Webinar: Protect your rights with Research Agreements at ODU

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AGENDA

I. Confidential Disclosure Agreement
II. Material Transfer Agreement
III. Cooperative Research and Development Agreement
IV. Volunteer or Visiting Scholar Agreement
V. Resources (Demo of ODU's new Agreements website)

CONFIDENTIAL DISCLOSURE AGREEMENT (CDA)

- Purpose: Transfer of confidential information from one party to another.
- Can be a one-way transfer (→ or ←) or two-way exchange (↔) of confidential information between the parties.
- Entered into by various parties (corporations, universities, startups, government agencies, military, hospitals, and individuals).
- In which contexts do you need CDAs?
  - collaborations to apply for federal and/or state grants
  - consulting relationships
  - discussions related to licensing/commercialization
  - discussions related to purchasing certain equipment and services

CONFIDENTIAL DISCLOSURE AGREEMENT - WHAT IS CONFIDENTIAL?

- Samples, materials, data, drawings, sketches of a secret or proprietary nature concerning a particular project or collaboration.
- Other information (oral and written) of a secret or proprietary nature concerning a particular project or collaboration
- Information, if in tangible form, that is marked "CONFIDENTIAL"
- Information that is confidential should be identified (or summarized) as confidential by the discloser at the time of disclosure.

WHAT CAN YOU DO WITH CONFIDENTIAL INFORMATION?

Permits you to use the other party's Confidential Information for the **purpose** expressly described in the Confidentiality Agreement.

WHAT CAN'T YOU DO WITH CONFIDENTIAL INFORMATION RECEIVED?

- Do not disclose, directly or through others.
- Do not copyright.
- Do not publish.
- Do not present at a conference or seminar.
- Do not use confidential information for any purpose other than stated in the Confidential Disclosure Agreement

What is the standard for preventing disclosure of confidential information?

Must use **all reasonable diligence** to prevent disclosure of confidential information to any third party.

Exception: **Employees or agents** of the receiving party with a **need to know** who have **agreed in writing** to the terms and conditions of the agreement **prior to obtaining access** to the confidential information.

When can Confidential Information be disclosed?

- If explicitly approved for release by written authorization of the disclosing party;
- If already in the receiving party's possession on a non-confidential basis prior to receipt from the disclosing party;
- If properly obtained by the receiving party from a third party not under a confidentiality obligation to the disclosing party;
- Is independently developed or discovered, without any use of the Disclosing Party's Confidential Information.
- If otherwise required by law (e.g. Freedom of Information Act) or court order to be disclosed.

WHEN DOES THE AGREEMENT END?
(TRICK QUESTION – READ THE FINE PRINT)

- Each agreement specifies when the exchange of confidential information terminates (often after one year)

  - unless terminated earlier by either party for any reason by providing written notice to either party

- However, a separate provision of the Agreement will often extend the receiving party's obligations to maintain confidentiality from the receipt of Confidential Information for a specified period (e.g. 1 to 5 years).

WHAT SPECIAL OWNERSHIP RIGHTS DO I GET WITH ACCESS TO OTHER PARTY'S CONFIDENTIAL INFORMATION?

Answer: **No** transfer of ownership, license, express or implied, in the disclosing party's Confidential Information or derivatives thereof.

WHAT IF I HAD A PRIOR ARRANGEMENT WITH MY COLLABORATOR ON SHARING INFORMATION?

Doesn't matter→ This Agreement supersedes all prior written and oral communications and agreements on sharing information between the parties.

EXPORT-CONTROLLED SENSITIVE INFORMATION

U.S. government controls exports of sensitive equipment, materials, software and technology to promote national security interests and foreign policy objectives.

**For our confidential disclosure agreement, prior to disclosing any International Traffic in Arms Regulations (ITAR) or "Export Control" sensitive material, disclosing party must get the written approval of the receiving party.

