preamble - Good Faith in Fair Dealing

GENERAL PRINCIPLES:
Industry funding is provided for the purposes of corporate responsibility, developing commercial applications, or gaining a commercial advantage. The Sponsor needs to pursue its business model, and the results of the research presumably further that goal.

Universities engage in industry-related research to provide relevant topics for research and student support, to establish strategic partnerships that leverage Industry / University relationships for multiple purposes.

The Sponsor has the right to information about the University’s research team relationships that might reasonably appear to affect Sponsor’s access to the results of the sponsored project.

The University needs to inform investigators regarding Sponsor’s access and use rights to results of the research.

Universities have a responsibility to confirm that rights, licenses or other transfers anticipated are allowable within the context of other third-party agreements.

Conflicts of interest, real and potential, should be disclosed and reduced, eliminated, or managed.

A person from each party should be identified as “Principal Investigator” (PI) or “project champion” and responsible for establishing effective and consistent communications with respect to the technical aspects of the SRA.

A person from each party should be identified to be responsible for establishing effective and consistent communications with respect to the administrative aspects of the SRA.
Contract Accord 1: Statement of Work

The Statement of Work (SOW) is an integral part of the sponsored research agreement. The SOW should define the who, what, when, where, why, and how of the project effort, governing and providing direction for the conduct of research.

Milestones and deliverables should be defined in the SOW or in the contract terms. Such milestones and deliverables should be consistent with the parties’ expectations but are not guaranteed; however, the University has an obligation to perform research on a reasonable efforts basis. The contract clauses and the SOW should be consistent, but in the event of an inconsistency the contract clauses control and take precedence over any statements made in the SOW. The SOW defines the specific aims and activities to be undertaken; any significant or material changes or modifications should be reduced to writing and agreed to by authorized representatives of the Sponsor and the University.

EXPLANATION:

THE STATEMENT OF WORK SHOULD IDENTIFY:

- The principal investigator(s) (PI(s))
- Project staffing
- Project objectives
- Description of the research to be conducted
- Locations where the research work will be conducted
- Deliverables and milestones, defined in a sufficient level of detail such that one can determine if they are met
- The period of performance
- Any special resources required
- Timing and frequency of meetings and reports

PRINCIPLES:

- The SOW should be sufficiently detailed as to define the project and distinguish it from other research undertaken by the investigators.
- The SOW may include items that are subject to change due to the nature of the research (e.g., research activity).
- The SOW should define the research plan and not presume an outcome, but should address goals and aims.
- The SOW needs to be aligned with the budget.
- The term “deliverables” should be used only when there is, in fact, tangible property, such as, but not limited to, software, reports, computer hardware, or other engineered material that is expected to be provided by the University to the Sponsor.

- The responsible administrative office at the University should review the SOW and any significant and material changes after each redraft.
- The PIs should explain any known dependency on background IP in the SOW (See Contract Accord 5).
- The boundaries for any foreground intellectual property (FIP) (to which the Sponsor may have a license or option) are set by the project description and by the contract dates. (See Contract Accord 6)
- No contract (legal) terms should be incorporated in the SOW.

OUTLIERS:

- The University may, with the consent of the PI, agree not to accept funding from the Sponsor’s competitors for closely related research.
- A master/blanket/umbrella agreement would generally set all contractual terms for several projects, except those that are project-specific. The master agreement may allow modification of IP or other terms by mutual agreement for a specific project.
- A project that involves extensive collaboration, exchange of personnel, access to the Sponsor’s facilities, industrial internships for the graduate students, and so forth may require unusual terms regarding the actual conduct of the research.
Contract Accord 2: Indemnification

Specific indemnification depends on the type of project (e.g., basic or applied, clinical trial), the expected outcomes and the potential risks of harm. Indemnification, if provided in the contract, should be triggered by a defined event(s) or circumstance (such as the use of intellectual property, use of a drug or device provided by the Sponsor, or the use of human subjects). Rather than offering indemnification, it may be more appropriate for a party to offer to the other party a clause which provides that each shall be responsible for the actions of its employees, its conduct of the research, and its use of the results.

EXPLANATION:

- Indemnification and warranty clauses must be coordinated and consistent.
- Insurance and other representations should be referenced.

PRINCIPLES:

- State institutions and universities often cannot be responsible for actions other than their own. In some states it has been determined that indemnification is an unfunded liability, and only the legislature has authority to obligate funds. Universities can be responsible for their own acts and omissions.
- In an indemnification, the indemnitor will typically defend, pay damages, control litigation, control negotiations to settle at its own expense, mitigate damages in a manner that won’t harm indemnitor (or indemnitee); indemnitor will typically only have the right to approve a settlement on behalf of an indemnitee when there is no admission of liability, wrong-doing or other potential harm to the indemnitee.
- The indemnitor and indemnitee may agree to allow the indemnitee to manage the litigation and be reimbursed for expenses including attorney fees and any judgment.
- It is reasonable for a University to expect a Sponsor to indemnify it against liability arising from the performance of a company-designed study protocol.
- It is reasonable for a University to expect a Sponsor to indemnify it from any loss or damage arising out of company’s use, commercialization, or distribution of information, materials, or products developed by the University that result in whole or in part from the research.
- Required language regarding indemnification must be consistent in both the sponsored research agreement and the protocol governing the study or clinical trial agreement as approved by the University Institutional Review Board.
- Universities should not require indemnification for their own negligence.

OUTLIERS:

- Indemnification as part of a patent license. For some industries this may be negotiated at the same time as the research agreement and is often attached as part of the agreement.
- Material transfer agreements
  (These are separate agreements and fact-specific.)

Contract Accord 3: Publications

PUBLICATIONS

Universities need to be free to publish, present, or otherwise disclose results in a timely manner following review by Sponsors within a mutually agreed upon time frame. Sponsors have the right to require the removal of any of the Sponsor’s confidential information. Upon request, an additional delay of publication may be appropriate to allow time to file a patent application. Generally, the time a publication can be delayed must be specific and limited.

EXPLANATION:

The Sponsors’ need to protect commercially feasible technologies, products, or processes must be balanced with the University’s public responsibility to freely disseminate scientific findings for the advancement of knowledge and the academic freedom of faculty and students to publish the results of their research.

Universities conduct research as tax-exempt organizations. Research conducted by tax-exempt organizations must be performed for the public benefit and is expected to lead to information that is published and available to the interested public. Research that is subject to restrictions on publication may be considered a trade or business activity that is unrelated to the public purpose of the University.

Freedom to publish is a requirement for protecting the University’s fundamental research exclusion (FRE) under export control regulations, which permits unreasonable delays only for patent prosecution.

PRINCIPLES:

- The primary missions of a University are to educate, create and disseminate new knowledge.
- Universities have an obligation to protect identified confidential information that a Sponsor provides to the University in connection with a sponsored project. It may also be reasonable for a Sponsor to ask that such information be deleted from publication.
- The Sponsor’s right to restrict publication cannot be through inaction, i.e., the assumption that results cannot be published until the Sponsor reviews will prohibit publication unless the review period is specified. Sponsors should not be able to restrict publications that depend on information that was not identified as confidential.
- Publication delays should not jeopardize academic progress of students.
- Universities and companies have a mutual interest in protecting intellectual property (IP).
- Universities and companies recognize that premature disclosure may jeopardize patentability.
- Publication of research results in a timely and appropriate manner can be beneficial to opening markets and expanding product options.
- Preservation of open research environments is important.
Contract Accord 4: Other Research Results (ORR)

Sponsored research may produce results in a variety of forms. Potentially patentable results are addressed in Contract Accord 6. Copyrightable results, such as software, are addressed in Contract Accord 8. For purposes of this accord, ORR include tangible (TORR) and intangible (IORR) products of the research not addressed in those Contract Accords. This accord is concerned with the Sponsors’ rights to ORR.

ORR are often the results of open exchange of information, may have application in multiple research projects and have potential to impact broad research programs. Sponsor ownership of research results is not required so long as the Sponsor is granted appropriate access to the results both for the Sponsor’s varied purposes (i.e. for commercial purposes, such as regulatory filings).

OUTLIERS:
- Freedom to publish is beneficial to open dissemination of research results as contemplated in certain open collaboration research agreements.
- In collaborative research, each party should be able to publish research. Sponsors involved in a collaborative project may develop publications based upon the findings of the project if the University decides not to pursue.
- All authors should be included in the publication subject to the principles of authorship customary for the discipline.
- Any separate agreement between University and Sponsor researchers that is not part of the documented contract may jeopardize the designation of research as being for the public benefit and precludes the University’s exercise of the FRe.
- The concept of Trade Secrets is generally incompatible with the University’s publication objective.

