

Best Practices for Negotiating Research Agreements with Non-public Entities

Southern Association of Agricultural Experiment Station Directors

Association of Southern Region Extension Directors

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Introduction

Public funding for applied agricultural research has declined in recent decades resulting in Universities seeking multiple sources of funding, including research sponsored by commercial entities with proprietary interests. Performing research sponsored by for-profit companies is justified when there is a public benefit, when the research is funded at cost and the University retains appropriate intellectual property rights and the right to publish relevant results. We recognize conflicts may arise between the Land Grant mission and the objectives of for-profit companies. This statement of Best Practices is an attempt to minimize conflicts between Sponsors and the Universities represented by the Southern Association of Agricultural Experiment Station Directors and the Association of Southern Region Extension Directors.

Definitions

Sponsored Research means research performed by Universities in exchange for specified contractual obligations. These obligations may include funds, material, proprietary information, equipment or other resources provided by a Sponsor.

Agreement means the fully executed document governing the terms and obligations of Sponsored Research. Agreements include Memoranda of Agreement, Sponsored Research Agreements, Service Agreements, Material Transfer Agreements, Stewardship Agreements, Master Service Agreements, Master Research Agreements, Testing Agreements and all amendments and attachments.

Investigator means a University employee assigned and obligated to perform Sponsored Research.

Sponsor means the entity funding research financially or providing Materials for performing University research.

Confidential Information means proprietary information, materials and intellectual property of the Sponsor provided to Universities for performance of services or research.

Material or Background IP means all relevant biological material, compounds, formulations, chemistry, products, product descriptions, processes, designs, business and operational detail, proprietary instructions and plans, and pre-existing intellectual property rights provided by Sponsor to University for performing Sponsored Research.

University means a land-grant institution represented by membership in the Southern Association of Agricultural Experiment Station Directors.

Signature Authority

Situation: Occasionally an investigator or an immediate supervisor is asked to sign an agreement.

Best Practice: Only an administrator who has been authorized in writing by the University may sign an Agreement on behalf of the University. Appropriate signatories may vary according to the institution, nature of the Agreement and the Investigators involved. If investigators reporting to two administrative units are involved, then authorized signatory or signatories representing both units should execute the Agreement.

Best Practice: Agreements should be signed before materials are delivered and investigators begin work.

Best Practice: Investigators are given opportunity to review all relevant Agreements and are provided a copy of all signed Agreements. Agreements should have an acknowledgement line for Investigators to sign or initial indicating their awareness of Investigator obligations.

Confidential Information (CI)

Situation: Sponsors generally seek broad definitions of CI and long terms of confidentiality. Universities prefer narrow definitions of CI and short terms of confidentiality. Investigators occasionally fail to keep proprietary information in confidence for extended periods of time. Companies may request stringent terms of confidentiality incompatible with the land grant mission.

Best Practice: Universities agree to hold proprietary information in confidence only for a well-defined and specified time period. With substantial justification and buy-in from Investigator, administration may agree to an extended confidentiality period for certain investigations (e.g. regulated trials where commercialization is not certain and several years away).

Best Practice: All CI should be clearly marked "Confidential". In the case of oral disclosure, CI should be promptly reduced to writing and marked "Confidential".

Best Practice: All Agreements should explicitly allow Universities to disclose their results, data and conclusions to the public following a clearly defined and appropriately limited review period.

Best Practice: All Agreements should explicitly allow Universities to disclose their results, data and conclusions to the public if Sponsor discloses data, inventions, Material, offers Material for sale or seeks regulatory approval for Material.

Best Practice: Universities should not agree to allow Investigators to be exposed to Sponsor's trade secrets without substantial justification. (Note: Because trade secrets derive value only if kept in confidence and may be held in confidence forever, access to trade secrets can conceivably prevent an Investigator from publishing forever.)

Best Practice: Universities do not agree to keep the mere existence of an Agreement in confidence.

Best Practice: Universities do not agree to destroy all records regarding Sponsored Research. Rather, Universities should maintain file records of all data relevant to Sponsored Research in compliance with state or University records retention policies.

