Working with Industry and Intellectual Property



Kevin Stewart Associate Director, Industry Contracts

Cara Winnewisser Industry Contracts Officer

Jenna Nakano MTA/NDA Officer

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General 2023/2024 STAR Program Information

- STAR Certificate consists of 11 courses. To obtain a certificate, you must complete all 11 courses within two (2) years.
- For any STAR Program questions: contact Betsy Lazarine and/or Clarissa Cabrera at training@research.ucsb.edu
- Reminder to complete the STAR Evaluation. Emailed to registered participants via e-mail used in UCLC.

Why do we work with Industry?



Benefits of Industry/University Collaboration

- Provide faculty with "cutting edge" experience with "real world" problems to enhance their teaching and research
- Help students gain valuable educational opportunities and gain marketability
- Develop ties to provide future funding to support new or ongoing research in areas useful to society.

Benefits of Industry/University Collaboration

- Facilitate informal technology transfer
- Offer research opportunities through which faculty can make contributions to knowledge.
- Assist in fulfilling the university's mission for public service.

The University/Industry Challenge:

Industry

- Closed environment
- Hierarchical
- Swift moving
- Results-oriented
- Primary responsibility is to company bottom line

University

- Open environment
- Non-hierarchical
- Slow to change
- Process and general knowledge oriented
- Primary responsibility is to the public

Ways UCSB Works with Industry

What we'll talk about today. . .

Part 1

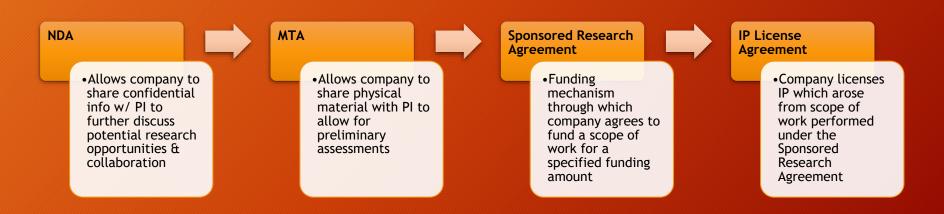
- Gifts and Endowments
- Research Agreements
- Material Transfer Agreements
- Non-disclosure/Confidentiality Agreements
- Data Use Agreements

Part 2

- Technology Transfer
 (Intellectual Property Licensing)
- Faculty Consulting Agreements

Ways UCSB Works with Industry

Outline of a potential relationship with a single industry sponsor



Ways UCSB Works with Industry

Other ways...

- Use of certain facilities on a fee-for-service basis (e.g. UCSB "cleanroom" facilities)
- University-Industry exchange programs and student internships
- Participation of industry representatives on campus and university-wide advisory groups

Before We Begin:

• The common principle that guides all industry interactions, regardless of type:

".. first consideration must be given to the University's mission of teaching, research, and public service. In pursuing relationships with industry, the University must keep the public trust and maintain institutional independence and integrity to permit faculty and students to pursue learning and research freely."

From UC Guidelines on University-Industry Relations (May 1989)

Gifts and Endowments



Gifts

- What they are: in general, research funds are classified as gifts when:
 - The donor does not impose contractual requirements in connection with the acceptance or use of the funds.
 - The funds are awarded irrevocably.
- May be in the form of funding, equipment, or other in-kind benefits.
- Indirect (F&A) costs are not assessed on gift funds.
- May be given as entirely unrestricted, or may be as specific as for use by particular research group for particular purpose.

Gifts: Benefits to Industry & UC

- Provides general support use of the money is not restricted to a specific scope of work.
- Provides mechanism to assure UCSB's research base in a specific area remains strong.
- Allows industry to build strong, close relationships with UCSB faculty.
- Through gifts which fund graduate students, industry can help create high quality future workforce.

Gifts From Industry: Challenges

- The Conflict of Interest (700U) review process does apply to gifts from industry.
- Donors are increasingly sophisticated.
 - Transactions start as "no strings" donations, strict contractual obligations creep in over time.
 - Requests for intellectual property rights in exchange. (It is against policy to honor this request.)
 - Unclear whether it is a gift? See:
 - "Gifts, Grants, Contracts and Sponsorship Determinations" at www.policy.ucsb.edu (also included as handout for this presentation)