PRINCIPLES RELATED TO INTANGIBLE OTHER RESEARCH RESULTS (IORR):
- Control of and access to IORR should be treated separately from the intellectual property provisions of the SRA.
- Premature disclosure of preliminary findings may jeopardize the patentability of inventions.
- Generally the Sponsor is granted a free nonexclusive right to use IORR for any purpose consistent with any other intellectual property provisions in the SRA that may include, but not necessarily limited to further internal research and development, preparation of product information for customers, qualifying products and processes with customers and government regulators.

THE SPONSOR’S RIGHTS IN SOME IORR MAY BE SUBJECT TO REGULATORY CONSTRAINTS:
- The University needs to consult with the principal investigator(s) regarding the Sponsor’s access and use rights.
- The University retains the right to control use of the IORR for any purpose and to publish based on the results of its use of such materials.
- The Parties may need to have access to the other Party’s data, know-how, etc., to do the research. Such access may be subject to a separate nondisclosure agreement, material transfer agreement, confidentiality agreement or use clause in the sponsored research agreement.
PRINCIPLES RELATED TO TANGIBLE OTHER RESEARCH RESULTS (TORR):

• Control of and access to TORR should be treated separately from the intellectual property provisions of the SRA.
• Premature disclosure of preliminary findings may jeopardize the patentability of inventions.
• The SRA should address the Sponsor’s rights to acquire and use TORR. Generally the Sponsor is granted a free nonexclusive right to use TORR for any purpose consistent with any other intellectual property provisions in the SRA that may include, but not necessarily be limited to, further internal research and development, preparation of product information for customers, qualifying products and processes with customers and government regulators.
• The Sponsor may have limited access to TORR that can be consumed without the potential for renewing their supply. Examples of such results include but not necessarily limited to biological specimens and samples, prototypes, and samples of difficult-to-synthesize small molecules. Such products may be exhausted during the course of the research project, thereby restricting access for validation of the science and other research uses. Access to such research results requires special consideration.
• The Sponsor’s rights in some TORR may be subject to regulatory constraints such as Institutional Review Board (IRB) oversight, human subjects protections such as privacy and consents, export control or other limitations. These limitations should be described in the sponsored research agreement.
• The University needs to consult with the principal investigator(s) regarding the Sponsor’s access and use rights.
• The University retains the right to control use of the TORR for any purpose and to publish based on the results of its use of such TORR.
• The University shall retain physical custody of TORR.
• The Parties may need to have access to the other Party’s data, know-how, etc., to do the research. Such access may be subject to a separate nondisclosure agreement, material transfer agreement, confidentiality agreement or use clause in the sponsored research agreement.

OUTLIERS:

• In cases of applied research projects (clinical trials, agricultural field trials, testing agreements, fee-for-service arrangements, etc.), the Sponsor may be accorded ownership of specified types of results, including tangible research property, but the University should retain the right to use such results for its own research and educational purposes.
• Applied research projects: It is unlikely that IoT would be generated in the course of the work.
• Research data that contains confidential or proprietary information of other sponsors, or information that should not be released because of privacy/HIPAA concerns must be addressed differently than standard research results.
• Exclusive rights to other research results are rare and should be negotiated separately.
• Using terms such as “unpatented inventions” or “discoveries” in the list of Other Research Results, must be considered carefully. They are difficult to define unambiguously, and the University usually has no legal mechanism to restrict access or enforce limitations on such abstractions, especially since the legally protectable category of “trade secrets” is generally thought to be incompatible with the University environment and mission.
• While “know-how” could be considered to be an IORR, it is difficult to define and fraught with difficulty, since know-how can be thought of as a characteristic of an individual scientist and not the intellectual property of the University. This contract accord suggests omitting these terms from license provisions in research agreements.

ADDITIONAL COMMENTS:

• What is covered by the agreement as “Other Research Results” will vary by industry sector.
• IP grant of rights should be specified in the research agreement. The clause may depend on whether IP is contemplated that will be subject to a separate license agreement at some future date.
**Contract Accord 5: Background Intellectual Property**

**PURPOSE:**
Research may lead to discovery of new intellectual property (foreground intellectual property, or FiP) that, in order to be practiced, may require access to background intellectual property (BiP) that is owned or controlled by the University, the Sponsor or by a third party that exists prior to, or outside of, a sponsored research agreement (SRA). The purposes of BiP clauses in agreements are:

- To clarify and manage the expectations of the parties
- To provide a framework for disclosure of BiP and
- To provide access to the BiP if it is needed for the Sponsor to exercise its license rights for newly discovered IP.

The BiP clauses help to mitigate the risk that the Sponsor or University may not have access to BiP which is needed to practice IP that results from the sponsored project. BiP clauses help licensors understand and track the obligations they are making in the agreement with respect to pre-existing IP or that which arises outside a SRA. BiP is an important asset to both parties and should be recognized and handled as such.

**PRINCIPLES:**
- Identifying the technical relevance of BiP to proposed research is a shared responsibility among the sponsored research office, technology transfer professional, the principal investigator (PI), and the Sponsor’s technical and contracting representatives.
- The scope of rights (and terms) of BiP clauses needs to be addressed in two contexts: the sponsored research agreement and the license agreement, as applicable. The sponsored research agreement needs to define the rights of access to BiP for the performance of the research as well as the breadth of commercial rights in BiP a Sponsor can expect to obtain in the license agreement.
- The parties should consider the extent to which they may require access to the other Party’s BiP in order to practice the FiP and negotiate those rights explicitly.

**UNIVERSITY BIP CAN BE FURTHER DEFINED AS FOLLOWS:**

<table>
<thead>
<tr>
<th>University BIP IS:</th>
<th>University BIP IS NOT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal invention disclosures submitted to the University’s responsible office</td>
<td>IP developed under individual consulting agreements to which the University does not have ownership rights</td>
</tr>
<tr>
<td>Patent applications in preparation or filed; issued patents</td>
<td>Results of ongoing research that have not been disclosed to the University administration (or the University’s responsible office)</td>
</tr>
<tr>
<td>Licensable intellectual property (inventions or software)</td>
<td>IP not owned or controlled by the University unless explicitly incorporated into the research project and for which the University has obtained rights</td>
</tr>
<tr>
<td>IP that might be necessary for the practice of FiP</td>
<td>Research results that are not subject to patent or copyright laws</td>
</tr>
</tbody>
</table>

**COMMON EXPECTATIONS:**
Identification of relevant BiP will involve the University’s sponsored research office, the tech transfer office, the PI and the Sponsor’s technical and contracting representatives.

Because exclusively licensed IP may become relevant BiP in the future, Universities are expected to follow licensing practices that retain a research right to use and are mindful of potential future uses beyond the interest of the licensee. In order to achieve the broadest possible application of the technology, exclusive licenses may be used. For research tools resulting from government-funded projects, recipients will ensure consistency with the Bayh-Dole Act and requirements of the funding agency. These tools are expected to be made available to the research community for the public good. Any license issued will contain language to appropriately address dissemination or distribution of the research tool.

<table>
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<tr>
<th>Universities’ Expectations</th>
<th>Sponsors’ Expectations</th>
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<tbody>
<tr>
<td>BIP is not necessarily available for free.</td>
<td>The Sponsor will have freedom to operate, and will not be blocked from commercializing technology; “no surprises.”</td>
</tr>
<tr>
<td>University discoveries will benefit the public.</td>
<td>The University is willing to facilitate discussions with others for third party licensing if necessary.</td>
</tr>
<tr>
<td>The Sponsor needs to negotiate with the authorized institution office (no private deals with PIs).</td>
<td>The University should use reasonable effort to identify and disclose known University-owned BIP along with its availability for licensing.</td>
</tr>
<tr>
<td>The University may expect to recover patent costs.</td>
<td>IP and BiP clauses in SRAs are reviewed by someone in the University with technology licensing expertise.</td>
</tr>
</tbody>
</table>
**Contract Accord 6:**

**Foreground Intellectual Property**

Throughout these documents, “University” refers to the university participant in a specific Sponsored Research Agreement (SRA) and “Sponsor” refers to the industry sponsor of the SRA.