Publication and Presentation

Situation: Sponsors sometimes seek to restrict publications, exert editorial or content control, or require approval of publications or delay publications for extended periods of time.

Best Practice: Universities retain the right to publish their findings for the public good, regardless of sponsorship.

Best Practice: Sponsors may be granted the right to review and comment prior to submission of publications. Thirty-day review periods are generally acceptable, but may be extended to sixty days with substantial justification. Universities should seek to honor Sponsor requests to withhold Confidential Information from publications.

Best Practice: Universities do not withhold publication due to unfavorable results of Sponsored Research.

Best Practice: Publication rights extend to all forms of public disclosure, including posters, oral presentations, PowerPoint presentations, abstracts, as well as peer-reviewed and technical articles. Publication rights extend to all venues of public disclosure including scientific meetings, field days, workshops and classroom instruction.

Best Practice: Universities do not agree to impede traditional outreach and Extension functions, including field days and public education initiatives, by restricting dissemination of non-confidential information.

Best Practice: Once a Sponsor reviews and comments on a publication, Universities may present the same publication in other forums without giving Sponsor further review and comment.

Best Practice: If patentable subject matter is identified by Sponsor, publication may be delayed up to 60 days to allow for preparation and filing of patent.

Legal

Situation: Universities function as an agency or entity of their respective states and cannot be subject to certain contractual obligations that Sponsors seek in Agreements.

Best Practice: Universities cannot waive sovereign immunity of the State. (Note: Legal redress for negligence, gross negligence or willful misconduct is available through state Claims Commissions or similar bodies, or via a limited waiver of sovereign immunity under a State's Tort Claims Act or similar legislation.)

Best Practice: Universities typically cannot agree to subject themselves to the law or jurisdiction of another State or nation. However, Agreements may be silent on choice of law or jurisdiction.

Best Practice: Universities cannot indemnify other parties. Acceptable language: “Nothing in this Agreement is to be deemed or construed as a waiver of any immunities to suit legally available to the University, its officers, agents or employees.”

Best Practice: Universities cannot make guarantees or warranties. However, Universities may choose to make representations. Acceptable language: “University represents to Sponsor that to the best of its knowledge as of the Effective Date...” or “University represents that all reasonable effort will be made...”.

Reservations

Situation: Sponsors often wish to exercise control over research, inventions and work product in exchange for sponsoring research. Universities have obligations such as academic freedom, public right-to-know and Bayh-Dole requirements that are sometimes in conflict with Sponsor’s goals.

Best Practice: Universities retain the right, on their behalf and other educational or non-profit institutions, to practice inventions that may arise from sponsored research, whether patentable or un-patentable inventions. This right may be restricted to research and educational purposes; not for commercial purposes.

Best Practice: Universities notify Sponsor if its Investigator(s) perform federally funded research or other Sponsored Research substantially the same as described in the Agreement. Universities cannot agree to refrain from research that may be substantially the same as described in the Agreement.

Best Practice: Universities may agree to refrain from modifying, isolating, analyzing, sequencing, or replicating any Material or Background IP provided by Sponsor.

Inventions

Situation: Sponsors often wish to own, take assignment, or control the disposition of inventions in exchange for Sponsored Research. University Policies often prohibit automatic assignment of rights to Sponsors.

Best Practice: Inventions arising from Sponsored Research should be promptly disclosed to Sponsor.

Best Practice: Universities should engage Sponsor to determine inventorship, ownership and patent responsibilities within 60 days. “Yours, Mine, & Ours” language is preferred for defining University inventions and joint inventions.

Best Practice: In consideration of Sponsored Research, Universities may grant the Sponsor a time-limited option to negotiate an exclusive or non-exclusive license to the University rights in any invention

conceived under the terms of an Agreement. Universities should not agree to specific license terms prior to receiving an invention disclosure from the Investigator(s).

Best Practice: Results of Sponsored Research should be defined as the work product including data, lab books, field books, devices, sequences and novel processes. Results belong to the party that produced them. Results are not to be treated as Sponsor's Background IP or Material.

Indirect Costs/Facilities and Administration

Situation: Universities negotiate with Federal agencies for reasonable indirect costs or facilities and administration costs (IDCs) based on independent third party audits of the enterprise costs of research. Sponsors occasionally restrict the rate of IDCs for Sponsored Research.