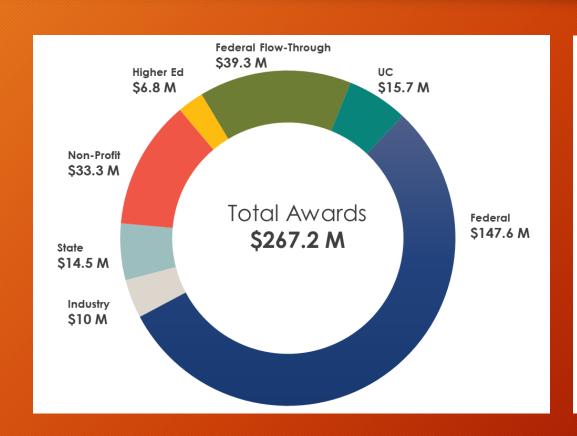
Industry Sponsored Research Agreements



Industry Research Agreements

 What they are: A written agreement between UCSB and an industry sponsor in which UCSB agrees to conduct a specific research project, over a defined period of time, in exchange for compensation, subject to mutually-agreeable contractual terms.

UCSB Industry Sponsored Research for FY2024



Note*:

UCSB TIA-administered sponsored research agreements include:

- + direct industry
- + all industry "flow-through"
- + a few others

FY24: \$18.8M

Types of Research Agreements with Industry

- Grants
 - Assistance funding provided to support research.
- Cost-reimbursement Contracts
 - Expenditures on project are reimbursed as incurred.
- Fixed-Price Contracts
 - Defined deliverables are produced by the University and the sponsor pays a pre-set amount for each deliverable/scope of work.

Note: Contract type is separate issue from payment terms (advance payments vs. reimbursements vs. milestone payments).

Essential Items addressed in Industry Research Agreements

- Intellectual Property Rights
 - Definition of IP, Ownership of IP, License Rights to IP
- Publication Rights
- Payment Terms
- Rights of Termination by either party
- Statement of Work/Deliverables

Research Agreements with Industry: Benefits

- Funds projects that Federal Agencies may not fund.
- More rapid proposal review funding decisions are made more quickly.
- Administrative burden for Principal Investigator and Department is minimal (usually).
 - Statement of Work and Detailed Budget are typically all that is needed for negotiation.
 - Budget restrictions that apply to many federallyfunded projects are usually not incorporated.

Research Agreements with Industry: Challenges

- Length of negotiations can vary (very) greatly.
- Strict contract provisions
 - based on private sector business/procurement practices (B2B transactions)
 - Terms need to be revised significantly in order to fit a contractual relationship with a university
 - Ex.: Purchase Order Terms & Conditions
 - designed to protect private sector interests
 - Unreasonable confidentiality provisions
 - Stringent documentation requirements
 - Anti-competition clauses
- Potential for negotiation impasse
 - May not be able to align interests or arrive at agreeable terms!

Challenges Specific to Federal Flow-through Industry Contracts

- T&Cs that the Federal agency gave to company are flowed down (unaltered) to university subcontractor (FAR clauses)
- Company's own commercial procurement T&Cs are layered over Federal T&Cs
 - Potentially "the worst of the worst" for a university contractor.

International Challenges

- Different Business Processes/Forms
- Payment Currency and/or Tax Considerations
- Language
- Culture



Other Agreements

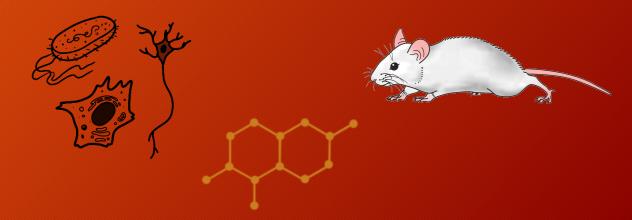
- Types of TIA-administered Other (Unfunded) Agreements:
 - Material Transfer Agreements (MTAs)
 - w/ all entity types
 - Non-Disclosure/Confidentiality Agreements (NDAs/CDAs)
 - w/ all entity types
 - Data Use Agreements/Data Transfer & Use Agreements (DUAs/DTUAs)
 - w/ all entity types
 - Other
 - Research-related MOUs (with industry), Software License Agreements (from all entity types), IP Agreements (for STTR Programs), etc.

UCSB TIA-Administered Other Agreements for FY2024

- FY 2024 Other Agreement Numbers
 - 147 Incoming MTAs
 - 50 Outgoing MTAs
 - 59 NDAs
 - 31 DUAs

Material Transfer Agreements





What are Material Transfer Agreements (MTAs)?