**DEFINITION:**

Foreground Intellectual Property (FiP) means potentially patentable inventions conceived and reduced to practice during performance of the sponsored research agreement (SRA) covered by the SoW.¹

**PURPOSE:**

The purposes of FiP clauses in agreements are:

- To set out the expectations of the parties with respect to resulting intellectual property.
- To provide the requirements for reporting and disclosure of FiP.
- To provide a framework for protection of FiP.
- To provide a mechanism to ensure that the FiP benefits the public.

The FiP clauses help to assure that the Sponsor has clearly defined access to results from the sponsored project. FiP clauses describe for licensors, research administrators, and Sponsors the obligations they are making in the agreement.²

The FiP clauses help to ensure that new inventions have the opportunity to be commercialized or further disseminated to the benefit of the public.

**PRINCIPLES:**

- Inventorship is a legal determination made pursuant to controlling patent law. Patents must name all inventors³ and cannot name persons who are not inventors. Incorrect inventorship can jeopardize the validity of a patent.
- Ownership of FiP is a contractual determination, subject to the policies of the inventors' respective employers, and in some cases, other contractual commitments. Ownership of FiP should not be confused with inventorship.

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¹ Note that potentially patentable inventions that have been conceived but not reduced to practice are covered in Other Research Results Contract accord 4. Inventions conceived but not reduced to practice outside the scope of research described in an SRA are covered in the Background intellectual Property Contract accord 5. Copyrightable materials are covered in Contract accord 8. SoW is covered in Contract accord 1.

² The University administrators who negotiate FiP license option language in the SRA are often not the same people who will actually negotiate the license or license option for FiP, or who will actually administer the FiP license.

³ www.uspto.gov “The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he or she is not an inventor. Insuffar as defining an inventor is concerned, reduction to practice, per se, is irrelevant” www.hollandandhart.com: Consequences of inventorship errors: patent may be invalidated, considered unenforceable, and involve significant cost and time to defend.
• The SRA establishes the pathways for the Sponsor to access the FIP and the limitations, if any, on the University’s continued access and use or it.
• The SRA generally does not include terms that would be found in a license agreement, e.g., royalty rates, liability, milestones and diligence requirements.
• The SRA should address the parameters and breadth of rights in FIP that a Sponsor can expect to obtain in a license agreement. Such rights in FIP may include the right to make, have made, use, have used, sell, offer to sell, import or other right to transfer through assignment or sublicense of those rights.
• The SRA should address the parameters and breadth of research and educational rights retained by the University in FIP which may include licensing to other non-profit organizations and to other commercial entities. Such rights should not conflict with rights previously granted to SRA sponsor.
• The parties should consider the extent to which they may require access to the other party’s background intellectual property (BIP) in order to practice the FIP and negotiate those rights explicitly. (See Contract Accord 5)
• Rights for defined affiliate organizations of the Sponsor are generally included under the same terms and conditions as those of the Sponsor.4
• Generally, the Sponsor expects, and the University will assure, that all personnel that will be involved in the sponsored research are subject to the University’s IP assignment policy or have separately entered into an assignment agreement that allows the University to convey rights to the Sponsor, unless otherwise explicitly agreed.
• The parties should recognize that if certain persons, e.g., unpaid participants, visiting scholars, undergraduate and graduate students, interns, are inventors of the FIP ownership of the FIP may not wholly vest with the University. To the extent possible, the parties should identify such individuals prior to their participation in the project.
• University should inform the Sponsor of any proposed third party funding or resources to be used in the project and how they might affect FIP.
• The agreement should contain an adequate description of the invention disclosure process between the parties. The process should describe the obligation to disclose, to whom to disclose, who the contacts are, and the timeline and process for disclosure and election of rights.
• The SRA will not convey rights to the Sponsor to results of future related research not funded by the Sponsor.

COMMON EXPECTATIONS REGARDING FIP IN SRAS

FIP TERMS IN SRA GENERALLY
The inclusion of an FIP clause is at the option of the Sponsor. Absent an FIP clause, the Sponsor acquires no rights in FIP invented by the University in performance of the research, except as a result of the operation of law, e.g., the Sponsor would generally have joint ownership rights in FIP that is jointly invented by employees of the University and the Sponsor. FIP terms in an SRA typically provide for the following:

Minimum Rights to the Sponsor. At a minimum, University grants the Sponsor the right to a non-exclusive royalty-free (NERF) license to use the University FIP within its own organization for any internal purpose.
The scope of this automatic grant of right is generally limited to internal research use by the Sponsor. The scope can be adjusted by mutual agreement of the parties depending on the research project. Access to full commercial rights is addressed below in the “licensed term section”.

Option Period. There is generally a specified period of time during which the Sponsor may elect to enter into:
• A confirmatory license5 for the nonexclusive rights granted in the agreement;
• A formal option agreement extending the period of the option so that the Sponsor has sufficient time to determine its interest in obtaining a commercial license; or
• An exclusive or non-exclusive commercial license as described in the agreement.

Patent Application Control and Reimbursement. The University prefers to control prosecution of patent applications covering FIP to insure that the patent application maximizes the scope of the protection and potential ability to license the invention.

The University does not want to be obligated to expend funds to protect FIP unless it is reasonably assured the funds can be recovered from a licensee.

Provisions covering the process for determining if and when a patent application covering FIP will be filed may include terms addressing:
• Patent Control – which party files and oversees patent applications
• Right to review – the scope of the non-filing party’s right to review the application, office actions etc.
• Choice of counsel – the party’s respective roles in choosing, reviewing or approving patent counsel.
• Patent costs – who pays and when.
• Default or discontinuance - what happens when the party that is paying patent costs or handling prosecution discontinues doing so
• Provisions might also be included that require the University to reimburse patent expenses paid by the Sponsor if the option is ultimately not exercised and the FIP is licensed by the University to a third party.

The provisions above are negotiable in circumstances in which control is more logically exercised by the Sponsor, e.g., the FIP is an improvement to Sponsor-owned IP. In cases where the Sponsor files the patent, the University may seek assurance that the attorney chosen by the Sponsor will represent the University as an equal client, and can do so without a conflict of interest.

Reservation of Rights. The University generally retains rights in FIP for its own purposes to include at least continued research and education. The inclusion of this provision is generally not negotiable since it protects the University’s ability to continue to conduct research, teaching, and other activities related to the FIP even after the FIP is exclusively licensed. Such use should not conflict with rights previously granted the SRA Sponsor.

4 Consider export control implications if there are foreign affiliates. See Contract Accord 7.
5 A separate document formally conveying the rights promised in the research agreement.
OPTION OR LICENSE
Universities typically prefer to grant an option to the Sponsor to negotiate a license to rights to FIP rather than addressing all the provisions that would be contained in a license agreement. This provision allows the parties to negotiate terms of a license that are consistent with and based on the value of the FIP that is ultimately disclosed. Terms and conditions of these licenses are to be negotiated in good faith and agreed upon between the University and the Sponsor, and should reflect that Sponsor has funded the research that led to the FIP.

Negotiation of a royalty rate prior to disclosure of the related FIP may have negative tax consequences to the University. While uncommon, a range of royalty rates may be included if the scope of the project is such that it is possible to anticipate the nature of the FIP with reasonable certainty.

The University is interested in getting a decision from the Sponsor as soon as possible so that if the Sponsor is not interested, the University is able to pursue support from another sponsor or license the FIP to a third party without undue delay.

LICENSE TERMS
While specific details of licensing terms are generally not included in an SRA, variations in option and licensing rights may include the following:

Non-exclusive commercial use by Sponsor of University FIP. Some common variations on nonexclusive commercial rights licenses provided in SRAs include:

- NERF (Non-Exclusive, Royalty-Free license) to use FIP for commercial purposes subject to limitations and considerations such as commercial use tied to field of use, fully-funded process patents, promotion of a strategic relationship, or provision of significant programmatic support;
- Non-exclusive in exchange for patent cost reimbursement, royalty, fully paid fee, other fee, etc.; or
- Unlimited non-exclusive with no further consideration beyond the research support e.g., for research tools and other precompetitive types of FIP.

Exclusive rights to Sponsor in University FIP. These rights are generally contingent on patent cost recovery and may also be.

- In exchange for consideration (royalty, fee, equity, etc.),
- Limited to a field of use,
- Limited to a territory of use.

