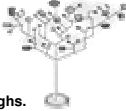





## NIH Inter-Institutional Agreements (IIAs): Core Concepts

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**Science. Ideas. Breakthroughs.**



## NIH IIAs: Overview

- Underlying Principles & Rationale
- Types of IIAs
- NIH Reservations
- Core Concepts in an IIA
- Anatomy of an IIA
- Practical Considerations

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## Underlying Principles

- Arise from inventive collaboration between NIH/FDA and University/Non Profit/Company
- Avoids parallel patent filing(s) & unnecessary costs
- Exclusive license from one party (co-assignee) to another
- IIA parties may change during patent prosecution

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## Rationale

- Consolidate (joint) IP rights for efficient patent prosecution and technology management
- Foster rapid commercialization of undivided interests through licensing

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## Types of IIAs at NIH

- NIH lead IIA
- Institution lead IIA
- Cost Sharing Agreement

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## NIH Reserved Rights

- Absent prior written approval of NIH, IIA partner cannot assign or issue any royalty free or paid up licenses
- NIH retains right to review and approve all ensuing exclusive/partially exclusive sublicenses
  - US Gov retains irrevocable, royalty-free, paid-up right to practice and have practiced the Patent Rights throughout the world by or on behalf of the US Gov and on behalf of any Foreign Gov or international organization pursuant to any existing or future treaty or agreement to which the US Gov is a signatory

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## NIH Reserved Rights

- Also reserve right, in accordance with 35 USC § 200-212, to require IIA partner, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by US Federal Regulations.
- Reserve right to require IIA partner to grant nonexclusive Research Licenses on reasonable terms and conditions to encourage basic research, whether conducted at an academic or corporate facility.
- Sublicenses must also include obligation to report on utilization of the invention as set forth in 37 C.F.R. §401.14 (h)
- Substantial US manufacturing requirement for product sales in US

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## Core Concepts/Definitions

- Patent Rights
- Net Revenues
- Expenses
- Research License
- Practical Application

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## Anatomy of an IIA

- Grants & Reservation of Rights
- Patent Infringement/Governing Laws/Settling Disputes
- Term and Termination
- Patent Prosecution & Licensing Obligations
- Royalties & Expenses

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## Patent Prosecution & Licensing Obligations

- Leading Party Obligations
  - Licensing
  - Prosecution
  - Reporting
- Joint Input
  - Licensing
  - Patenting

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## Royalties & Expenses

- Factors considered in negotiating share/split
- Distribution of Net Revenues between IIA parties
- Responsibility of disseminating royalties

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## Practical Considerations

- Negotiable Points
  - Split
  - Patenting
  - Licensing
  - Termination
- Multi-party Issues
- IIA or Cost Sharing Agreement?
- Who should take the lead and why?
  - Dominant Party
  - Timeliness
  - First to Patent

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Thank you!

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