Nonprofit Funder - Research Institution Partnership

Current and Planned Initiatives

February 28, 2019

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Nonprofit Funder - Research Institution (NFRI) Partnership

Three primary areas of focus/working groups:

- Intellectual Property and Technology Transfer
- Research Project Support Costs (F&A)
- Streamlining Administrative Requirements

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Nonprofit Funder - Research Institution (NFRI) Partnership

- Meetings on May16 and November 7, 2018 hosted by the Government University Industry Research Roundtable (GUIRR)
- Nine Subgroups
- Monthly calls
- Two meetings scheduled in 2019: May 22 and September 24

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Contact us!

Jilda Garton – Institution lead IP: jilda.garton@gtrc.gatech.edu
Vivian Holmes – Institution lead streamlining: vholmes@bu.edu
Jim Luther – Institution lead RPSC: james.luther@duke.edu
Lisa Nichols – lnichols@cogr.edu

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NFRI Partnership: Streamlining Administrative Requirements

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NFRI Partnership: Streamlining Administrative Requirements

"Streamlining Foundation Requirements and Processes To Reduce Administrative Burden and Cost" COGR, September 2017

Working Group Leads:

Andrew Smith, Susan G. Komen for the Cure

Vivian Holmes, Boston University

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NFRI Streamlining Workgroup
May 2018 Breakout Session Goals

- Identify causes of administrative burden for both funders and institutions, including central offices and PI's, and name potential solutions.
- Develop effective practices and guidelines to streamline that can be shared with the broader funder and institutional communities.
- Determine next steps and areas for collaboration with other Working Groups (Research Operating Costs and IP).

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NFRI Streamlining Workgroup
May 2018 Breakout Session Topics

Proposal Submission

Communication

Award Issuance and Acceptance

Financial and Progress Reporting

Terminology

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NFRI Streamlining Workgroup
May 2016 Breakout Session
Recommendations/Suggestions

Areas of Agreement: communication, consistency…

Near-term Deliverables: contact info, delegated authority…

Longer-term Deliverables: all policies/procedures on site…

Areas for further discussion: access to clearinghouse info…

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NFRI Streamlining Workgroup
November 2018 Breakout Session

Common challenges and goals – Subgroup Leaders

Application Process:

Marti Dunne, NYU; Calvin Ho, TSA

Financial Reporting:

Charles Greer, UC Riverside; Mehvish Khan, Conquer Cancer

Policies, Terms and Conditions:

Missy Peluso, Upenn; Whitney Steen, Lymphoma Research Foundation

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Streamlining Administrative Requirements - Working Group on Streamlining Application Processes

Working Group Goals: Identify ways of reducing burden for both higher education institutions and nonprofit funders in the application process

Chair for subgroup for IHEs: Marti Dunne, New York University
Chair for nonprofit funders: Calvin Ho, Tuberous Sclerosis Alliance

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Members

Calvin Ho	Tuberous Sclerosis Alliance
Susan Fargo	American Epilepsy Society
Andrew Murtishaw	Alzheimer's Association
Erik Lontok	Lipedema Foundation
Stacy Cloud	Donaghue Foundation
Dario Dieguez	Foundation for Physical Therapy
Vidya Browder	Children's Tumor Foundation
Kristen Mueller	Melanoma Research Alliance
Marti Dunne	NYU
Surya K. Mallapragada	Iowa State University
Marcia Landen	University of Southern Mississippi
Stephanie Endy	Case Western Reserve University
Nancy Daneau	NYU
Sheila Lischwe	Clemson
David Ross	Notre Dame
Laura Fuentes	Johns Hopkins
Maggie Cho	UCSF
Cathy Cuppett	University of Georgia
Anna Jackson	University of Chicago
Esther Pratt	Washington State University
Jeanne Wicks	University of Nebraska, Lincoln
Lisa Nichols	Council on Government Relations

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Current Initiatives

- Expanding the FDP Clearinghouse:
  - Expand the data available in the Federal Demonstration Partnership (FDP) Clearinghouse to include information of interest to nonprofit funders.
    - Encourage funders to use the institutional profiles in the Clearinghouse, eliminating the need for requests to obtain entity-based information. Every participating research institution has a single profile in the database and is committed to keeping the information up-to-date. The working group will explore which additional data fields should be proposed to the FDP. The database is open to anyone seeking profile information. https://fdpclearinghouse.org/

Collaboration with grants management system providers

- Altum, the developer of proposalCENTRAL (the application submission system used by many nonprofit funders), has offered to make changes that would streamline proposal submissions for both institutions and funders. The working group will explore what changes users would like to see to the system.
- Altum has also just developed an institutional portal so that submissions may be tracked by IHEs and progress and final reports monitored.

Just-in-Time

- Borrowing from streamlining efforts by the Federal government, we are asking both funders and institutions to suggest areas which may be conducive to Just-in-Time submission.
  - Human and animal subjects reviews are two obvious areas which could save effort on both sides.
  - Suggestions for other areas are now being sought.