Joint FIP. Collaborative research projects create the opportunity for the creation of joint intellectually property. As previously noted, joint ownership of intellectual property is controlled by the SRA terms while joint inventorship is controlled by patent law. In the event that a Sponsor wishes to commercialize joint FIP exclusively, the Sponsor typically is expected to pay full patent costs for protection and maintenance and is given an option to negotiate an agreement to acquire sole rights to the University’s undivided share.

Third party rights and sublicensing. For non-exclusives, sublicensing is not generally considered. The University typically will not grant a nonexclusive licensee the right to sublicense since it can grant those licenses itself and prefers to do so.

For exclusives, the right to sublicense is sometimes included in the rights available to the Sponsor under the option clause.

Affiliates of the Sponsor as defined by the SRA have the same rights as the Sponsor.

Federal government may have reserved rights and universities may have reporting requirements in BIP related to the FIP.

6 Refer to Rev Procs 97-14 and 2007-47.

7 Ownership of inventions is generally assigned to the inventor's employer.
Assignment of Ownership of FIP. Assignment by the University of ownership of FIP including assignment of the University’s rights in joint IP is uncommon and would be negotiated on a case-by-case basis and would be dependent on unique circumstances. Note that the ability of the University to enter into some assignment agreements may be limited by statutory requirements.

OUTLIERS:
This FIP Contract Accord does not address a number of situations. Some of these are addressed by professional organizations and associations that have particular expertise in these areas of research.

- Sponsor-Initiated Clinical Trials
- Consortia
- Faculty Consulting Agreements
- Non-disclosure Agreements – see Contract Accord 9
- Material Transfer Agreements8 see Contract Accord 10
- Field Trials and Fee for Service Agreements – see Contract Accord 11
- Gifts and Donations related to Research – see Contract Accord 12

In some University-Industry Research agreements, “Foreground Intellectual Property” may be defined as potentially patentable inventions conceived or reduced to practice during performance of the SRA rather than those potentially patentable inventions conceived and reduced to practice during the Research. In negotiating such agreements, the parties should consider the following scenarios and address them in the SRA:

- An invention conceived but not reduced to practice prior to the effective date of the Research Agreement may be considered Background Intellectual Property (BIP) belonging to one of the parties (see Contract Accord 5) or it may be covered by a non-disclosure agreement (see Contract Accord 9).
- An invention conceived during the research but not reduced to practice before the project concludes may later be reduced to practice. Sponsors may fund further research at the University to reduce the invention to practice.
- The Sponsor may conduct research under its internal NERF (Section A.1 above) that reduces the invention to practice resulting in a jointly-developed invention. The University may conduct research that reduces the invention to practice (Section A.4 above) using the University’s funds, federal funds, or funds from another company. Unless an option right is extended, the Sponsor may not have rights to the invention’s reduction to practice.
- In the case of collaborations during which University researchers and Sponsor researchers jointly conceive an invention that is not reduced to practice prior to the conclusion of the Research, the parties generally have a joint and undivided interest in the invention and either party may conduct research to reduce it to practice.

Therefore, it is in both party’s interest to determine whether any inventions related to the subject matter of the proposed research have been conceived by researchers of either party to be prior to the project start date, and see to it that they are included in the SRO.

Contract Accord 7:
Export Control

Export Control Regulations and the Fundamental Research Exclusion

OVERARCHING PRINCIPLE: COOPERATIVE COMPLIANCE
The UIDP comprises U.S.-based Sponsors, Industry, and Universities; therefore most UIDP members are subject to U.S. Export Laws & Regulations. The two agencies that most commonly govern U.S. Export Controls are the Department of Commerce and Department of State which utilize Export Administration Regulation (EAR10) and International Traffic in Arms Regulations (ITAR11), respectively. Additionally, the Department of Treasury’s Office Foreign Assets Control (OFAC) administers and enforces economic and trade sanctions including the embargoed country and restricted entity list. While universities strive to conduct research in an unrestricted academic environment and broadly publish their research results, most industrial organizations strive to gain competitive advantage by restricting access to information, technologies and product characteristics and maximize revenues. All parties must balance these cultural differences and comply with their respective obligations under the export laws and regulations. It is the goal of UIDP to assist in meeting these obligations in a spirit of cooperative compliance.

FUNDAMENTAL RESEARCH EXCLUSION
Fundamental Research, as defined by the regulations,12 is excluded from EAR and ITAR.13 Such research can be distinguished from proprietary research and from industrial development, design, production and product utilization, the results of which ordinarily are restricted for proprietary reasons or specific national security reasons.14 This Fundamental Research Exclusion (FRE) applies to information (but not to export controlled physical items or software) resulting from “basic and applied research in science and engineering” conducted at an “accredited institution of higher education” (EAR) or “higher learning” (ITAR) “located in the United States” that is “ordinarily published and shared broadly within the scientific community” and that is not “restricted for proprietary reasons or specific national security reasons” (EAR) or subject to “specific U.S. government access and dissemination controls” (ITAR).

10 Export Administration Regulations: The Export Administration Regulations (EAR) is found at Title 15, sections 730-774, of the Code of Federal Regulations (CFR). These regulations implemented by the Department of Commerce control the export of goods and services identified on the Commodity Control List (CCL), Title 15 CFR 774, Supp. 1. Goods and services on the CCL are not inherently military in nature; they are primarily commercial. Note: The EAR regulates “items designated for potentially commercial purposes but that can have military applications” (“dual use”).
11 International Traffic in Arms Regulations: The International Traffic in Arms Regulations (ITAR) is found at 22 CFR, sections 120-130, implement Section 38 of the Arms Export Control Act (22 USC 2778). These regulations implemented by the Department of State control the export of articles, services and related technical data that are inherently military in nature, as determined by the State Department. These “defense articles,” “defense services” and related “technical data” are listed on the Munitions List (USML), 22 CFR 121.
12 15 CFR 738.8
13 22 CFR 120.11
14 15 CFR 734.11(b)
This exclusion generally permits U.S. universities to allow members of their communities who are not U.S. citizens or permanent residents to participate in research projects on campuses in the U.S. where research will be made publicly available. The FRE avoids the need to secure a deemed export license.15

Both the EAR and the ITAR treat fundamental research as a subset of the “publicly available” or “public domain” exemptions.16 The EAR provides that research conducted by scientists, engineers or students at a university normally will be considered fundamental research (15 CFR 734.8(b)(2) through (6)). The ITAR does not contain that affirmative statement, but instead states that university research will not be considered fundamental research if the information resulting from the project or activity or the research is funded by the U.S. Government and specific access and dissemination controls protecting the information resulting from the research are applicable and/or the University or researchers accept restrictions on the publication of the resulting technical data (22 CFR 120.11(a)(8)).

The FRE essentially incorporates the provisions of the National Security Decision Directive (NSDD) 18917 issued in September 1985 and reaffirmed by the Bush Administration in 2001. The Directive states, “[i]t is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted. It is also the policy of this Administration that, where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification.” Further, “[n]o restriction may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification, except as provided in applicable U.S. Statutes.” In a Memorandum, entitled Fundamental Research, for Secretaries of the Military Departments, issued May, 2010, the Department of Defense (DoD) issued clarifying guidance to include subcontracts.

According to the memo, contracted fundamental research includes research performed under grants and contracts that are (a) funded by budget Category 6.1 (Basic Research), whether performed by universities or industry or (b) funded by budget Category 6.2 (Applied Research) and performed on-campus at a university.

“This means that DoD awards for the performance of contracted fundamental research should not involve classified items, information, or technology other than in exceptional circumstances. Furthermore, unclassified contracted fundamental research awards should not be structured, managed or executed in such a manner that they become subject to controls under U.S. statutes and regulations, including U.S. export control laws and regulations. The performance of contracted fundamental research also should not be managed in a way that it becomes subject to restrictions on the involvement of foreign researchers or publication restrictions. There may be exceptional cases in which these guidelines should not be applied . . . but these cases will be extremely rare . . .”

PRINCIPLES

Industry and universities have an obligation for export control compliance and should designate a responsible official or Point of Contact (POC). This person is normally different from the technical POC or principal investigator. It is recommended that all parties working on a research award that could be related to export controls should establish an export control policy within their organization.17

Primary mission. The primary mission of universities in the U.S. is to create and disseminate new knowledge. That unique mission is recognized by export control laws and regulations.

A primary mission of industry is to develop products or services that generate revenue for the company and shareholders.