 A binding contract in which one party (the provider) agrees to provide physical materials (e.g. plasmids, cell lines, compounds) to another party (the recipient) for testing, evaluation, experimentation, or other research purposes

Key Parts of an MTA:

- Liability and intellectual property (IP) clauses
 - Both used to protect the Provider
- Scope of use for the materials
 - Sets parameters and conditions on who can use the materials and for which projects
 - How long the materials can be used

Types of MTAs:

Incoming MTAs:

- Provider is sending material to UCSB researcher(s)
- Provider typically issues the MTA to UCSB

Outgoing MTAs:

- UCSB is sending material to an external party (e.g. company, another educational institution)
- UCSB issues MTA to receiving party

How do you get an MTA in place?

- Researcher needs to complete the MTA Request Form (found on the TIA website under "Forms & Policies") and submit it to the TIA Industry Contracts group at mta@tia.ucsb.edu
 - Also include any related documents, such as the draft MTA from the provider (if incoming)
- Once intake process is complete, MTA will be assigned for full review and MTA/NDA Officer will reach out to the provider/recipient to address any problematic terms

MTA Request Form

| | | Section 1. Prin | cipal Inve | | _ | | | rmation | | | | |
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| PI Name | | | Lab Contact Name (if different) UCSB Department & Mail Code | | | | | | | | | |
| Pl Phone | PI E-mai | 1 | | UCSB Dep | partn | nent & 1 | Mail Code | | | | | |
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| | | rial (complete this | | | • | _ | Providing 1 | | | | | |
| Material is: Plasmid or (check all that apply) Viral Vector | | | ■ Embryonic Stem Cell or Indu Pluripotent Stem Cell (iPSC) | | | | ompound/ Chemical | Cell Human Line Specimen | | | Animal/Animal Specimen | |
| Scientific Description of Quantity to transfer/rec | | nd | | | | | , | | | | | |
| Will the Material be con | | ces, or sent to entit | ties, outsid | e of the US | 5? | ☐ Yes | (specify coun | try (-ies)): | | | | No |
| Anticipated Time Period Material Will Be Used By UCSB/C | | | Outside Organization | | | | Begin Date | | | End Date | | |
| Are you receiving any funds (contract, grant, or gift) from the | | | | the Outside Organizati | | | n? Yes | | | | □ No | |
| Section | 4. Questions | for Incoming Ma | terial | | | | Section | 5. Questio | ons for Ou | rtgoing M | aterial | |
| Intended Use of the Material/Scope of Work for Project using the Material: | | | | | | Do you want to charge a fee for the transfer of the Material? | | | | | □ No | |
| Funding source(s) to be used for research with Material (specify Sponsor(s) and award number(s)): | | | | | | Did you receive the Material from others, and this is a re-transfer of the same Material? | | | | and | Yes Yes | □ No |
| Do you intend to modify the Material in any way? | | | Yes No | | | Does the Material <u>otherwise</u> contain materials received from others? | | | | rials | Yes | □ No |
| Does the Material contain biological matter? | | | Yes | □ No | 1 | (For biological materials) is the Material: | | | | | | |
| Do you expect to pay any costs associated with the transfer of the Material? | | | ☐ Yes | No | derived from materials received from others? a modification of material rec'd from others? | | | | | | Yes Yes | □ No |
| Will the Material be used in humans, or will its use otherwise constitute human subjects research? | | | Yes | | | | you published on the Materials and/or the ad methodology? | | | | Yes | □ No |
| If yes, please indicate the status of the IRB protocol: | ☐ IRB proto | - | | | Does the Material relate to any patentable invention disclosed, or about to be disclosed, to the UCSB TIA Office? | | | | | Yes | □ No | |
| Was a decision to undertake this research based on receiving access to the Material by the Outside Organization? | | | | □ No | □ No If yes, please list the UC Case Number (if k | | | | | known). | | |
| Does a financial relationship exist between the Principal Investigator and the Outside Organization (if not a Federal agency)? | | | ☐ Yes | No | No Was the Material developed with any S Research Funding? | | | | th any Spo | nsored | ☐ Yes | □ No |
| Are you aware of any co agreements/requiremen | | ne Material? | ☐ Yes | No | | | please specify or(s) and awa | | : | | | |
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Instances when MTAs are <u>NOT</u> needed

- See Research Circular E.1. Section III for details (copy included with presentation handouts)
- Transfer of material to a nonprofit research organization for that organization's internal research use, provided that:
 - Prior to transfer of any animal materials, or materials that could be used in humans, researcher sending materials expressly tells recipient, in writing, the materials cannot be used in humans or further distributed.