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Coming up

- Standardizing:
  - Eligibility criteria
    - Who may submit
    - How many applications may an institution submit
  - Application guidelines
    - Average award for the competition
    - Annual Deadlines (dates and how many per year)
    - Just-in-time information (?)
  - Applications
    - Cover page
    - Biosketch
    - Others?

Financial Reporting and Invoicing Subgroup Membership

Leads:

Charles Greer, University of California, Riverside

Mehvish Khan, Conquer Cancer Foundation of the American Society of Clinical Oncology

Members:

Jim Hulbert, Patient-Centered Outcomes Research Institute(PCORI)

Amanda Humphrey, Northeastern University

Maneesha Joshi, Yale University

Ellyn McCaffrey, University of California, San Francisco

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Working Group Goals

- Develop standardized and customizable templates for budgets, invoicing, and financial reporting;
- Develop recommendations for financial reporting timelines; and
- Evaluate current financial reporting practices and procedures and provide further streamlining recommendations to both funders and research institutions.

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Discussion Topics and Themes

- Research institutions management of funding
- Non-Profit funders financial restrictions
- Controls in place at research institutions
- Budget categories – line item changes from budget to actual expenditures

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Discussion Topics and Themes

- Financial requirements due to donor restrictions
- Hard time letting go of controls due to fears the budget might go off track and you would have to explain the price increase to the board
- The adoption of federal requirement by non-profit funders can allow more focus on program changes and be easier for all parties
- Good communication is valuable

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Approach

- Discussions between Non-Profit Funders and Research Institutions on financial reporting and invoicing differences and similarities
- Utilizing federal invoicing and financial reporting as foundation for templates
- Develop rebudgeting recommendations
- Survey Non-Profit Funders and Research Institutions

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Survey for Non-Profit Funders (sample)

(1) What types of awards do you issue by percentage?

(2) How do awardees submit invoices for payment?

(3) Who reviews invoices prior to payment (select all that apply)?

(4) What are your standard payment terms upon receipt of an invoice?

(5) Does your organization have a formal financial compliance or audit program to test awardee compliance with your allowable cost guidelines?

(6) When does your organization financially close-out an award from the award end date?

(7) During award closeout, when do financial closeout activities begin?

(8) What budget categories would you like the following expenses budgeted and charged to?

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Survey for Research Institutions (sample)

(1) What types of awards do you receive by percentage

(2) How does your institution submit invoices for payment?

(3) Who reviews invoices prior to submission to the funder?

(4) What is your preferred standard payment terms upon receipt of an invoice?

(5) Does your institution have a formal financial compliance or audit program to test your compliance with your allowable cost guidelines?

(6) What is your institution's preferred days for financial closeout of an award from the award end date and why?

(7) During award closeout, when does your institution begin financial closeout activities?

(8) What budget category would you most likely budget the following expenses to based on your accounting system/general ledger?

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Financial Reporting and Invoicing Subgroup

Please send any comments and/or additional questions on the financial reporting and invoicing survey to:

Charles.greer@ucr.edu by Thursday, March 7,2019.

Thank You!!

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NFRI Contracting Subgroup

Leads:

Whitney Steen (Lymphoma Research Foundation)

Missy Peloso (University of Pennsylvania)

Members: Jennifer Ponting (Harvard), Ruchika Dhussa (University of California), Felice Lu (UCOP), Nate Martinez-Wayman (Duke), Kerry Peluso (Florida State), Lois Brako(Michigan), Jackie Bendall (COGR), Lisa Nichols (COGR), Toni Russo (COGR), Lynne Elmore (American Cancer Society), Tamara Croland (JDRF)

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Contracting Subgroup Initiatives

- Develop sample contract language that is generally acceptable to both institutions and funders (primarily compliance as initial focus)
- Create whitepaper explaining the rationale for both funder and university positions on contracting issues

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Contracting Subgroup Current Activities

- Catalog of contract language in current non-profit funder agreements received by subgroup member institutions

- Draft of mutually agreeable sample contract language for select areas:
  - General compliance language
  - Responsibility/Indemnification
  - Export Compliance/Anti-terrorism
  - Research Misconduct
  - Conflict of Interest
  - Use of Animal/Human Subjects and clinical trials
  - Data Sharing
  - Public Access
  - Use of Name

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NFRI Partnership: Research Project Support Costs

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NFRI Partnership: Intellectual Property

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Patient Access Subgroup Overview

Leads:

- Amy Laster, Foundation for Fighting Blindness
- Felice Lu, University of California Office of the President

Research ways that intellectual property polices could promote patient access to therapies

- Ways to increase access to clinical trials
- Adoption of patient access programs that improve treatment affordability, availability, and geographic accessibility
- Development of inventions to treat orphan diseases
- Access in developing countries

Aim: Share research findings and offer guidelines for promoting patients access through licensing

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Patient Access Subgroup Initial Progress

Adoption of patient access programs (PAPs) that improve treatment affordability, availability, and geographic accessibility

- PAPs have been widely adopted by pharma companies and the first opportunity to offer PAPs should continue to remain with the commercializing entity
- Would it be possible to inform funder (e.g. through a reporting obligation) when the commercializing entity declines to offer a PAP? Funder may want to take action to assist patients.