The FRE is a vital organizing principle that reflects global collaboration among scholars and the international nature of graduate education. Freedom to publish is a requirement for protecting the FRE. The FRE enables the timely submission of scholarly publications, graduate theses and dissertations.

University-based research conducted by scientists, engineers, or students normally will be considered fundamental research when conducted at an accredited institution in the U.S. This exclusion may not apply to collaborative research with foreign entities.

Not all research conducted at U.S. universities qualifies for the FRE and may be restricted based on several factors. For example:

- Confidential Information restrictions
- Flow down clauses from federal awards, e.g., restrictions on publications, export controls, participation of foreign nationals
- Movement of personnel from university to industry may result in the loss of the FRE and may require a license (including outside consulting, SBIR/STTR, students, interns, visiting scientists, etc.).

15 A deemed export is a term as used by the Commerce Department to describe the situation where a foreign national on U.S. soil may be exposed to, or have access in any manner to, an export-controlled item or export controlled software or information.

16 15 CFR 734(b) (3); 22 CFR 120.11(a)

17 The export control regulations are dynamic. This Contract Accord was updated on December 7, 2010 based on then current regulations. Readers are encouraged to refer to current regulations and policies.
Under certain conditions, industry may have the FRE under EAR; however this does not apply to projects or data whose results are not going to be in the public domain. The need to innovate, develop, manufacture and sell products and services worldwide presents challenges under the export control regulations.

Ultimately each party is responsible for its compliance with U.S. export regulations.

GUIDELINES
As early as possible and throughout the project, all parties should identify and disclose any export control implications or issues, especially where the parties are sharing confidential or proprietary information with one another.

Universities should engage in conversations early on in the collaborative relationship with industry so that industry can work with its federal sponsors to request flow down clauses related to export controls that will permit the parties to claim benefit of the FRE. It is important that industry has the opportunity to do this before they accept a federal award.

If the parties transfer export controlled items (software, equipment, technology, materials, background IP, etc.), the providing party should notify the receiving party if the item is controlled by EAR or ITAR. If EAR, the Controlled Commerce List (CCL) category should be provided; if ITAR, the United States Munitions List (USML) category should be provided. The providing party should be responsible for categorizing and marking the materials before sending as part of cooperative compliance effort.

If the parties involved identify a potential export control violation, they should work collaboratively to submit simultaneous Voluntary Self Disclosures, as appropriate.

All parties should prohibit informal side deals between one of the parties and individual employees of the other which may make activities subject to export control.

Prior to providing access to export controlled projects or information, each party should ensure that individuals who are not their employees will be properly screened for denied parties/entities.

SUMMARY:
It is important that the contractual relationships between universities and industry recognize and respect the different compliance obligations and/or exemptions permitted under these laws and regulations, to ensure balance between the parties’ strategic, research and organizational objectives. Industry needs to recognize most universities cannot conduct restricted research under agreements that include the following provisions as these terms could compromise the FRE:

- The research requires the incorporation of export controlled information or materials into the research results;
- The terms restrict publications by requiring the sponsor’s approval of publications or public release of research results; or
- The project limits researcher participation by citizenship.

As a general rule, universities obtain few, if any, export licenses due to their desire to maximize use of the FRE and their adherence to policies that do not restrict research participation according to citizenship. Most universities rely on industry and/or vendors for classification of the items they regularly export. Properly understood, compliance with the export control regulations allows universities and industry to work collaboratively in the best interests of both.

APPENDIX 1
Examples of key clauses under federal awards that present potential compromise of the fundamental research exclusion include:

FAR 52.227-17 Rights in Data –Special Works
http://tinyurl.com/8d9po8e

DFAR 252.204-7000 Disclosure of Information
http://tinyurl.com/2cczyhn

DFAR 252.204-7008 Requirements for Contracts Involving Export-Controlled Items (April 2010)
http://tinyurl.com/992rmsg

18 NDA, RFP, MTA, etc.
Contract Accord 8: 
Copyrights and Software

NOTE:
Throughout this document, “institutions” refers to the universities, national labs, and/or non-profit research organizations in a specific Sponsored Research Agreement (SRA) and “Sponsor” refers to the industry funding entity of the SRA.

COPYRIGHT CONSIDERATIONS:
As defined in 17 USC, copyright works include any original works of authorship that are fixed in any tangible medium of expression19, now known or later developed. The categories of works eligible for copyright protection include:

- Literary works including aspects of software that can be fixed in any tangible medium of expression.
- Musical works, including any accompanying words;
- Dramatic works, including any accompanying music;
- Pantomimes and choreographic works;
- Pictorial, graphic, and sculptural works;
- Motion pictures and other audiovisual works;
- Sound recordings; and
- Architectural works.

A copyright exists upon creation and fixation in a tangible form of a work automatically and requires no formal registration. The initial owner of a copyright is the author unless the work is owned by the author’s employer when the work is created within the scope of employment (“works made for hire”) unless there has been a written agreement to the contrary signed by both the employer and the employee. Under very limited circumstances, a third party may own works as “works made for hire” if such works fall within the nine categories enumerated in 17 USC, and there is a written agreement between the initial owner and the third party.

The owner of a copyright, subject to the limitations in 17 U.S.C. Chapter 1, the exclusive rights:

- To reproduce the work;
- To make derivative works based on the work;
- To distribute copies of the work to the public;
- To perform the work publicly; and
- To display the work publicly.

The owner of the copyright may license each of these five rights individually or together. The right to create derivative works and whether a work constitutes a derivative work are legal determinations.20

In order for the title to copyrights to be held jointly, the creators of the work must have had a stated intent to create the work together. Absent such an agreement, each creator owns his or her own specific contribution, and the whole work can only be used by either creator by agreement with the other.

Under the law, if copyright in a work is held jointly, each owner has all these rights and an obligation to the other owners to share income from the exercise of these rights.

Copyrights considered for this contract accord are those copyrightable works that are created in the performance of the work outlined in the SOW of a Sponsored Research Agreement (SRA).

PURPOSE:
The purposes of clauses that cover copyright rights in SRA's are to:

- To make a clear differentiation between contract clauses governing patentable works (inventive works) and copyright works (works of authorship);
- To provide a pathway for Sponsors to benefit from copyright works created under their sponsorship;
- To set out the expectations of the parties with respect to the exercise of the copyright.

PRINCIPLES:
Researchers in institutions typically own the copyrights in their scholarly works, including journal articles, presentations, textbooks, curricula, and works of art. Therefore, Institutions may not have sufficient rights in all copyright works to assign or license to third parties.

The policies governing disposition of ownership of copyrights in software and digital works varies among Institutions. In some cases software is treated as Institutional works and in some cases as scholarly works. Sponsors should inquire as to the particular Institution regarding the Institution’s policy.

19 “when its embodiment in a copy or phonorecord, by or under the authority of the author, is sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. A work consisting of sounds, images, or both, that are being transmitted, is “fixed” for purposes of this title if a fixation of the work is being made simultaneously with its transmission,” 17 USC 101.

20 “The copyright in a compilation or derivative work extends only to the material contributed by the author of such work, as distinguished from the preexisting material employed in the work, and does not imply any exclusive right in the preexisting material. The copyright in such work is independent of, and does not affect or enlarge the scope, duration, ownership, or subsistence of, any copyright protection in the preexisting material.” 17 USC 102.b.
Copyrights are a unique and distinct form of intellectual property that should be managed by clauses and provisions specific to their nature as distinct from clauses and provisions that manage patent rights.

The SRA should address the parameters and breadth of rights in copyright protected works that a Sponsor intends to acquire. Provisions regarding copyrights resulting from an SRA should address all five of the rights granted in a copyright. In particular, the Institution and Sponsor must clearly define rights in and to derivative works.

Institutions need to retain a minimum of non-commercial rights for academic and research purposes. See Contract Accord 6.

The SRA should attempt to capture the deliverables anticipated under the SRA in the SOW.

The Institution and the Sponsor should clearly articulate the form of the work(s) that the parties desire and whether rights are available in those works. An example would be the inclusion of language to indicate whether the sponsor needs the source code or only the executable.

Institutions and Sponsors have explicitly designated signature authority. The Institution and Sponsor administrators who negotiate copyright language in the SRA are often not the individuals authorized to transfer rights in copyrights that result from the SRA. 21

If the SOW of the SRA calls for collaboration in creating a copyrightable work, there should be a provision in the agreement that addresses joint authorship and ownership of the work.

