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SPEAKERS

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AGENDA

- Types of Collaboration Agreements
- General Terms in a Collaboration Agreements
- Key Terms of the Collaboration Agreements
- Wrap-up
- Questions?



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POLL-Question 1

Is your office responsible for reviewing the Collaboration Research Agreements, with not-for profit institutions and for-profit organizations?

- A. Yes, we review and negotiate both types of agreements in totality
- B. No, we review and negotiate the IP related terms
- C. Yes, we review and negotiate the Collaboration Agreements only with not-for profit institution
- D. Yes, we review and negotiate the Collaboration Agreements only with for profit institution



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TYPES OF COLLABORATION AGREEMENTS

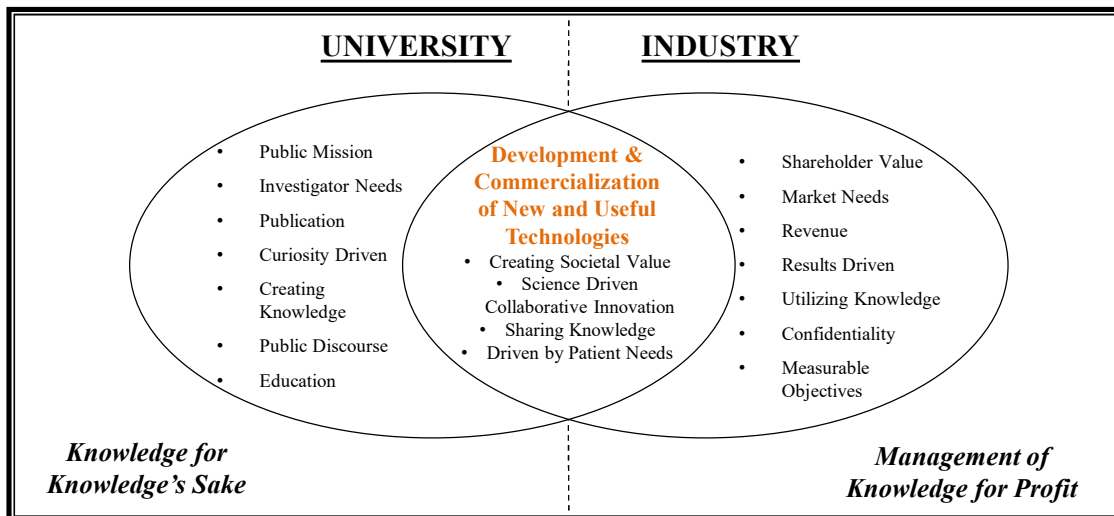
1. Academic Collaborative Research Agreements
2. Industry Sponsored Collaborative Research Agreements

Goal: Both parties work together on a common scientific goal to foster innovation and help people.



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CONFLICTING VALUES- Common Interest



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THINGS TO KNOW BEFORE YOU START

- Understanding of the Research Project: IS IT A TRUE COLLABORATION?
- Timeline
- Overlapping projects in the lab
- Any third party obligations
- Researcher and collaborator expectations



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TERMS IN A COLLABORATIVE RESEARCH AGREEMENTS

- Research Project
- Intellectual Property (IP)
- Transfer of Materials Among Parties
- Confidentiality
- Publication
- Human Subject Language (if needed)
- Compliance with Laws and Regulations
- Use of Name
- Assignment
- Governing Law



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RESEARCH PROJECT

- Statement of Work
 - Aims and Responsibilities
 - Transfer of Materials Among Parties
- Go/ No-go Decision Points
- Duration of the Research Project
- Reporting of the Research Results
- Budget – Amount and Payment Schedule



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SAMPLE LANGUAGE-Research Project

STATEMENT OF WORK

Title:[One sentence description]

Background: [Summary of the research leading up to the collaboration]

Principle investigators:

- Dr. _____, Party A
- Dr. _____, Party B

Project Timeline: [Anticipated time of the research]

Materials provided by Party A: [Description of materials being provided in enough details for the lab to track the transfer, i.e: mice, plasmids, cell lines]

Materials provided by Party B: [Description of materials being provided in enough details for the lab to track the transfer, i.e: mice, plasmids, cell lines]

Study Design: [detailed description of the research, i.e.:

- 1) Aim-1:
- 2) Aim-2:
- 3) Aim-3:

Responsibilities: [a general description of what each party will bring to the collaboration, i.e.:

Party A:

- Provide materials noted above.
- Provide expertise and advice to perform the project and analyze data together with Party B.

Party B:

- Provide materials noted above.
- Provide expertise and advice to perform the project and analyze data together with Party A.]

Payment Schedule :[a general description of the payment installments, frequency and indirect costs]



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POLL Question-2

What type of license grant would you offer to a for-profit collaborator under a collaboration agreement?