Federal Agency	Regulation/Statute	Controls what?	Penalties
Department of Commerce	EAR – Export Administration Regulation; IEEPA – International Emergency Economic Powers Act	Technology with commercial, research and/or potential military applications. Commerce Control List: https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl	Criminal penalties up to $1,000,000 and/or 20 years imprisonment per violation. Civil penalty: max - $295,141 per violation or twice the amount of the underlying transaction
Department of State	Arms Export Control Act (AECA); International Traffic in Arms Regulations (ITAR)	Military technology and services. U.S. Munitions List: https://www.ecfr.gov/cgi-bin/text-idx?SID=86008bdffd1fb2e79cc5df41a180750a&node=22:1.0.1.13.58&rgn=div5	Criminal penalties up to $1,000,000 and/or 20 years imprisonment per violation. Civil penalty: max - $1,134,602 per violation

Note: For export control compliance assistance at ODU, please contact Adam Rubenstein of Office of Research via email at: ARubenst@odu.edu or phone: x33686

OVERLAP BETWEEN CONFIDENTIAL DISCLOSURE AGREEMENTS (CDA) AND SPONSORED RESEARCH AGREEMENTS (SRA)

- There is a risk of conflict of terms (e.g. publication rights, confidentiality procedures and periods, etc.) between CDAs and SRAs or industrial collaborations that cover the same subject matter.

CONFIDENTIAL DISCLOSURE AGREEMENT (WITH PARTY A) AND SPONSORED RESEARCH AGREEMENT (WITH PARTY B)

- Confidential Disclosure Agreement – Confidential information is to be used only for the stated purpose (e.g. research on a particular project) in the CDA. Reasonable diligence to prevent disclosure for stated term (one to five years) unless prior written consent is obtained from the furnishing party.
- Sponsored Research Agreement (standard) – For three years, parties will disclose Proprietary Information only to its employees or agents for research purposes only and not disclose to anyone else unless prior written consent is obtained from furnishing party.
- If conflict is discovered, please notify Monti Dutta ASAP at: ADUTTA@ODU.EDU at X34027

Beware of your Collaborator inserting problematic clauses in Agreements

Problematic clauses in which collaborator is trying to get ODU to surrender rights that are <u>given to ODU by the federal government or state government</u>

- Financial terms in CDAs, MTAs and CRADAs are not allowed by ODU.
- Intellectual property terms in CDAs and MTAs are not allowed by ODU.
- Pre-negotiation of business terms in CDAs, MTAs and CRADAs are not allowed by ODU.
- Agreeing to indemnification and payment of attorney fees by university is forbidden.
- Agreeing to jurisdiction under the laws of another state.
- Declaring joint inventions before work is completed (forfeiting rights under Federal patent law).
- Requiring collaborator to be included as a coauthor (violates Code of Authorship)

RISK: Surrendering ODU's rights in agreements will expose you and ODU to auditors and liability for violations.

MATERIAL TRANSFER AGREEMENT (MTA)

Purpose: Agreement governs transfer of biological materials (including human tissues and specimens, genetically modified organisms), chemicals or other materials between parties for research purposes with legal protections for the transferor.

What is the first step before you can initiate an MTA?

- If human subject research is federally supported, there must be a protocol approved by the Institutional Review Board (College Committee if non-federally supported) before an MTA can be executed.
- If research using recombinant-DNA, Biohazards and Bloodborne Pathogens, there must be a protocol approved by the Institutional Biosafety Committee before an MTA can be executed.
- If animal research is involved, there must be a protocol approved by the Institutional Animal Care and Use Committee (IACUC) before an MTA can be executed.

Nexus between Research Protocol reviews and MTAs

- Certain material are part of research protocols that are subject to prior approval by university review committees (e.g. Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Institutional Review Board or Radiation Safety Committee).
- Only after the material has been approved by the appropriate university review committee/board, if applicable, can the MTA be initiated and executed.
- The MTA must either specify or define the material within the body of the MTA or in a signed exhibit that is part of the MTA. Future additions to the approved material list will require a signature by the Vice President of Research.

What is covered “material”?

Material Transfer Agreement clearly specifies and defines the material.

Note: If a vendor supplying the materials does not request an MTA, then ODU does not request an MTA. The specification of material is typically required in an MTA if the vendor requires an MTA.

For biological materials – typically includes:

- original material
- progeny - descendent from the material – e.g. virus from cell, cell from cell, or organism from organism.
- unmodified derivatives - substances created by the recipient which constitute an unmodified functional subunit or product expressed by the Original Material (e.g. subclones of unmodified cell lines, proteins expressed by DNA/RNA supplied by the provider, monoclonal antibodies secreted by a hybridoma cell line)
- Excludes modifications to the original material.

WHO RETAINS OWNERSHIP OF THE MATERIAL?