Ownership of copyrighted works should be a contractual determination, subject to the policies of the author’s respective employer, and in some cases, other contractual commitments. Ownership of copyrighted works should not be confused with authorship.

Typically the types of works created under SRA’s do not qualify as eligible works for “work made for hire” as established by copyright law.

The SRA establishes the pathways for the Sponsor to access copyrighted works, and should include any limitations on the Institution’s continued access and their use.

The parties need to determine whether there is background intellectual property to be used in the project. Such background intellectual property will need to be handled differently than foreground copyright works.

The SRA should be explicit about the use of third party software, including open source software, that might be derived, modified, or incorporated in software developed under the SRA. This information should include details regarding the license(s) to the third party rights.

Because open source software licenses vary widely in their terms and such terms of use could be onerous on the Sponsor (i.e.: post or make available to the public all developments under its use), the parties may need to agree that either no open source software will be included on the deliverables, or that it be properly identified on the SRA before the project starts.

If software is involved in the project, the SRA should address various limitations and prohibitions to provide clarity, including whether there is access to source code, whether reverse compiling is permitted, etc.

Title to the copyright of a work does not include title to the data described in the work; just the expression of that data. Data rights are considered under Contract Accord 4; Other Research Results.

OUTLIERS:

This Accord does not address:

• Copyrights derived from fee for service or work for hire arrangements.
• Copyrights developed under foreign (non-United States) law.
• Copyrights that may also be subject to patent rights.
• Compilations of data, such as a database, where the database may or may not be protectable.
• The scope or applicability of Fair Use22.
• Implications regarding terms that are common to the use of open source software.

FORMS OF “ANY TANGIBLE FORM OF FIXED EXPRESSION”

Covered

Literary Works: Books, Periodicals, Manuscripts, Phonorecords, Computer Programs, Film, Tapes, Discs

Musical and Dramatic Works: Musical Compositions (including lyrics), Stage Plays, Screenplays, Television, Plays, Pantomimes and Choreographs, Motion Pictures, and other Audiovisual


Sound Recordings: Music, Spoken Work, Sound Effects

21 Typically, researchers cannot obligate the Institution, or the Institution’s rights in intellectual property, including copyrights. See Contract Accord 0 (Preamble) for more information

22 http://www.copyright.gov/fus/ft102.html
Contract Accord 9: Confidential Disclosure Agreements

OVERVIEW
Industry and Academia diverge sharply with respect to their perspectives on disclosing and sharing information with individuals and organizations. Industry wishes to generate market value and be profitable; therefore, it needs to maintain the secrecy of certain information. Universities (and the researchers and students that pursue scholarly activities) create and disseminate knowledge; therefore the ability to publish and share information is critically important to a University’s academic research mission. The parties may hold differing views and interpretations of certain provisions of a confidential disclosure agreement (CDA). Thus the basic assumptions and practical implications regarding a confidentiality agreement should be discussed to ensure that all parties’ expectations, both short term and long term, are addressed. CDAs should not restrict publication but may allow a party to delete its own confidential information.

Not all interactions between Industry and university may require a CDA. However the contractual mechanisms by which Industry and Academia share confidential information are commonly referred to as a Confidential Disclosure Agreement (CDA), a Non-Disclosure Agreement (NDA), or a Proprietary Information Agreement (PIA). For the purposes of this contract accord, only the term CDA will be used.

INDUSTRY PERSPECTIVE
Industry seeks to keep information confidential to protect essential proprietary information and thereby ensure a competitive advantage in the marketplace for as long as possible or as needed. In order to maintain a competitive advantage, Industry often seeks technologies or expert advice available at Universities. Pursuit of these relationships may require Industry to disclose its proprietary information.

Industry faces a conundrum in that it must disclose its own confidential information in sufficient detail for University researchers to understand that information, while at the same time the confidential nature of the information must be preserved. Once the information is disclosed, Industry is at risk that its confidential information may be shared with others and its valued competitive advantage may be lost.

Thus Industry needs to ensure that certain core information will remain confidential for a sufficient length of time – perhaps indefinitely – in order to preserve the value of the information in the market place. An agreement ensuring confidentiality of proprietary information may be the only means available to Industry to protect that information in situations when it must be disclosed.

UNIVERSITY PERSPECTIVE
Universities have a culture of openness and shared knowledge, as their mission includes educating students and publishing research results for the public good. However, Universities may benefit from receiving confidential information from an Industry partner as well as by keeping their own discoveries in confidence for some period of time.
Universities typically avoid CDAs in which shared information must be maintained as confidential in perpetuity because of efforts and costs associated with ongoing monitoring and compliance or a lack of mechanisms to do so, and because they have no ability to control students after graduation or employees who leave the University.

Universities are experienced in maintaining the secrecy of certain types of information related to patients and students and are required to do so by law. They may also have the need to maintain confidentiality of other types of information, such as unpublished data or inventions not yet covered by a patent, as discussed above. A faculty member who is engaged in research may want to disclose his or her research results to Industry in hopes of having Industry sponsor all or a part of a research project or with the hope that Industry may license and commercialize a University-based invention.

A CDA allows Universities to manage the receipt or disclosure of confidential information. Each CDA should be tailored to match the requirements of a specific situation.

**PRINCIPLES**

CDAs enable the sharing of confidential information for the purpose of exploring potential interactions between two prospective partners while protecting the information from uncontrolled dissemination and possible subsequent disclosure. A CDA follows non-confidential interaction and typically precedes other agreements (e.g., sponsored research, membership, licensing). This means:

- Confidential information should not be exchanged unless and until a CDA has been executed, and it should always be limited to the scope of the CDA. Information shared outside of the scope is not protected.
- The CDA should define the scope and permitted uses of the information as well as duration and obligations of the parties. The scope of the CDA must be sufficiently narrow and clear to meet the purposes of the exchange of confidential information. If necessary, the scope should be updated as necessary to reflect any potential change in the interaction between the partners.
- Trade secret information, or other information that should be kept confidential in perpetuity, should never be disclosed.
- Confidentiality in perpetuity would be inconsistent with the University’s fundamental research exemption.
- No work or research that could result in invention and the creation of intellectual property should be performed under a CDA. Such work or research should only be performed under a separate, formal agreement.
- Discussions or brainstorming sessions that may lead to the creation of intellectual property (IP) should be avoided, but if such discussions are anticipated, then the CDA should include provisions for protecting such IP.
- Any exchange of confidential information under consulting arrangements involving individual faculty members are not covered by CDAs that have the University as a party.
- The agreement must be enforceable and meaningful. It is good practice to designate a Disclosure Coordinator for each party who is responsible to ensure proper procedure by and thus protection for the participants in a CDA.

- Termination terms may not be appropriate in a CDA: neither party should be able to terminate any of the obligations, and the disclosure period can be terminated at any time by either party refusing to talk or listen. In the event that termination terms are applicable, the parties need to insure that the confidentiality obligations survive throughout the Protection Period.

**COMMON CONSIDERATIONS IN CDAS**

**Purpose of the CDA.** In many jurisdictions the disclosure of information from one party to another without specifying and limiting the purposes for which the receiving party may use the information constitutes a license to use the information for whatever purpose the receiving party desires, even though the recipient must preserve the confidentiality of the information.

It is therefore generally recommended that the CDA specify the reason why the parties are exchanging information, the ways in which the receiving party may use the information, and clearly state that the receiving party may not use the information for any other purpose.

**Scope of Disclosure.** In many cases neither party intends to disclose all of its confidential information, nor does it wish to undertake obligations to ensure the confidential handling of more information than is necessary. Moreover, it is often impractical to compile an exhaustive list of the information to be shared that will be subject to the obligations of confidentiality.

Two useful techniques are (a) to specify the range of subject matter that the parties to the agreement anticipate being received and held in confidence and (b) to specify that information is only subject to the terms of the agreement if either (i) it is provided in writing suitably marked as confidential or (ii) if it is disclosed other than in writing, it is designated as confidential at the time of disclosure (some organizations do not require this), writing, marked as confidential, and delivered to the other party within a specified period of time, e.g., 30 days.

It is important to keep in mind that the Scope of Disclosure cannot limit what is disclosed, but only what is legally protected if disclosed. If a party chooses to share confidential information that is outside the Scope, then the receiving party legally has no obligation to protect that information and could use the information for any purpose. In the interest of preserving a positive collaborative relationship, the receiving party should therefore verify with the disclosing party whether the scope of the CDA should be changed to cover this information, or whether the information should be returned or destroyed.