1. Non-exclusive internal research use license
2. Non-exclusive internal research and clinical use license
3. Non-exclusive license for all field of use
4. Exclusive license for all field of use



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INTELLECTUAL PROPERTY

- Background IP-
 - Transfer of Materials
 - Permitted Use and Restrictions
- Project IP-
 - Inventorship: Legal Determination
 - Ownership: Sole Invention, Joint Invention
 - Permitted Use: Internal Research Use vs Clinical Use
 - IP Strategy and Expenses
 - Licensing and Commercialization



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SAMPLE LANGUAGE-Transfer of Materials

Transfer of Materials Among Parties. Biological and other research materials, as hereinafter defined, may be transferred between the Collaborator and the Institutions in connection with the Research Project. The following terms shall govern any transfer of materials pursuant to the Research Project:

- a. **In General.** It is expected that the Collaborator will transfer to the Institutions materials developed outside the course of the Research Project as set forth in Attachment A, and the Institutions will transfer to Collaborator materials developed outside the course of the Research Project as set forth in Attachment A. In addition, other materials developed during the course of the Research Project may be transferred between the parties as part of the Research Project. Materials developed solely by the Collaborator, whether developed before or after the Effective Date, together with progeny and unmodified derivatives, will be owned solely by the Collaborator ("Collaborator Materials"); materials developed solely by Institutions, whether before or after the Effective Date, together with progeny and unmodified derivatives, will be owned solely by Institutions ("Institutions Materials"); materials developed jointly by researchers at the Collaborator and the Institutions in the course of the Research Project will be owned jointly ("Jointly Developed Materials"). Collaborator Materials, Institutions Materials and Jointly Developed Materials are sometimes hereinafter referred to as "Research Materials," singly or collectively.
- b. **No Warranties.** All Research Materials transferred in connection with the Research Project are experimental in nature and shall be used with prudence and appropriate caution, since not all of their characteristics are known. ALL RESEARCH MATERIALS ARE PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. A party providing its Research Materials makes no representation or warranty to the receiving party that the use of such Research Materials will not infringe any patent or other proprietary right.
- c. **Legal Title; Use.** Legal title to any Research Materials transferred hereunder shall be unaffected by this Agreement or the transfer made hereunder. The Institutions will use Collaborator Materials **only in work done in the course of the Research Project**, and only in Dr. [Institute Investigator Last Name]'s laboratory in research by laboratory personnel under [his/her] immediate and direct control. The Collaborator will use Institutions Materials **only in work done in the course of the Research Project**, and only in Dr. [type in last name of Collaborator's investigator]'s laboratory in research by laboratory personnel under [his/her] immediate and direct control. In addition, during the term of the Research Project, any Jointly Developed Materials will not be used by the parties other than in the Research Project.
- d. **Limitations.** Research Materials transferred under this Agreement are provided only for use in animals or in vitro. Research Materials transferred under this Agreement will not be used in humans, including for purposes of diagnostic testing.
- e. **Recipient Rights in Transferred Materials.** The transfer of Collaborator Material to the Institutions, and the transfer of Institutions Materials to the Collaborator, gives the recipient no rights in such material other than those specifically set forth in this Agreement.



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SAMPLE LANGUAGE- Intellectual Property

Invention definition example:

- For purposes of this Agreement, an “Invention” is any invention or discovery, whether patentable or nonpatentable, or copyrightable or non-copyrightable, that is conceived or reduced to practice **in the course of the Research Project**.

Important to retain rights for your own use:

- Following the collaboration, each party shall have an unrestricted right to use for its own internal research purposes all research results, including without limitation any Sole Invention of any party and any Joint Invention (as such terms are defined below), obtained from the Research Project.



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SAMPLE LANGUAGE- Intellectual Property

Academic Collaborations:

- If an Invention is of potential commercial value, the parties agree to enter into negotiations in good faith for a separate agreement to determine each institution’s rights in such substances and corresponding responsibilities for commercializing such substances; such agreement shall be memorialized in a written inter-institutional agreement (“IIA”).
- In case of any patent protection of Inventions, Party A and Party B shall in good faith discuss the course of action to be taken and agree on terms and conditions for commercial use, which shall be memorialized in a written inter-institutional agreement (“IIA”).



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SAMPLE LANGUAGE- Intellectual Property

Industrial Collaborations:

- Party A shall grant to Party B a non-exclusive, paid-up, worldwide, royalty-free license to any Inventions/its rights in any Joint Invention for *internal use purposes only*.
- Party A agrees that Party B shall have the right to negotiate an exclusive, royalty-bearing world-wide license to acquire the rights to any such Invention made by Recipient ("**Option**"). Party B may exercise the Option within ninety (90) days of receiving such Invention disclosure, Party A shall negotiate in good faith such a license. In the event that Party B does not elect to negotiate a license, or notifies Party A of its desire to obtain such a license, but the parties are unable to enter into a definitive license agreement within one hundred and twenty (120) days thereafter ("Negotiation Period"), then the rights to such Inventions shall be disposed of in accordance with Party A's policies with no obligation to Party B.