SUBJECT TO NEGOTIATION

- PROVIDER RETAINS OWNERSHIP OF THE MATERIAL, INCLUDING ANY MATERIAL CONTAINED OR INCORPORATED IN MODIFICATIONS.
- RECIPIENT RETAINS OWNERSHIP OF:

  MODIFICATIONS (EXCEPT THAT, THE PROVIDER RETAINS OWNERSHIP RIGHTS TO THE MATERIAL INCLUDED THEREIN)

  SUBSTANCES CREATED THROUGH THE USE OF MATERIAL OR MODIFICATIONS, BUT WHICH ARE NOT PROGENY, UNMODIFIED DERIVATIVES OR MODIFICATIONS.
- IF MODIFICATIONS OR SUBSTANCES ABOVE RESULT FROM THE COLLABORATIVE EFFORTS OF THE PROVIDER AND THE RECIPIENT, JOINT OWNERSHIP MAY BE NEGOTIATED.

WHAT ABOUT THE RIGHT TO DISTRIBUTE?

The Recipient and Recipient Scientist shall have the right to distribute substances created by the Recipient through the use of the Material only if:

For biological materials: not the Progeny, Unmodified Derivatives or Modifications

For chemicals: do not contain or incorporate the Material.

How does the Recipient and Recipient Scientist agree to use the material?

- Used solely for teaching and academic research purposes;
- Will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects;
- Used only at the Recipient organization and only in the Recipient Scientist laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision; and
- Will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.

WHAT DO YOU DO IF SOMEONE OUTSIDE OF YOUR DIRECT SUPERVISION REQUESTS THE "MATERIAL"?

Answer: Simply refer them to the Provider.

Caution: Do not distribute the material.

*Provider agrees to make material available, under similar terms, to other scientists (at least at nonprofits) who wish to replicate Recipient Scientist's research and will reimburse preparation and distribution costs.

CAN RECIPIENT PROVIDE MODIFICATIONS OF BIOLOGICAL MATERIAL FOR COMMERCIAL PURPOSES?

- No, not without written consent from the Provider.
- Recipient may require a commercial license from the Provider, who has no obligation to grant a commercial license to its ownership interest in the material incorporated in the Modifications.

CAN YOU USE OR LICENSE THE MATERIAL FOR COMMERCIAL PURPOSES?

No, unless the Recipient in advance of such use negotiates with the Provider to establish the terms of a commercial license.

CAN YOU FILE FOR A PATENT FOR AN INVENTION THAT YOU EXCLUSIVELY MADE THROUGH THE USE OF THE PROVIDED MATERIAL?

Yes, but you should notify the Provider upon (not before) filing a patent application claiming Modifications or method(s) of manufacture or use(s) of the Material.

TAKING MATERIAL "AS IS"

Material is experimental and may have hazardous properties.

*Except to the extent prohibited by law (e.g. gross negligence or willful misconduct by the Provider), **Recipient** assumes all liability for damages which may arise from material's use, storage or disposal.

No representations or warranties provided by Provider.

MATERIAL AND PUBLICATIONS

Recipient scientist must provide appropriate acknowledgement of the source of the Material in all publications.

If written information about the Material is stamped "Confidential" or any oral disclosures from the Provider are subsequently identified as "Confidential" in a written notice, Recipient must maintain the confidentiality for the designated period (e.g. 1 to 5 years) and not disclose in publications.

MATERIAL AND OTHER REGULATIONS

Recipient must adhere to applicable statutes and government regulations and guidelines in using the Material.

Examples: Regulations on animal research, human subject research, recombinant DNA, etc.

SPECIAL REQUIREMENTS FOR DE-IDENTIFIED HUMAN TISSUES AND SPECIMENS

- Recipient must obtain Institutional Review Board approval, as appropriate, to use de-identified human tissues and specimens.
- Provider must label, package and transport in accordance with laws and regulations and not provide personally identifiable patient information (5 USC Section 522) or Protected Health Information (45 CFR 164.501).
- Recipient must not contact or try to identify human subjects from whom the original material was obtained without specific written approval from the Provider. Any information that can be later used to identify a donor individual, must be treated as Protected Health Information or personally identifiable information by the Recipient.

POTENTIALS FOR CONFLICT BETWEEN A PROPOSED MTA WITH ANOTHER UNIVERSITY AND AN AGREEMENT WITH A COMPANY

Proposed MTA between ODU and another university (Provider) states:

- Any commercial use of biological materials and know-how, or any other use outside of research purposes is strictly prohibited.
- Biological materials shall not be used in research that is subject to funding, consulting, reporting, or licensing obligations, options or rights to or of a third party as consideration for providing funding for the research conducted under the MTA unless prior written permission is obtained from the Provider.
- ODU shall not transfer or provide biological materials to any other organization without the prior written consent of the Provider.

WHAT HAPPENS TO THE MATERIAL WHEN THE AGREEMENT TERMINATES?