Instances when MTAs are **NOT** needed (cont'd):

- Transfer of unmodified, naturally-occurring, non-hazardous materials that do not contain any human/animal tissue (e.g. a rock).
- Material sent to another non-profit for personal use by a UCSB researcher (e.g. sending ahead where faculty is going on sabbatical)
- Commercially available materials
- Transfer of purchased equipment/instrumentation for repair or replacement
- Transfer of documents

Exceptions to when "no MTAs are needed"

- Remember even if an MTA is not needed, U.S. export control laws still apply and there may be restrictions on the transfer of certain materials
 - Do not send materials outside the U.S. without first checking with the Export Control Officer in Office of Research's Research Integrity group
- Outgoing MTAs are strongly encouraged, regardless of the "no MTA" policy, if the material relates to a patentable invention that has been disclosed by a researcher to the Office of Technology & Industry Alliances.

A few other things to consider about Incoming MTAs

- Incoming MTAs can have complex terms that rival industry contracts
- The provider may ask for terms that can directly injure UCSB research activities:
 - Publication restrictions
 - IP ownership
 - Free commercial use of discoveries
- If these types of issues are present in the MTA, they may affect the timeline to get the agreement in place or result in an impasse

A few other things to consider about Incoming MTAs (cont'd)

- Other compliance approvals that may relate to MTAs:
 - Human Subjects
 - Animal Subjects
 - Stem Cell Research Oversight Committee
 - Environmental Health & Safety Biological Use Authorization
 - Conflict of Interest
 - Export Control

Things to remember with MTAs

- Researchers should not receive materials on campus until an MTA is legally in place
- PIs are not authorized to sign MTAs (i.e. researchers cannot legally bind the University to the MTA terms), only TIA authorized official can sign MTAs
 - If a researcher does sign, they are subjecting themselves to personal liability
- If a PI fails to get an MTA in place prior to using the material, this could jeopardize their research, ability to publish, and risk forfeiture of IP rights associated with the material
- Keep an eye out for the mention of materials in project proposals

Non-Disclosure/ Confidentiality Agreements







What are Non-Disclosure or Confidentiality Agreements (NDAs/CDAs)?

- A legal agreement establishing that a receiving party will not disclose proprietary information shared by a disclosing party (may be unilateral or mutual)
- For UCSB's purposes, we primarily use NDAs for two (2) scenarios:
 - 1. A company wishes to review a patent application in order to determine if it wishes to license technology
 - 2. A company wants to discuss a potential research collaboration with a researcher but before having the discussions, the company wants to make sure its confidential or proprietary information will be sufficiently protected

How do you get NDAs/CDAs in place?

- PI needs to complete the NDA/Other Agreement Request Form (found under the "Forms & Policies" section of TIA website) and send it to the TIA Industry Contracts group at mta@tia.ucsb.edu
 - Similar to MTAs, provide any additional documentation like the draft NDA
- Once the intake process is complete, MTA/NDA
 Officer will review form and the NDA and work with
 the researcher and other party to reach agreeable
 terms

NDA/Other Agreement Request Form

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| Purpose of Agreement | , | , | | | | | | | |
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| Does the Agreement relate to Sporepored Research? | o a proposal for | E 1 | Yes (list (| ORBITE | lacon | d No. if known | ŧ | □ No | |
| Will you either receive or pro | vide any physical material | s or semple | × 1 | ITI Yan I | nlan | a describe): | | | □ No |
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Key concerns for NDAs/CDAs

- Clear marking requirements for confidential information
- Narrow, limited scope/purpose of NDA (specific researchers, no students, confidentiality terms don't apply to UCSB-generated data and results
- Export control (e.g. Technology Control Plan)
- Ability to publish
- Ability to follow safeguarding and storage requirements (e.g. data security)

A few reminders for NDAs/CDAs

- For any NDAs related to University research, PIs are not authorized to sign these agreements
- Time frame for negotiations varies, depends on terms and if additional approvals are needed (e.g. export control)

Data Use Agreements







What are Data Use Agreements (DUAs)?

- A binding contract between parties to define how data and/or data sets provided by one party (the "Provider") can be used by the other party (the "Recipient").
- A DUA can have terms that are important to review carefully including, but not limited to,
 - limitations on who can access the data,
 - whether and how the data can be published in academic writing, and/or
 - how the data must be physically secured and/or accessed.
- If the terms of a DUA are problematic, the Office of Technology & Industry Alliances will reach out to the provider to try to negotiate revised terms.

