WHAT DO RESEARCHERS NEED TO KNOW TO STAY IN COMPLIANCE WITH THE UNIVERSITY’S AGREEMENTS?

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AGENDA

Three primary Legal Agreements

I. Confidential Disclosure Agreement
II. Material Transfer Agreement
III. Cooperative Research and Development Agreement
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).
- Why 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- Do not publish.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.

Confidential Disclosure Agreements
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.**

<table>
<thead>
<tr>
<th>Federal Agency</th>
<th>Regulation/Statute</th>
<th>Controls what?</th>
<th>Penalties</th>
</tr>
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<tbody>
<tr>
<td>Department of Commerce</td>
<td>EAR – Export Administration Regulation; IEEPA – International Emergency Economic Powers Act</td>
<td>Technology with commercial, research and/or potential military applications. Commerce Control List: <a href="https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl">https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl</a></td>
<td>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</td>
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<td>Department of State</td>
<td>Arms Export Control Act (AECA); International Traffic in Arms Regulations (ITAR)</td>
<td>Military technology and services. U.S. Munitions List: <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=86008bdfdd1fb2e79cc5df41a180750a&amp;node=22:1.0.1.13.58&amp;rgn=div5">https://www.ecfr.gov/cgi-bin/text-idx?SID=86008bdfdd1fb2e79cc5df41a180750a&amp;node=22:1.0.1.13.58&amp;rgn=div5</a></td>
<td>Criminal penalties up to $1,000,000 and/or 20 years imprisonment per violation. Civil penalty: max - $1,134,602 per violation</td>
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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 given to ODU by the federal government or state government

• 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.
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.
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.
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.

Material Transfer Agreements
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.
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.

- ODU shall **not disclose know-how or discoveries to any third party 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.
Purpose: An agreement between a Federal laboratory and a non-Federal party (e.g. ODU) to perform collaborative research and development.

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.

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 a trade secret or 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.
CONCLUDING THOUGHTS/REMINDERS

• 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.

• 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.

• 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.