- Recipient will discontinue using the Material, and will, upon direction of the Provider, return or destroy any remaining Material.
- Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of the Agreement on Modifications.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

Purpose: An agreement between a Federal laboratory and a non-Federal party (e.g. ODU) to perform collaborative research and development to solve technical and industrial problems, often of broader societal impact.

Scope: Federal laboratory may provide personnel, services, facilities and equipment, but no funds for the collaborative research or development. A non-Federal party may provide funds, in addition to personnel, services, facilities and equipment for the collaboration.

Defines topic of research and includes Statement of Work or Joint Work Plan.

Specifies deliverables and milestones.

Authorization: 15 USC §3710a

WARRANTIES AND CRADAS

- No express or implied warranty as to any research, invention, or product, whether tangible or intangible.
- No warranty, express or implied, as to any cooperative work, subject invention, subject data, or other product resulting from the Cooperative Work.

WHAT ARE REPORTING REQUIREMENTS FOR CRADAS?

- Collaborators must submit Interim Written Reports to each other on the progress of the collaborative work.
- You must provide a Final Report (often within four months) of the completion of the Agreement with the Results Obtained and a list of Subject Inventions made.
- Within 60 days of making an invention from Cooperative Work, prior to disclosure of invention to any third parties, inventor shall submit an Invention Disclosure to employer.
- You must provide written notification to the collaborator immediately upon being aware that an export or foreign disclosure has been made without the required export license or foreign disclosure authorization. (Exporting collaborator responsible for obtaining any export licenses and foreign disclosure reviews required by U.S. law.)

WHAT IF YOU WANT TO PUBLISH OR DO A PUBLIC DISCLOSURE OF INFORMATION OF SUBJECT DATA?

- Prior to any publication or public disclosure of Subject Data, each Collaborator shall be offered a period of up to 30 days to review any proposed abstract, publication, presentation, or other document for public disclosure.
- Objecting collaborator must notify other Collaborator within 30 days of date of notice of Intent to publicly disclose. No objection means concurrence is assumed.
- Grounds for Objection (patent rights may be compromised, information is proprietary, restricted by U.S. Security laws or regulations)

WHAT ARE YOUR RIGHTS TO THE DATA?

Subject Data

- Each collaborator shall have title to all Subject Data generated by that Collaborator.
- Each collaborator grants Unlimited Rights in Subject Data that does not contain Proprietary Information to the other collaborator.
- For subject data that contains other party's Proprietary Information, you have the right to use, modify, reproduce, release, perform, display or disclose Technical Data within the university for any internal purpose excluding commercial purposes.
- You will have a Limited Right to use or reproduce (but must maintain confidentiality of) the Subject Data that may describe an invention that the Government owns or may own, if such Data was provided by the other party.

Non-Subject Data

- Each collaborator shall have Unlimited Rights in any Non-subject Data that are not Proprietary Information or protected under 35 U.S. Code § 205 provided under this Agreement.
- You shall have a Limited Right to use, reproduce or disclose Non-Subject Data provided by the other party that may describe one or more Inventions in which the Government owns or may own a right. Non-Subject data must be *properly marked* by the other party.

WHAT ARE THE MARKING REQUIREMENTS ON EACH MEDIUM USED FOR RECORDING DATA THAT MUST BE FOLLOWED?

- FOR NON-SUBJECT DATA THAT ARE PROPRIETARY INFORMATION, MARKING SHALL STATE: "PROPRIETARY INFORMATION OF OLD DOMINION UNIVERSITY - <*INSERT GOVERNMENT LAB*"> MAY USE ONLY FOR PURPOSE OF CRADA NUMBER_____"

- FOR SUBJECT DATA THAT ARE PROPRIETARY INFORMATION, MARKING SHALL STATE: "PROPRIETARY INFORMATION OF OLD DOMINION UNIVERSITY – GOVERNMENT HAS CERTAIN RIGHTS UNDER CRADA NUMBER _____"

CONFIDENTIALITY AND CRADA

You agree not to disclose for up to five years from date of generation, data produced by the other government party that would have been considered commercial or financial information that is privileged or confidential if it had been produced by ODU.

HOW ARE ENVIRONMENTAL, SAFETY AND HEALTH STANDARDS APPLIED?

- Each collaborator is responsible for the handling, control and disposition of hazardous substances in its custody. Must obtain all necessary permits and licenses at its own expense required by U.S. Federal, State and local law.
- For cooperative work performed in host facility, must abide by environmental, safety and health directives of the host facility and any applicable federal, state and local laws and regulations.