**Duration of the Confidentiality Agreement and Confidentiality Period.** Generally, the duration of confidentiality is understood as the period of time information must be kept in confidence. However, two time periods are frequently involved in a confidentiality agreement.

One is the disclosure period, i.e., the period during which information subject to the obligation of confidentiality will be disclosed. The disclosure period begins on the effective date of the agreement and ends when the agreement expires.

The other is the protection period, i.e., the period of time information must be kept confidential. The
protection period usually begins with actual disclosure of confidential information and ends as specified in the agreement (typically 3-7 years).

The protection period should reflect the actual useful life of the confidential information. Industry may desire longer protection periods, at least long enough to evaluate and file for IP protection. In contrast, Universities typically prefer shorter time periods, primarily because they often do not have mechanisms in place to ensure campus-wide compliance with such an agreement and because they prefer to have a cut-off date after which they are free to use and publish any information related to the project.

Individuals Covered by the CDA. Confidential information should be provided to individuals on a “need to know” basis. Universities usually see the CDA as being specific to a particular researcher or project, e.g., evaluating specific information in contemplation of a collaborative research project or technology licensing opportunity. But since the disclosing party will expect all individuals who receive its confidential information to be covered by the obligations of confidentiality, care should be given as to who actually receives this information.

This is particularly true if involved who are not employees of the University or parties to the agreement. CDAs should require all individuals receiving confidential information to acknowledge and agree to be bound by the confidentiality obligations defined in a CDA, even if they are not University employees or parties to the CDA.

It is best practice to name the individuals who are authorized or present to receive information in the agreement and have them sign an acknowledgment that they have read and understood the CDA. Individuals who are not employees of the University can agree to be bound by the agreement on their own behalf. An addendum may be required to update both the scope (i.e. the definition of the confidential information) and the list of individuals who receive confidential information as necessary as the discussions or the project may progress.

The parties should consider a single point of contact for the exchange of confidential information, i.e., a Disclosure Coordinator responsible for each party, and they should refrain from exchanging confidential information directly with unauthorized individuals. This practice is very valuable in order to keep any disclosures clear in terms of maintaining adherence to the intended scope and ensuring proper follow-up documentation, storage etc. It is common to see behavior - from both Industry & University participants - that assumes that a CDA provides the protection when it really just provides the framework for the participants to ensure protection. In other words the important part is not getting a CDA signed but being disciplined in defining & reinforcing what is or is not confidential during any project-based interaction.

The parties may reserve the right to refuse acceptance of confidential information, for instance if they believe this could compromise their IP position or put them into an untenable situation with regards to export control.

Exceptions. Exceptions are typically made for the confidentiality obligations and for potential charge of liability in case of disclosure where the information was:

- Within the public domain prior to disclosure by the disclosing party to the receiving party or thereafter becomes part of the public domain other than as a result of breach of the CDA by the receiving party;
- In the possession of the receiving party on or before the date of disclosure, as evidenced by competent written records;
- Acquired by the receiving party from a third party not under an obligation of confidentiality, as evidenced by competent written records;
- Independently developed by the receiving party without reference to the confidential information of the disclosing party, as evidenced by competent written records;
- Disclosed pursuant to operation of the law or a legal process.

Export Control. Export control laws apply to everyone, including Universities. Confidential information transferred under a CDA is not covered by the fundamental research exclusion as defined in 22 CFR 120.11(8). Loss of this exclusion could require the University to obtain export licenses to allow certain foreign students or employees to receive confidential information. Failure to comply exposes the employees of the parties to personal criminal liability. See Contract Accord 7.

Copy Retention. CDAs often state that upon expiration of the term of the agreement, or at the disclosing party’s written request, the receiving party will either return all confidential information to the disclosing party or destroy all copies of the confidential information in their possession. The receiving party is generally allowed to retain one archival copy in its records, but in order to prevent unauthorized use of the confidential information, these copies are generally kept in offices other than those of the individuals who initially received the information (for example, the archival copy may be kept in the office of the receiving party’s legal counsel).23

23 The parties should bear in mind that universities frequently have obligations to maintain laboratory notebooks in order to verify the integrity of work performed and results published. For this reason it is good practice to avoid including confidential information obtained from another party in a laboratory notebook.
Trade Secrets. A trade secret is information that provides a key economic advantage to its owner and for which reasonable measures of secrecy are maintained, typically in perpetuity. The parties should avoid providing or accepting trade secret information under a CDA. Universities do not generally have mechanisms in place to implement extensive security provisions or keep information confidential indefinitely and have virtually no control over students after graduation or employees who leave the University.

Delegated Signature Authority. Industry employees generally understand that they are unable to sign documents that are legally binding upon their employers. University faculty members are not always cognizant that the documents they sign may purport to bind the University but that they personally lack the capacity to sign such agreements. Industry should consult with the University’s relevant office, e.g., office of sponsored programs or technology transfer, to determine who has the authority to sign a CDA on behalf of the University.

“Open Record Laws” and State Universities. State-supported Universities may be subject to a state’s “open record” or “public record” laws. These laws require a University to make information in its possession available under “freedom of information” requests filed by third parties. These requests can be used to compel a University to disclose information unless that information meets specific criteria set forth in the law. In such situations, it is good practice to indicate that the University has a duty to inform the company so that the company has an opportunity to request some form of protection from whatever body that is requesting the information.

Such laws override the obligations of confidentiality in CDA between the University and Industry even if the CDA does not specifically call out the applicability of the law (since contracts requiring parties to break a law are not enforceable,) so care must be taken in drafting CDA to ensure that they comport with those laws. In these situations the University should provide specific reference to any such laws that are applicable so that Industry can properly evaluate the risk of disclosure of its confidential information.

Controlling Law and Jurisdiction. Generally both parties to a CDA will be most knowledgeable about the laws of their home state and therefore prefer that agreements be governed by those laws. State Universities may be prevented from entering into agreements that are subject to the laws of other states or of foreign countries. Similar prohibitions may apply to agreements specifying or allowing jurisdiction in courts outside of the University’s home state. Many agreements do not specify the legal venue even if controlling law is specified.

It should be noted that jurisdiction and venue are most important to the parties in the event of a breach of a CDA but do not generally affect the terms or performance other than as noted above. The parties to a CDA may agree to remain silent as to controlling law or specify the laws of a neutral jurisdiction. Companies that do business nationally may be more willing to specify venue in a state other than their home state, while Universities are reluctant to be subject to the venue of a state in which they do not do business.

Arbitration or Mediation. In many cases arbitration or mediation may be more desirable than trying to assert a party’s rights through litigation in a dispute. Some universities are prohibited from participating in binding arbitration either because of policies, legislation or principles of state sovereignty. Also, some companies are averse to engaging in binding arbitration. In such cases it may be advisable to require representatives of each party to participate in non-binding mediation prior to initiating litigation. Many states court rules require mediation in cases meeting a certain monetary threshold.

Limitation of Liability. The disclosing party has valid concerns about the possible consequences of the recipient party violating its obligations under a CDA. To address these concerns, language in a CDA may seek to place financial obligations on the party violating the terms of that agreement. In some circumstances, particularly when dealing with a state University, the liability of one party may be controlled by statute limiting the liability of any state agency, including its Universities. Any such limitation of liability should be clearly stated in the CDA.

Injunctive Relief. Industry may wish to include language in a CDA to ensure adequate remedy for breach or threatened breach of the confidentiality obligations including the right to injunctive relief or specific performance, as is customary in the commercial environment. Such language may include wording to the effect that all parties agree that monetary damages would not be sufficient to remedy a breach.

Universities may find such wording unacceptable, as it may constitute a violation of principles of state sovereignty or be construed as an open door to additional litigation or contractual admission of fault. If this is the case, any such limitation by a state University should be brought to the attention of the prospective industry partner.

Industry should be aware that the inclusion of language specifying that the parties may seek injunctive relief - rather than language stating that the parties are entitled to injunctive relief - may be misleading because the actual ability of Industry to successfully obtain injunctive relief when dealing with a State University may not really exist.

ADDITIONAL CONSIDERATIONS
Inclusion of confidential information and potential embargo of Student Publications, particularly works that are required for obtaining a degree, are a particular concern as Universities have an obligation to ensure that they do not enter into agreements that prevent or impede students from graduating. Such work should never require the use of another party’s confidential information unless it is clear to everyone that the student will be able to complete publication of the work without violating a CDA.