Types of DUAs:

- Incoming DUAs
 - The provider (whether a company, a nonprofit, governmental agency) is sharing data/data sets with a UCSB researcher
 - Provider typically drafts and issues DUA to UCSB
- Outgoing DUAs
 - UCSB is sharing data/data sets with others (e.g. company, another educational institution)
 - UCSB will draft and issue DUA to receiving party

Types of Data Shared in DUAs

- Confidential/sensitive information
- Often, needs human subjects review/approval, for access to:
 - De-identified Data
 - Human Subjects Data where all 18 of the personal identifiers specified by HIPAA have been removed.
 - Limited Data Set
 - Human Subjects Data where certain identifiers have been removed
 - Protected Health Information/Personally Identifiable Information
 - Note: recommended that researchers should determine whether PHI/PII is actually necessary for the research project. Often, either a limited data set or completely de-identified data can be effective in the proposed research project, where the extra obligations and responsibilities associated with accepting PHI may not be necessary.

Key Considerations for DUAs

- Legal terms similar to MTAs, NDAs, and SRAs
- Special data security provisions and/or human subjects protection requirements that may require coordination with different campus departments and units including:
 - Research Integrity (Office of Research)
 - The researchers' respective departmental IT groups
 - Information Technology Services (ITS), which may include use of Secure Computing Research Environment (SCRE).
- For DUAs from some governmental and state agencies, may signature of the UCSB Chief Information Security Officer (CISO) and the Senior Official (SO)
 - All DUAs that require security signoff must follow the process implemented by the UCSB Information Technology Services group.

Key Considerations for DUAs

- For transfers of data/data sets <u>from</u> UCSB researchers <u>to</u> another party (Outgoing Data):
 - An Outgoing DUA must be put in place for any data is transferred if
 - Any of the data is from human subjects; and/or
 - The data to be transferred is HIPAA protected.

Note: If the data to be shared is completely de-identified and there is no means to re-identify, a DUA is not needed. To meet this qualification the data must be stripped of the data elements cited above in personally identifiable information. If the data contains any of these identifiers then a DUA must be in place. DUAs must also be in place if sponsored funding was involved and there are data ownership and/or dissemination requirements.

How do you get a DUA in place?

- Researcher needs to complete the DUA Request Form (found on the TIA website under "Forms & Policies") and submit it to the TIA Industry Contracts group (via e-mail to mta@tia.ucsb.edu)
 - Also include any related documents, such as the draft DUA sent by the provider, if for incoming data/data sets
- Once initial intake process is complete, TIA will review form and DUA terms and reach out to the provider/recipient to address any issues

DUA Request Form

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Questions?

TIA Industry Contracts Contact Information

Kevin Stewart

Associate Director, Industry Contracts

893-5197

stewart@tia.ucsb.edu

Cara Winnewisser

Industry Contracts Officer

893-2396

winnewisser@tia.ucsb.edu

Jenna Nakano

MTA/NDA Officer

893-2367

nakano@tia.ucsb.edu

Technology Transfer

But first. . . .

What is Intellectual Property?

Intellectual Property

- General Principles:
 - Intangible Piece of Property
 - May sell, license, assign, inherit, use as collateral
 - License v. Assignment
 - Exclusive v. Non-exclusive v. field of use

Types of Intellectual Property

- Patents
- Copyrights
- Trademarks
- Trade Secrets

Patents

- What do they cover?
 - useful processes, machines, manufactured items or compositions of matter
- What, exactly, are they?
 - A grant by the Federal Government of the right to <u>EXCLUDE</u> others from practicing an invention
- How long do they last?
 - Twenty years from the date they are filed.

Who Owns The Patent, UC or the PI?

- All UC employees, including faculty, sign a Patent Acknowledgement agreeing to assign title to all patents to UC.
 - It is critical that ALL visiting researchers sign patent acknowledgments to prevent future disputes.
 - Exceptions rarely granted, and must be vetted through the UCSB TIA Office for approval.

UC Patent Policy

Applies to:

- All Employees (including faculty and staff)
- Individuals using University research facilities
- Individuals receiving gift, grant, or contract funds through the University

Does NOT apply to:

- Students with respect to academic course work
 - Does apply if they are also employees (GSR, TA, etc.) or work on extramurally sponsored research

UC Patent/IP Acknowledgement (as of July 1, 2024)

- Mandatory disclosure
- Agreement to assign inventions and patents to the University, except those resulting from permissible consulting activities without use of University facilities
- University agrees to share royalties, if any, with inventor(s).
- Exceptions to policy require approval, <u>rarely</u> granted.

