Information for Extramural Grantees & Contractors

Inventions made under NIH extramural grants and contracts are generally owned by the funded institution. Information on the grant process and components of grant applications can be found below:

- Sample IP Management Plans are provided to assist extramural funding applicants in preparing intellectual property (IP) management plans for their partnerships with industry in order to address certain programmatic objectives and goals of particular funding announcements.
- The Model Organism Sharing Policy describes NIH support for efforts that encourage the sharing and dissemination of important research model organisms.
- The Research Tools Policy is designed to provide NIH funding recipients with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds.
- Researchers submitting grant, cooperative agreement, or contract applications seeking $500,000 or more in direct costs in any year of the proposed research grant are expected to include a Data Sharing Plan or a justification for why data sharing is not possible under the specific circumstance.
- Sponsored Research Agreements between NIH grantees and commercial entities require careful consideration on several issues, including academic freedom, intellectual property and dissemination of research results.
- iEdison is a database assisting government grantees and contractors comply with the Bayh-Dole Act and its implementing regulations that requires government funded inventions be reported to the federal agency that made the award.

For more information on the NIH grant process, please visit the Office of Extramural Research (OER) website.

Sample IP Management Plans

The content below provides general guidance for preparation of IP Management Plans and lists various sample plans that can be used by extramural funding applicants to prepare intellectual property management plans when required by program announcements that cite this website as a resource. These sample plans are provided to assist applicants in preparing the intellectual property management plans in their partnerships with industry in order to meet certain programmatic objectives and goals of particular funding announcements.

The guidance and sample plans are not exclusive and should not be considered an exhaustive or comprehensive listing of acceptable approaches. Applicants are encouraged
to use their own discretion to independently develop and submit their own plans for consideration. Applicants should confer with their institutions' office(s) responsible for handling technology transfer related matters and/or sponsored research in the development of the intellectual property management plans. Applicants should obtain the concurrence of the collaborating institutions to the intellectual property management plans. If applicants or their representatives require additional guidance in preparing these plans, they are encouraged to contact the appropriate person(s) listed in the program announcements as well as to research and review approaches considered by other institutions. For more information about IP Management Plans, contact Wendy Patterson at pattersw@mail.nih.gov.

The approaches for consideration, described below, reflect a variety of mechanisms utilized by applicants to address the programmatic objectives of certain funding announcements for similar NIH programs.

**Collaborations involving a single industry partner:**
- Nonexclusive licenses may be sufficient for certain products;
- Some degree of exclusivity may be necessary to ensure commercialization of the final product;
- One option is to offer exclusivity for a limited time period followed by a nonexclusive license; and
- An applicant may wish to grant exclusive options to negotiate exclusive, world-wide, royalty-bearing licenses for all commercial purposes, including the right to grant sub-licenses, to all inventions resulting from the use of a collaborator's proprietary material and/or technology.

**Collaborations involving multiple institutions and industry participants:**
- Frequently involved in a plan to develop diagnostic assays based on novel biomarkers and created in part with proprietary biomarkers/reagents/technologies supplied by industry collaborators;
- Applicant's institution might consider granting an exclusive option to license inventions within narrow fields of use, so as not to preclude additional individual collaborations with other companies to develop these inventions;
- Applicant's institution might also consider entering into a multi-party agreement that could provide appropriate incentives to companies for moving products forward.
  Possible approaches could include:
  - granting nonexclusive licenses;
  - granting an exclusive option to each individual company for an exclusive commercialization license relating solely to such company's product; or
  - granting an exclusive option for a co-exclusive license of intellectual property relating to a combination of products.

In situations where multiple patents are involved but exclusive (or co-exclusive) access is not required, applicants and their collaborators may wish to explore the creation of patent pools, which would enable all necessary patents relating to a technology to be licensed nonexclusively at reasonable royalty rates.
- For more information and a discussion on the use of patent pools for biotechnology patents, see *Patent Pools: A Solution to the Problem of Access in Biotechnology*
Regardless of the strategy chosen for managing resulting intellectual property, the scope of the commercialization license should be commensurate with the research plan and relate specifically to the proprietary product (drug, test, device, etc.) of the collaborator(s).

**Further Points for Consideration:**
- Applicants should address how they will coordinate patent prosecution and licensing activities, if necessary to enable a licensee to access the bundle of intellectual property needed to effectively bring a product to market. Possible strategies include:
  - assigning intellectual property rights to related inventions to an invention management firm;
  - designating one organization to take the lead on patenting and licensing related inventions; and/or
  - agreeing in advance that if multiple parties are to independently license related inventions, the total of stacked royalties will not exceed a predetermined percentage rate.
- Institutions should reserve a research use license for any resulting inventions in the final negotiated commercialization license, which ideally should include the right to share such inventions with others for noncommercial purposes.
- In the event that institutions desire to use intellectual property resulting from such collaborations for the benefit of third parties for commercial purposes, institution may consider obtaining the consent of the relevant industry collaborators before doing so.

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**Source**
**URL:** https://techtransfer.cancer.gov/intellectualproperty/ip-information-grantees-contractors