24 Example: “Tort Claims Act”
Many Universities allow their researchers to enter into Consulting Agreements with industry. In these situations the researchers are allowed to work as private contractors rather than as employees of the University. The researchers have an obligation to ensure that they abide by the terms of any CDA into which they enter as private contractors and to realize that disclosure in the course of their academic work of the information gained under such agreements may be a violation of those agreements.

Control over Authorship on Scholarly Articles lies solely with the principal investigators rather than with the University. The content of a publication, at least to the extent that it contains any confidential information, may, however, be subject to the terms of the CDA between the University and the Company. The University would be expected to compel its employees to abide by the terms of the CDA.

In some cases it may be possible to provide a receiving party with protected or Trade-Secret information embedded in a Product or Service with a prohibition on reverse engineering of materials. The advantage of this arrangement is that it allows the receiving party to publish its research results in compliance with the terms of the CDA.

The parties should avoid language concerning Residual Information - i.e. information that is kept in non-written form in a person’s unaided memory - or at least carefully consider the use of a Residual term in a specific circumstance because of the inability to protect ambiguous or undefined information and control its later use. This pertains in particular to company confidential or trade secret information that another individual may learn as a result of a collaboration or a visit to the other party’s facilities. Residuals terms are typically contentious. If one side values and insists on them, the best advice for the other party is to very carefully consider the motivation for and the potentially very significant consequences of including such terms.

For both Industry and Universities, the disclosing party may want to avoid “Contamination” through Inadvertent Exposure to confidential information that it does not own or have rights to use. For example, a party disclosing a confidential new product may not wish to be informed about the receiving party’s ideas for improving that product for fear of “contaminating” the disclosing party’s own planned improvements for that product. Thus the parties should consider whether the situation warrants explicitly specifying certain types of information that, if possible, should not be disclosed in order to avoid such contamination, and whether a one-way or a two-way agreement may be more adequate for the situation.

**SUMMARY**

The goal of a CDA is to protect the information from uncontrolled dissemination. Confidential information provides its holder with a competitive advantage, be it academic or economic, that may be lost if the information is disclosed.

Procedures of working with industry and obligations on the part of academic researchers to keep information confidential are often unclear or non-existent in an academic environment. Industry may request specific safeguards which might be unusual in agreements between business entities. Such safeguards may include spelling out specific measures that need to be observed, for instance how confidential information is received and controlled and secured by the University and how the initial disclosure as well as any subsequent sharing of the information with others should be tracked to properly protect it.

The reputations of University researchers depend upon them being the first to publish significant findings from their work; therefore, it is important for University researchers to ensure that confidentiality agreements with Industry will not compromise their ability to be the first to publish, whether via a patent application or a peer-reviewed journal.

An incremental exchange of information is often a better way to proceed by allowing the parties to become familiar with each other's norms and potential incompatibilities while minimizing risks associated with sharing proprietary information. This approach may be prudent if the parties are not certain that they share similar perspectives on the identification, sharing and handling of sensitive information.
Contract Accord 10: Material Transfer Agreements

Material Transfer Agreements (MTAs) considered under this contract accord are contracts which govern the transfer of tangible materials from industry to academia for use in research – no company funding is provided, other than a nominal fee to reimburse the provider for its preparation and distribution costs. Relevant sections of the contract accord apply to Sponsored Research agreements when materials are also being provided. Tangible materials may include chemical compounds, living organisms, seeds, devices, and biological materials such as proteins, antibodies, cell lines and tissues etc., that are consumed in the course of the research. Since this contract accord deals with a type of contract rather than a specific contract issue or term, only those issues that bear specifically on MTAs will be addressed here, and principles dealt with in other contract accords will otherwise apply.

PRINCIPLES:

- In general, companies are under no obligation to share their proprietary materials with academic investigators. When they do so, however, they should recognize that any constraints they put on the use of the materials should be consistent with principles outlined in other contract accords.

- Publications by industry or academic scientists describing results which are dependent upon the use of the materials should be consistent with principles outlined in other contract accords, and/or on terms consistent with this Contract accord, so that the integrity of published research is maintained by allowing other scientists the opportunity to reproduce reported results.

- The university’s freedom to publish should not be compromised by use of a company’s material in the research. Terms in the MTA that limit disclosure of the material or associated company information to the extent that publication of the research would be precluded are not appropriate. (Contract Accord 3 describes the parameters under which publication may be delayed.) The parties should recognize that there may be cases in which the material is considered so valuable to the company that it cannot be provided for use in university research.

- The material to be transferred should be defined in terms that are significant and relevant to the research that is being conducted in the MTA, since terms allowing access to foreground IP (“FIP” see Contract Accord 6), and ownership of and accompanying rights to new materials created by the Recipient are often dependent upon the way the material is defined.

- A company’s concerns about compromising its competitive advantage may lead it to expect intellectual property rights similar to those for sponsored research (See Contract Accord 6), although the scope of these rights would typically be more narrow and related in a specific way to the material.

- It is reasonable for the university to accept liability for claims brought against the University based on the University’s actions while using the material, and for the company to accept liability for any damages caused by the company’s gross negligence.

- The allowed uses of the material should be defined in a scope of work, and a termination date specified, upon which the material and any Confidential Information provided by the company is either returned or destroyed.

- The university should ensure that funding agreements used to support the work do not contain obligations which conflict with the terms of the MTA.

- If the material is subject to export control regulations, the parties should agree to assist each other on complying with those regulations. The provider of the material must be prepared to provide the information necessary to enable the receiver to comply with US Export Control Regulations (See Contract Accord 7).

- Companies should be aware that University may not be able to effectively protect trade secrets, so companies should be wary of providing Materials that are protected by trade secrets.

COMMON EXPECTATIONS:

DEFINITION/CONTROL OF MATERIAL

Should be limited to the original material provided, unless provision of biological material requires inclusion of progeny25 and unmodified derivatives.26

Defining materials as inclusive of “derivatives” and “improvements” without further definition should be avoided due to the lack of precision of those terms.27

New materials created by the university which contain the original material should not be included within the definition of “Material,” because rights and obligations relating to those new materials will vary from those related to the original material.

The company should retain ownership and/or control of any of the original material contained in the new material and any properties of the new material which are derived from the original material.

FIP (FOREGROUND INTELLECTUAL PROPERTY)

In some cases the University may agree to grant a NERF (Non-Exclusive, Royalty-Free license) to IP that is dependent upon the material as defined. For example, IP could be that which “necessarily uses or incorporates the Material,” which is a “new use of, improvement to, or new formulation of the Material,” or IP that is needed for Company to “make, use, or sell the Material.”

Please refer to Contract Accord 6, Foreground Intellectual Property, for further foreground IP rights not dealt with herein.

25 Progeny as defined by the National Institutes of Health in the Universal Biological Material Transfer Agreement (the UBMTA) are unmodified descendants from the originally provided material, such as virus from virus, cell from cell, or organism from organism

26 Unmodified derivatives as defined by the National Institutes of Health in the UBMTA are substances created by recipient which constitute an unmodified functional subunit or an expression product of the originally provided material. Some examples include subclones of unmodified cell lines, purified or fractionated sub-sets of the originally provided material, proteins expressed by DNA/RNA supplied by provider, monoclonal antibodies secreted by a hybridoma cell line, sub-sets of the originally provided material such as novel plasmids or vectors.

27 See a discussion of the use in of these terms in material transfer agreements in “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Dissemination Biomedical Research Resources, Federal Register Vol. 64, No. 246, p. 72090.”
USE OF MATERIAL OUTSIDE THE SCOPE

In some cases, when proprietary materials are of high value and in active development, a university’s work outside the scope of the MTA can damage or destroy the commercial value. Additional provisions may be discussed to mitigate these concerns.

OUTLIERS:

These situations are not addressed by this Contract Accord:

- Software – Transfer of software is covered in Contract Accord 8, Copyrights & Software
- Data – Transfer of data is covered in Contract Accord 9, Confidential Disclosure Agreements
- Clinical trials – Material provided for use in a clinical trial will be covered in Contract Accord 14, Clinical Trials
- Gifts of material – Material provided as a gift will be covered in Contract Accord 15, Gifts
- Loaned equipment – equipment that is provided with the expectation that it be returned at the termination of the contract will be covered in Contract Accord 16, Loaned Equipment
Contract Accords
For University Industry Sponsored Agreements