CAN YOU USE A SUBCONTRACTOR FOR COOPERATIVE WORK?

- YOU CANNOT ALLOW THIRD PARTIES TO PERFORM ANY PART OF THE COOPERATIVE WORK UNDER THE CRADA WITHOUT **EXPRESS WRITTEN CONSENT** OF THE OTHER COLLABORATOR.
- EVEN IF WRITTEN CONSENT IS OBTAINED FROM THE OTHER COLLABORATOR, ODU IS STILL FULLY RESPONSIBLE FOR THE WORK PERFORMED BY THE SUBCONTRACTOR AND THE SUBCONTRACTOR DOES NOT BECOME A COLLABORATOR UNDER THE CRADA.

CAN YOU USE THE GOVERNMENT AGENCY'S NAME ON A PRODUCT OR SERVICE RELATED TO THE CRADA?

- No, not without the prior approval of the government agency.
- You cannot imply that the government agency endorses any such product or service.

WHERE CAN YOU MANUFACTURE THE PRODUCT, PROCESS OR SERVICE USING INTELLECTUAL PROPERTY ARISING FROM THE PERFORMANCE OF THE CRADA?

Must be manufactured substantially in the United States to support U.S. competitiveness and under terms of the CRADA.

VOLUNTEER OR VISITING SCHOLAR AGREEMENT (VVSA)

Purpose – visiting researchers or scholars, who are not affiliated with ODU, are granted access to ODU's research facilities, information, materials or other ODU premises that are not typically available to the general public.

- Mutually benefit scholar's and ODU's instructional and research objectives.
- Volunteer or visiting scholar is granted in-person and/or remote access.
- Does not establish monetary compensation for the volunteer or visiting scholar.
- Volunteer assumes all physical and other risks of conducting research at ODU.

VVSA AND PUBLICATIONS

- Volunteer or visiting scholar must agree to not publish any portion of the research without the express written permission of the Vice President of Research at ODU.
- ODU shall be free to publish the results of the research conducted under the VVSA.
- ODU shall give appropriate recognition to the contributions made by the volunteer or visiting scholar.

VVSAs and Intellectual Property (IP)

- Volunteer or visiting scholar must assign to ODU all rights, title and interest in any intellectual property created as a result of his/her work at ODU. Each party retains all rights, title and interest in any pre-existing background IP owned by that party.
- Volunteer or visiting scholar must disclose to ODU's IP Manager in writing any intellectual property created as a result of his/her work at ODU.
- Volunteer or visiting scholar must deliver any papers, documents, instruments or affidavits required for ODU to apply for, obtain, maintain, and enforce any applications for a patent for intellectual property created as a result of his/her work at ODU.
- Volunteer or visiting scholar must agree to not file any patent(s) related to his/her work at ODU or related to any proprietary and confidential material provided by ODU, without the written permission of ODU's Office of Research.

Resources

Check out the newly launched **Agreements for External Research Collaborations website**:
https://www.odu.edu/facultystaff/research2/innovations-commercialization/office

- ODU Unfunded Agreement Request Form – to initiate agreement
- Descriptions of all four unfunded agreements (CDAs, MTAs, CRADAs, VVSAs)
- Select practices and principles of unfunded agreements at ODU
- Flow chart of agreement processing life cycle
- Frequently Asked Questions (with Answers)

CONCLUDING THOUGHTS/REMINDERS

- Initiate unfunded agreements by submitting online the ODU Unfunded Agreement Request Form: https://odu.co1.qualtrics.com/jfe/form/SV_eYdmG1wAZWboK8Z
- For an online reference on agreements at ODU, refer to: https://www.odu.edu/facultystaff/research2/innovations-commercialization/office
- If your work triggers a proposed CDA, MTA or CRADA, consider your existing Sponsored Research Agreements and industrial collaborations for a possible conflicting overlap on sharing of confidential information/material under the proposed agreement. If you see a potential conflict, please notify Monti Dutta in the Office of Research at adutta@odu.edu or phone: x34027 as soon as possible.
- Each Agreement is different. For example, no two CDAs or MTAs are exactly alike for terms. Common variances include duration of confidentiality periods, publishing protocols, etc. Therefore, always read each Agreement as a stand-alone document and don't try to apply your memory of another Agreement to the subject Agreement.
- Set up an annual calendar reminder to revisit and review the Agreement to ensure all terms continue to be followed by both parties and check if Agreement has outlived its purpose and can be terminated early.