









Working together to optimize investment in health research and training



Welcome to the Sub-group on IP and Tech Transfer We are delighted you have joined us!

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The National Academies of SCIENCES ENGINEERING MEDICINE IP and Technology Transfer is one of the central themes in the research funderperformer relationship.

From the Pre-meeting Survey Results we know that the major challenges regarding IP policy are a key concern for both funders and performers.



#### Recognizing the Common Purpose The IP and Tech Transfer Sub—group Was Formed.

#### Finding Cures



Stewardship of Resources for Research Meeting National & Global Challenges





Making the World a Better Place

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#### Purpose and Goals Intellectual Property and Technology Transfer Sub-group

.....explore enhancing and improving research engagements and collaborations between research-funding foundations and research-performing institutions.

.....focus on developing common understandings, identifying opportunities to streamline processes, examining policies and costs, and exploring ways to foster effective technology transfer.



#### Purpose and Goals

#### Intellectual Property and Technology Transfer Sub-group

Goals:

- Identify agreed-upon principles that underlie the parties' mutual interests.
- Identify areas of divergence in needs, policy, and practice between funders and research performers.
- Examine best practices and examples of innovative relationships.
- Endeavor to identify approaches that respect the constraints and missions of both parties while achieving the common goals.

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### The IP and Technology Transfer Survey

Now that we know intellectual property terms are a concern for both research funders and researcher performing entities, what specifically are the issues that are most significate?

What topics or issues are problematic?

What are your constraints?

What topics or issues are usually not a concern or easy to resolve?

What delays or prevents coming to agreement?

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# For a range of provisions typically found in research agreements, which are:



Rarely the topic of negotiations; the parties generally agree ✓ Sometimes the topic of negotiations; the parties are generally able to come to agreement easily Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

## Respondents







3 issues were considered "rarely" an issue by more than 58% of respondents and were seen as "sometimes or frequently" a difficult topic by less than 11%:

- Disclosure requirements (e.g., disclosing inventions to the sponsor)
- Conflicts of interest
- Disposition / Abandonment of patent protection



#### ≥58% Chose Rarely a Difficult Topic ≤10% Identified as Sometimes or Frequently a Difficult Topic

64.1% 🔵	10.3% 😑	Conflicts of Interest	
56.4% 🔵	10.3% 😑	Disclosure Requirements	
55.3% 🔵	5.3% 😑	Disposition/Abandonment of patent protection	

 Rarely the topic of negotiations; the parties generally agree  Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement





≥40% Chose Sometimes a Topic/Generally Able to Agree <16% Identified as Sometimes or Frequently a Difficult Topic

60.5% 🗕	7.9% 🗕	Patent decisions and patent costs; Costs for protection of IP		
60.5% 🗕	15.8% 🗕	Ownership/disposition of other research results		
57.9% 🗕	13.2% –	Publication Rights		
56.4% 🗕	12.8% 🗕	Sharing of research materials		
52.6% 🗕	15.8% 🗕	Research use of IP by funder or performer		
48.7% 🔴	15.4% 🗕	Ownership of new IP		

Sometimes the topic of negotiations; the parties are generally able to come to agreement easily

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Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

≥40% Chose Sometimes a Topic/Generally Able to Agree ≥16% Identified as Sometimes or Frequently a Difficult Topic

63.2% •	18.4%	Control of Licensing
53.8% 鱼	25.6%	Scope of definition of IP
45.9% •	18.9%	Access to background IP
43.2% •	16.2%	Disclosure of licensing efforts
41.0% •	17.9%	Joint ownership of IP absent joint inventorship

Sometimes the topic of negotiations; the parties are generally able to come to agreement easily Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

To borrow from UIDP, "Moderately Contentious" More than 40% find these sometimes the topic of negotiation

and a number of characterize them as difficult to resolve.

Publication Rights (right of performers to publish research results; Right of funders to review publication for potentially patentable subject matter)	Access to background IP
Joint ownership of IP	Ownership & disposition of
absent joint inventorship	other research results



#### Joint ownership of IP absent joint inventorship

#### Access to background IP

**17.2%** • Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement 37.9%

- Rarely the topic of negotiations; the parties generally agree
- Sometimes the topic of negotiations; the parties are generally able to come to agreement easily
- Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

## 21.4%

 Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

- Rarely the topic of negotiations; the parties generally agree
- Sometimes the topic of negotiations; the parties are generally able to come to agreement easily
- Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

#### **Publication Rights**

(right of performers to publish research results; Right of funders to review publication for potentially patentable subject matter)

17.9%

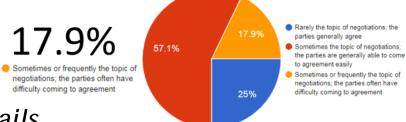
 Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

- 53.6% 17.9% 28.6%
  - Rarely the topic of negotiations; the parties generally agree
  - Sometimes the topic of negotiations; the parties are generally able to come to agreement easily
  - Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement

Group 3 Details

## Ownership & disposition of other research results

(e.g., data, prototypes, and other tangible and intangible research results



Two items in the survey were identified as sometimes or frequently the topic of more intense negotiation:

- Provisions for patient access
- Royalty sharing, distribution, and use for research



Rarely; Generally Agree	Sometimes; Generally Able to Agree	Sometimes or Often; May be Difficult	<ul> <li>Rarely the topic of negotiations; the parties generally agree</li> <li>Sometimes the topic of negotiations; the parties are generally able to come to agreement easily</li> <li>Sometimes or frequently the topic of negotiations; the parties often have difficulty coming to agreement</li> </ul>
33.3% •	40.7% •	25.9% •	Patient access to resulting drugs, devices, diagnostics and cures including requirements to flow license terms to licensees that require: (1) reasonable effort to assure patient access, (2) reasonable efforts to establish patient assistance program, (3) mechanism to assure patient access.
10.3% •	41.4% 🔴	48.3% 😐	Royalty issues / sharing / distribution; Use of royalties for future research

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Group 4 Details

# These findings are consistent with those of the larger group pre-meeting survey which found:

#### Non-Profit Funders

#### **Objectives:**

- Strengthen rights to royalties/equity
- Maximizing the impact; make sure treatments reach people

#### Uncertainty in negotiations:

- What is reasonable to ask for?
- Recoup our investment?
- Negotiate case-by-case?

#### Restrictions:

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Board mandates for IP treatment

#### **Research Performers**

- IP may come from mixed funding
- "March-in" complicates licensing
- State laws create challenges
- Non-profit funders are representing for-profits, where the for-profit terms are restrictive on IP policy <u>and</u> provide lower IDC.
- Willingness to find "middle ground"
- Impact of NERF on marketability
- Overreach on return on investment
- Compliance difficulty?
- Do requirements compromise mission?

This is not the first time or only group considering these issues.

Cultivating, Negotiating, and Managing Research Agreements with Philanthropic Organizations

Kathy Ku, Stanford University

http://techtransfercentral.com/marketplace/distance-learning/managingresearch-agreements-with-philanthropic-organizations/



## **Discussion for Today**

- Are the results of the survey generally valid?
- Are there other considerations that should be added?
- Priority of issues to address.
- For Group 3, is it possible to identify model clauses and provisions?
  - Would it be useful for Group 1 & 2?
- Can we identify the principles and perspectives of each party for Group 4 issues?



### Next Steps?



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