



BULLETIN

> CLINICAL TRIALS, SPONSORED RESEARCH, AND MATERIAL TRANSFER

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Best Practices: Interacting with Big Pharma

Key Terms:

Background intellectual property (IP): the University has patents, patent applications, licenses, or collaborations in similar or overlapping clinical or market areas.

Conflicting obligations: the University has a contract from the past that prohibits us from making certain commitments to a 2nd party.

Types of Interactions:

Materials Transfer Agreement (MTA): a legally binding contract used for the transfer of research or other tangible material for evaluation and experimental use; includes some IP rights for joint inventions.

Sponsored Research Agreement (SRA): an agreement between an outside institution and CU that allows the university to accept outside sponsorship while still maintaining some level of IP rights on the subsequent research.

Confidentiality Agreement (CDA): allows university researchers to discuss the details of confidential research with outside parties while still protecting IP rights on the research.

Clinical Trial Agreements: arranges for a research study to be performed at the University, with financial support from an industry sponsor; some IP rights may be preserved.

Guiding principles in TTO service contract management

- ◆ Ensure the University's obligations are consistent with University policy and law. The University of Colorado cannot enter into contracts having provisions that violate any laws without receiving permission from the proper authority (usually the President or the Attorney General of Colorado). There are practical limits to our discretion.
- ◆ Ensure faculty are informed about the process, and that their wants and needs are clearly contemplated when TTO decides its position on an individual contract. Faculty are our customers, so we generally follow their wishes unless 1) the University's interests are jeopardized, 2) another faculty member's interests are jeopardized. Contracts are binding at the level of the institution, not the investigator or project, unless otherwise specified.
- ◆ Avoid conflicting obligations with third parties. We must always avoid conflicting obligations (i.e. an exclusive commitment of IP to two different parties) and the associated legal risk that brings to the University.
- ◆ Choose our battles. Only a small subset of the agreements we see have substantial problems requiring protracted negotiation.

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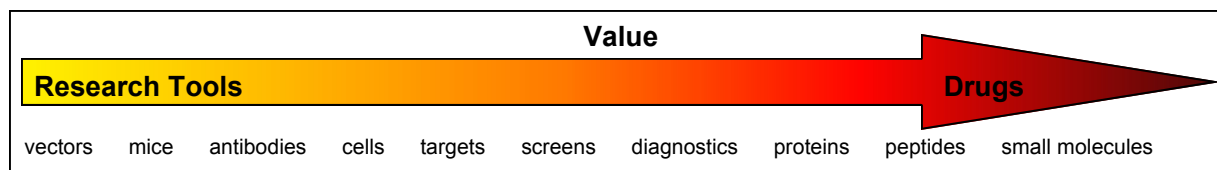


Myths about the process

<u>Myth:</u> TTO negotiates for IP where there is none.	<u>Truth:</u> We did 748 service agreements last year, so we are motivated to get the easy agreements through quickly and focus on those few that do need special attention.
<u>Myth:</u> Agreements can be rubber stamped immediately.	<u>Truth:</u> A service agreement is a <i>legally binding contract</i> and requires evaluation against CU and TTO contracting standards.
<u>Myth:</u> Agreements take weeks to be signed.	<u>Truth:</u> Less than 5 percent take more than 2 weeks; most can be turned around in 3-5 days if none of the delays noted above occur.
<u>Myth:</u> Since no IP is likely to result from the project, there should be no delay.	<u>Truth:</u> Many contracts provide the sponsor or material provider the opportunity to file patents at their discretion, which empowers the provider to create conflict. Publications rights, data rights and Colorado law are other <i>bona fide</i> issues that arise.

Internal quality control practices

- Database management system logs every incoming agreement and automatically generates emails to those in the chain of custody when delays occur
- TTO management receives weekly summaries of the docket in progress and follows up on delayed agreements
- Agreements that are problematic with respect to legal language are triaged and prioritized relative to their place on the continuum of commercial value, with reagents generally being of minimal commercial value and novel drug compositions being extremely valuable:



Summary

TTO strives to provide a high level of service to both our university and industry customers. We feel it is critical that rational and reasonable positions underlie those few contracts that require substantial negotiation by TTO. We strive to find the common ground where difficulties arise, ensuring mutually beneficial outcomes for our faculty customers and industry customers. We work with faculty to anticipate outcomes on projects, and ensure workable compromises when TTO does have to negotiate. Our team is charged with quickly finding solutions to problems and facilitating maximum degrees of freedom in both research and commercial projects.

Whether an MTA or a large-scale sponsored research agreement, these industry collaborations should be relatively easy to set up and mutually beneficial for both parties when complete.

To download disclosure forms: <http://www.cu.edu/techtransfer/disclose/>

For more info or to submit a disclosure, email your campus TTO contacts.