



Animal Product Trial Guidelines and Procedures . . .

Definition: An Animal Product Trial project uses a company's material, protocol, specific methods, or background intellectual property (IP), in conjunction with ISU-owned animal models or ISU's unique animal expertise. The scope of an Animal Product Trial may include feeding or testing, with examination of tissues, blood, urine, feces, etc., or recording measurable health or biological criteria in response to a medical device, pharmaceutical, supplement, or feed sample.

IACUC approval is generally required for these trials. No new IP is anticipated; improvements to background IP are owned by the providing party. The company has the right to review public disclosures, remove its confidential information, and request delay to protect patentable subject matter.

OIPTT will determine when an Animal Product Trial agreement is appropriate for a project.



Animal Product Trial Characteristics

- The Animal Product Trial will differ for each company by including a distinct combination of material, protocol, animal model, expert analysis and/or discretionary judgment. The agreement will cover the timeline, work plan, deliverables, and budget.
- Animal Product Trial agreements **may** be used when:
 - ISU evaluates or tests company-provided background IP, without improvement, reformulation, or redesign.
 - ISU uses expertise, animal models, unique capabilities, or specialized equipment, producing outcomes that include:
 1. Results outside of basic quality checks or standard summary graphics; and/or
 2. Analysis or discretionary judgment; and/or
 3. Publishable findings or results.
- Animal Product Trial agreements **may not** be used when:
 - ISU improves, reformulates, or redesigns what the company provides.
 - Performing research using animals.
 - Developing a protocol, standard operating procedure (SOP), or software is the main outcome.
 - Cost sharing or matching funds are included.
 - Subcontracts or pass-through funding to another entity is included.



GoldSheet Guidelines

- Animal Product Trials require a GoldSheet.
 - OIPTT manages the contract process after the GoldSheet is approved by OSPA.
 - In the Notes section of the GoldSheet:
 1. Indicate this is a Animal Product Trial.
 2. Provide the name, email address, and phone number (if available) for the contact person at the company.
 3. Indicate if the Animal Product Trial is ready for an agreement or if it is time sensitive.
 4. Provide the ISURF number, if ISURF background IP is being used.
 - Budget: Use the "Loaded BOB" budget template, available at <http://www.ospa.iastate.edu/forms>.
 - A 15% indirect cost rate (of total direct costs) applies to all Animal Product Trial agreements.
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Contact Information

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