Best Practice: For-profit Sponsors pay full indirect cost rates for Sponsored Research at Universities. IDCs may vary according to institution and location.

Best Practice: IDCs may be negotiated with not-for-profit institutions.

Third Party Obligations

Situation: Agreements may seek to place the burden of certain obligations on Universities, including training for third parties, resources provided by third parties such as land and equipment, stewardship agreements or separate signed agreements with third parties.

Best Practice: All third party obligations should be borne by Sponsor or shared by University and Sponsor.

Licenses

Situation: Universities have an obligation and a mission to broadly transfer knowledge and technology to the public. Sponsors often want to strictly control public access to new technology, especially when the new technology was conceived under Sponsored Research.

Best Practice: Universities should always consider licensing arrangements which offer broad and far-reaching applications for the benefit of society. Thus, depending on the maturity of the technology and the exploitable markets:

- Exclusive and non-exclusive licenses should be considered.
- Carving exclusive markets or exclusive fields-of-use for multiple partners should be considered.
- Performance Milestones regarding commercialization should be included in all exclusive licenses.
- Licensing through open processes, such as a Request for Proposal or Intent to Negotiate, should be considered.

Best Practice: Exclusive Licensee pays University patent costs. Non-exclusive Licensees pay pro-rata share.

Best Practice: Fees and royalties are negotiated in good faith between Universities and Sponsors.

Best Practice: Sponsors may be granted a non-exclusive, royalty-free, limited license to practice University Inventions conceived under Sponsored Research for research purposes.

Breeding Agreements

Situation: Universities and Sponsors occasionally share germplasm, advanced selections, GMO traits and other genetics under Breeding Agreements. Since Universities offer the benefits of a sustained broad-spectrum breeding effort, Universities represent the public's investment in developing genetic resources.

Best Practice: Universities may grant Sponsors rights to initial crosses or defined number of backcrosses in exchange for fees and royalties.

Best Practice: Universities are entitled to fees and royalties relative to the contribution of University genetics in a commercial cultivar.

Best Practice: The decision to release cultivars from their respective breeding programs remains the sole and exclusive right of Universities.

Best Practice: Universities should initially seek short-term breeding agreements and evaluate annually the value of the agreement, whether in value of the germplasm received, the benefit to the public, or the compensation to Universities.

Master Agreements

Situation: Universities and Sponsors may wish to reduce the time and effort of negotiating agreements when the parties anticipate multiple Sponsored Research opportunities. Further, the parties may desire uniform terms and conditions for a range of agreements. Both goals may be met under a Master Agreement, governing the overall conduct of Sponsored Research for an extended timeframe and across a number of Investigators.

Best Practice: Universities may enter into Master Agreements for three-to-five year terms.

Best Practice: Master Agreements allow the parties to terminate a Master Agreement in the event it no longer serves the intended purpose or becomes unfavorable due to unforeseen circumstances.

Best Practice: Since IDCs are subject to change over time, the IDCs in a Master Agreement should be tied to prevailing USDA rates or negotiated rate increases.

Best Practice: In the event of ambiguity or conflict between a Master Agreement and Service Agreements or Research Protocols, the terms and language of the Master Agreement prevails unless clearly stated and agreed to by both parties in the research protocol.

Best Practice: Amendments, Addenda and Exhibits defeat the purpose of a Master Agreement, may result in confusion between the parties, and should be avoided whenever possible.

Best Practice: A summary of relevant terms and conditions of a Master Agreement, in layman's language, should be provided to Investigators operating under a service agreement, service order or research protocol.

Public Access

Situation: The White House Office of Science and Technology Policy has directed federal funding agencies to ensure greater public access to federally funded data and publications. Further, the Land Grant mission includes making research results broadly, publicly available.

Best Practice: Universities notify Sponsor if federal funds are used in conjunction with Sponsored Research, which may subject the results of Sponsored Research to public scrutiny.

Best Practice: Universities should make every effort to avoid contractual conflicts with the directive to ensure public access to their research results if federal funds are also used to support the sponsored research.