

Review of Research-Related Agreements Between Academic Institutions and Other Entities.

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Standard research-related agreements between non-profit institutions and other entities

- Confidentiality
- Material Transfer
- Sponsored Research
- Collaboration
- Service
- Clinical Trial
- License

Confidentiality Agreements (CDA)

- Contracts between two or more parties agreeing to maintain certain types of information confidential.
- Also called Secrecy or Nondisclosure Agreements

Confidentiality Agreements (CDA)

- Agreement establishes a time during which disclosures are made and period during which confidentiality is to be maintained.
- Agreements state that no license to technology or information is granted to recipient.

Confidentiality Agreements (CDA)

- **Type of info that can be protected is unlimited:**
 - Data
 - Know-how
 - Engineering drawings
 - Computer software
 - Test results
 - Tools
 - Systems
 - Etc.

Confidentiality Agreements (CDA)

- Performs several functions:
 - Protects sensitive technical or commercial information from disclosure
 - Can prevent the forfeiture of valuable patent rights
 - Defines what info can/cannot be disclosed

Why is a CDA important for protecting valuable patent rights?

- In the U.S., an inventor may forfeit the right to patent protection if invention publicly disclosed more than one year prior to filing patent application.
- In the rest of the world, **NO** disclosure of any kind may occur prior to filing a patent application.
- Finally, if there is no record of confidentiality, the recipient of proprietary information can use such information for their own benefit.

Material Transfer Agreement (MTA)

- Contract that governs the transfer of research materials between two organizations.
- Utilized when recipient intends to use it for research purposes.
- Utilized when no research collaboration between scientists is planned.
- Defines the rights of the provider and recipient with respect to materials and derivatives

Potential Issues with MTAs

- **Confidentiality**

- Confidential information is exchanged along with material. The provider may request that such information not be disclosed.

- **Delay in Publications**

- Companies often demand a review period for the investigator's manuscripts but (1) may jeopardize the timeliness of publication and (2) requires confidentiality obligation.

Potential Issues with MTAs

- **Use of materials in sponsored research**
 - Many MTAs prohibit use of the material in research that is subject to licensing or consulting obligations to third parties.
- **Definitions of material**
 - Some definitions include not only original material, but also modifications or derivatives of the material incorporating the investigator's original idea or concept.

Potential Issues with MTAs

- **Loss of control of intellectual property**
 - Intellectual property restrictions may prevent the institution from owning and developing future inventions.
- **Conflicts with existing agreements**
 - Industry MTAs may contain obligations that conflict with other pre-existing agreements.

Sponsored Research Agreement (SRA)

A written agreement used when a company provides funds to an investigator to develop hypothesis-driven, non-clinical, basic research projects.

SRA

- **Company/Investigator interaction:**
 - At scientific meetings or through contacts with collaborators in industry
- **Company/Investigator contact Intellectual Property and Innovation (IPI) office:**
 - This allows IPI office to address questions early in the process to avoid later delays and complications
- **SRA form**
 - Defines terms and conditions of research
 - Generally, prefer to use our form

SRA Provisions

- **IP and Licensing**

- The rights to discoveries/inventions directly assigned to the Institution by institution inventor. In return for funding, sponsor is granted exclusive option to license technology resulting from the sponsored project. Institution reserves the right to use the technology for internal research and educational purposes.

- **Reporting and Use of Research Data**

- The investigator may be required to provide reports to sponsor which sponsor may be allowed to use for internal research purposes. These reports should be confidential to safeguard publication and IP protection rights of the Institution.

SRA Provisions

- **Publications**

- Institution reserves the right to freely publish research (academic freedom to publish has to be maintained).
- The sponsor is usually granted a time-limited review period of manuscripts and a brief delay to allow protection of patentable info (or to remove sponsor's identified confidential info).

- **Budget**

- The budget should be specific and should include time limits. Please remember to negotiate the appropriate indirect costs with the sponsor institution.

Indirect Overhead Research Costs of the Institution:

Sponsored Research/Service	40% (of the total research budget)
Clinical Trial	25% (of the total research budget)
Foundation Grants	10% (of the total research budget)

Collaboration Agreements

A written agreement used when two or more institutions decide to collaborate on hypothesis-driven, research-related projects.

Collaboration Agreements

- Many of the agreements provisions are similar to SRAs
- All parties participate in the research endeavors.
- Intellectual property
 - sole and joint inventions
 - provisions for commercialization of inventions
- Budget
 - Funding maybe provided by both parties
 - Funding provided by one party and in-kind support by the other

Service Agreements (SA)

A written agreement used when a company provides funds to an investigator to test the company's drug or device to perform non-clinical, basic research using the institution's established and/or published assays, protocols or animal models. Activities conducted under these agreements are considered for-profit activities for institution tax purposes.

SA Provisions

- **IP and Licensing**
 - The rights to modifications and new uses of the sponsoring company's drug or device ("Service Agreement Inventions) can be assigned to such company. However, rights to any other invention that is not a Service Agreement Invention (as defined above) shall reside with the institution.
- **Reporting and Use of Research Data**
 - The investigator may be required to provide reports to sponsor which sponsor will use for internal research, regulatory and marketing purposes.

SA Provisions

- **Publications**

- Institution would prefer the right to freely publish research under SA agreements. However, such publications may be subject to sponsor approval and time delays, although IPI office shall try to negotiate away from such restrictions.

- **Budget**

- The budget should be specific and should include time limits. Please remember to negotiate the appropriate indirect costs with the sponsor.

Clinical Trial Agreements (CTA)

A written agreement used when a company provides funds to an investigator to test the company's drug or device to perform protocol-based clinical research. Activities conducted under these agreements have to be approved by the institution's IRB and HIPAA compliance is mandatory.

Licensing Agreement

A contract by which the owner of IP conveys to another the right to make, use and/or sell a product or service.

Licensing Agreement

- Licensing is preferred means for realizing financial benefits from innovation.
- By licensing, the development, manufacturing and distributing risks avoided.
- By licensing, the owner and inventor of the innovation is able to enjoy royalties & other consideration from the licensee.

Licensing Agreement

- Commonly used to transfer rights in patents/patented products.
- Licenses can also apply to technical or business know-how, confidential information, trademarks, copyrights and computer software.
- Flexible --can be uniquely adapted to particular circumstances.
- Can be non-exclusive or exclusive.