Access in developing countries

- Addressed in 9th point of the 9 points to consider

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IP: Control of Licensing Subgroup

Leads:

Sally O'Neil (Stanford University)

Jeremy Nelson (University of Michigan)

Members:

Calvin Ho, TSA

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IP: Control of Licensing Subgroup

Themes identified:

- Control vs. Communication
  for both
- Pre- and post-license rights

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IP: Control of Licensing Subgroup

Pre-license:

- Licensing strategy
- Choice of licensee
- Negotiation process
- Approval/review rights

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IP: Control of Licensing Subgroup

Post-license:

- Licensee's progress
- March-in rights

IP: Control of Licensing Subgroup

This group could use more members, especially from one or more funders. If you'd like to participate, please contact Sally O'Neil or Jeremy Nelson:

sally.oneil@stanford.edu
or
jernelso@umich.edu

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NFRI Partnership
IP Definitional subgroup

IHE Leads:

Alex Albinak (Johns Hopkins University)

Kevin Wozniak (Georgia Tech)

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IP CHALLENGES BEYOND (BUT RELATED TO) ROYALTY SHARE AND LICENSING

PROJECT INTELLECTUAL PROPERTY	NON-PROJECT INTELLECTUAL PROPERTY
MAKEUP OF INTELLECTUAL PROPERTY	NONCONTRACT PERFORMER
	IDENTIFICATION OF RELEVANT, EXISTING IP
	FUTURE NON-PROJECT IP

PROJECT IP KEY ISSUE

- Admin. burden of:
  - certifying contract performers' relevant IP
  - identifying universities non-contract performers' relevant IP
  - tracking lineage of conception that leads to IP in the future (triggers royalty share obligation)
- Definition of IP ***can*** impact publication and licensing activities

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NFRI Royalty Sharing Subgroup

Leads:

Jackie Hausman, Kenneth Rainin

Fred Reinhart- UMass; John Ritter- Princeton

Members: Felice Lu- UCOP; Jilda Garten-GA Tech; Alex Albinak- Johns Hopkins; Jennifer Harris- JHMI; Tom Goodness- Cornell; Jan Thornton- Auburn; Cathy Cottle- U Washington; Dave Winwood- LSU; Rachel Webb- JDRF; Jeremy Nelson- Michigan; Sara Bible & Sally O'Neil- Stanford; Diane Bovenkamp- Brightfocus; Amy Laster- Foundation Fighting Blindness

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NFRI Royalty Sharing Subgroup

Issue: Negotiations on sharing revenue from successful licensing of an invention resulting from foundation funding take an inordinate amount of time and can be a significant source of disagreement between the parties.

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Irony: Major revenue "hits" are extremely rare. AUTM ALAS Survey data show:

- ONLY 189 out of 45,657 active academic license agreements (0.41%) have generated more than $1 million.

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NFRI Royalty Sharing Subgroup

Subgroup goal: Establish a set of principles and guidelines for both Funders and Performers to enhance understanding and find solutions to facilitate more efficient and productive negotiations.

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NFRI Royalty Sharing Subgroup

Initiative on Principles and Guidelines:

- Motivations and goals of parties
- Where is low hanging fruit?
  - E.G., Let's avoid complex calculations
  - Decide sharing terms up front, if possible

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NFRI Royalty Sharing Subgroup

Initiative on Principles and Guidelines:

- Factor: Amount of $$ support provided by Funder and risk profile
- Factor: Funder brings BIP or facilitates commercialization

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NFRI Royalty Sharing Subgroup

Initiative on Principles and Guidelines:

- Factor: Performer gets no/low RPSC (aka F&A) and pays for all patent costs
- Factor: Performer's BIP and extent of earlier work done on invention

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Q: Can we get consensus on standards, ranges, benchmarks, novel approaches?

- Royalty share % and when is it triggered (e.g., at $100,000, $500,000 etc.)?
- Is Funder's royalty share capped at 2X, 3X, 5X or never?
- Would a "Windfall Provision" yield a simpler agreement, lower administrative costs for the Performer and security for the Funder?

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Jilda Garton – Institution lead IP: jilda.garton@gtrc.gatech.edu
Vivian Holmes – Institution lead streamlining: vholmes@bu.edu
Jim Luther – Institution lead RPSC: james.luther@duke.edu
Lisa Nichols – lnichols@cogr.edu

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