More on Patents & the UC

• So, why all the fuss?

- Intellectual Property <u>can</u> be extremely valuable
- Top 5 Income-Earning UC Patents (FY23)

| Nephropathic Cystinosis Treatment (UCSD) | \$12.8M |
|------------------------------------------------------------------------|---------|
| Strawberry Varietals (UCD) | \$8.9M |
| Mandarin Varietals (UCR) | \$6.9M |
| Macromolecules for Drug/Diagnostic Delivery (UCSD) | \$4.9M |
| Pistachio Varietals (UCD) | \$3.1M |

- HOWEVER, most do not make money. UC has 13,000+ active patents (domestic & international).
- In FY23, the top 5 earned 26.7% of all income; the top 25 earned 42.1% of all income.
- That said, UC Inventor(s) receive: 35% of net income (after patent costs) and companies prefer NOT to pay royalties, so if IP hits big, there is a lot at stake

But if there's not a lot of money, what's the big deal?

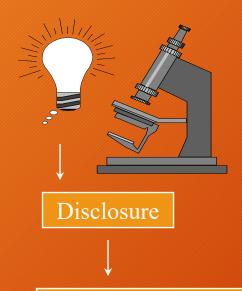
- UC also wants title, for several reasons:
 - Assure it can transfer technology freely, for the public benefit;
 - Assure it's research in that area continues unfettered;
 - Assure return on years of investment by taxpayers through licensing revenue
 - AND. . .our researchers developed it, our taxpayers helped subsidize it!

UC Patent Policy for Research Agreements

- It is UC policy to retain title to all patentable inventions.
- The industry partner may receive the following:
 - If it pays all costs, including academic year salaries, it may have a time-limited option to negotiate an exclusive or nonexclusive license.

The Patent Licensing Process:

What happens when researchers invent something?



Preliminary Evaluation

Patentability Assessment/ Commercial Potential

Sponsor Commitments
Tangible Research Products
Invention Overlap

Obtain Patent(s)

Identify and
Contact Potential
Licensees

Inventor Leads Professional Contacts Mass Marketing

> Secrecy Agreements

License or Option

Grant
License Issue Fee
Prosecution
Reimbursement
Minimum Royalties
Earned Royalties
Diligence
Reporting
Problem Resolution





Other Intellectual Property

- Trademarks ® ™
- Trade secrets
- Copyrights ©

Trademarks

- Nike swoosh ™
- Coca Cola® shaped bottle
- UCSB waves

"A trademark is a distinctive mark of authenticity through which the products of particular manufacturers may be distinguished from those of others."

Trade secrets

- Coca Cola formula
- KFC secret recipe
- A 'trade secret' means information, including a formula, pattern, compilation, program, data, device, method, technique, or process, that:
 - 1. Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
 - 2. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

Copyrights

- Protects distinct categories of works
- Protection granted as soon as the work is expressed in a tangible medium
- Lifetime of the author + 70 years
- Works created in 1928 or earlier, and works created by federal government employees, are in the Public Domain

Faculty Consulting

Faculty Consulting Agreements

- Private legal contract between faculty member and a company (University not a party)
- May not use University facilities
- May not interfere with University responsibilities
- May not use "University" time, i.e., may only consult 39 days a year (incl. weekends and holidays) (APM 025)
- Must disclose through Academic Personnel's annual disclosure (managed at department level)

Issues Which Arise

- Faculty member required to assign inventions made while consulting to the company.
- Patent Policy says "assign inventions and patents to the University, except for those resulting from permissible consulting activities without use of University facilities.."
- Due to conflict of interest rules, accepting large consulting agreements can affect the researcher's ability to accept research funds from that company for on-campus research.

Faculty Consulting: Resources

• "Guidelines on Faculty Consulting and Intellectual Property Policies" drafted by the UC Office of the President and located in the policy section of TIA's website (https://tia.ucsb.edu/forms-policies/) is an excellent compendium of the various policies that apply to faculty consulting.

IP Questions?

Contact UCSB Office of Technology & Industry Alliances

Claire Driscoll

Director

driscoll@tia.ucsb.edu

805-893-5180

Kevin Stewart

Associate Director, Industry Contracts

stewart@tia.ucsb.ed

805-893-5197