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POLL Question-3

University shall not publish any results or data without written approval of the Collaborator:

1. Acceptable
2. Unacceptable



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SAMPLE LANGUAGE - Confidentiality

Subject to the Publication provision below, during the term of this Agreement and for a period of five years thereafter, each party shall cause all information that is disclosed to it by the other party in connection with the Research Project and is identified in writing as confidential by the disclosing party (“Confidential Information”) to be treated according to the same internal security procedures and with the same degree of care regarding its secrecy and confidentiality as the party receiving the disclosure treats similar information of its own within its organization. Confidential Information does not include information that: (i) is or later becomes available to the public through no breach of this Agreement; (ii) is obtained from a third party who had the legal right to disclose the information; (iii) as of the date of disclosure, is already in the possession of the party to whom disclosure is made; or (iv) is required to be disclosed by law, government regulation, or court order



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PUBLICATION

Balance

- Important to consider academic missions of knowledge dissemination with industry needs to utilize that knowledge for products/services.
- MUST be a pathway to publish.

Sharing

- Important to allow for scientists to share any published material arising from the collaboration.



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SAMPLE LANGUAGE - Publication

It is contemplated that results of the Research Project will be *jointly published*; however, the Institutions and the Collaborator each separately reserve the right to publish information and data generated in the course of the Research Project. The parties agree to abide by the policies of journals in which publications will appear as to such matters as the public release or availability of data or biological materials relating to the publication. Authorship of results of the Research Project will be determined in accordance with academic standards and custom. Proper acknowledgment will be made for the contributions of each party to the research results being published. If a proposed publication is not a joint publication, the party wishing to make the publication shall provide a copy of the manuscript or abstract to the other party at least 30 days prior to publication in order to allow the other party an opportunity to protect proprietary information or intellectual property that might be disclosed by the manuscript or abstract. In addition, a party will not publish Confidential Information received from the other party (not to include results, information, data or materials generated in the course of the Research Project) without such other party's consent



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SAMPLE LANGUAGE - Sharing

Academic Collaborations:

- To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only
- If the RECIPIENT anticipates that it will generate cross-bred or genetically-modified organisms incorporating the PROVIDER's modified allele(s), RECIPIENT may transfer such cross-bred or genetically-modified organism(s) to non-profit institutions under the terms of a material transfer agreement that notifies the not-for-profit institution of the existence of PROVIDER's rights to the modified allele(s) and restricts the use of the transferred organism(s) by the not-for-profit recipient to teaching or not-for-profit research purposes only

Industrial Collaborations:

- Following a publication of the results of the research conducted pursuant to this Agreement that is made in accordance with this Section 5 (Publication) and which includes a ___ employee as an author, and notwithstanding anything to the contrary set forth in this Agreement, each party agrees to make data, software, and tangible research materials that are integral to the publication available to other academic and nonprofit scientists for research purposes on reasonable terms; provided, however, that the obligations set forth in this sentence shall not apply with respect to: (i) data, software, or tangible research materials that can readily be generated without restriction on use for research purposes by other scientists from information provided in the publication or (ii) data, software, or tangible research materials that can be obtained from third parties on reasonable terms.



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CRAs with Human Subject

- HIPPA
- IRB (informed consents)
- Indemnification (if needed)



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SAMPLE LANGUAGE- Human Subject

The PROVIDER represents that the collection of MATERIALS and its sharing with RECIPIENT for research purposes was approved or exempted by the relevant Institutional Review Board and authorized by donors under informed consent in accordance with U.S. federal, state and local laws and regulations which address protection of human subjects in research, including 45 CFR part 46. PROVIDER is prohibited under any circumstances from providing RECIPIENT with personal identifying information or the key to decipher the code for ORIGINAL BIOLOGICAL SAMPLES to reveal the identity of the donors. All ORIGINAL BIOLOGICAL SAMPLES and related information shall be de-identified as de-identified is defined by HIPAA (“DE-IDENTIFIED”) prior to transfer hereunder, and RECIPIENT shall make no attempt to re-identify any such ORIGINAL BIOLOGICAL SAMPLES or information. Notwithstanding the foregoing, if RECIPIENT believes it has received identifiable patient information hereunder, it will hold such information in strict confidence indefinitely, RECIPIENT will immediately inform PROVIDER and comply with PROVIDER’s instruction at PROVIDER’s expense, with respect to return or destruction of the same.



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ADDITIONAL TERMS IN A COLLABORATIVE RESEARCH AGREEMENTS

- Compliance with Laws and Regulations
- Use of Name
- Assignment
- Governing Law
 - Silence
 - “Swinging gate” – jurisdiction/venue of the defendant



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Comparison Chart

Terms	With Universities	With For-profit
Research Budget	Usually none- each party bears its own expense	Full support including indirect costs
IP Ownership	Inventorship reflect ownership	Inventorship reflect ownership
IP Prosecution & Expenses	Covered under IIA	Supported by the funder
Licensing & Commercialization	Covered under IIA	Funder receives a time-limited option
Rights to Background IP	None or solely for the collaborative research	None or solely for the collaborative research
Publication	Co-publication or prior review	Co-publication or prior review



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QUESTIONS?



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Thank you!

For any additional questions, please feel free to email us:

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