June 2012 COGR Meeting Thursday Morning Presentation MTA Challenge - Harsy

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Lowering the Barriers to Transfer of Research Materials between Non-Profit Institutions

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AUTM Efforts - Background

- The 2011 AUTM MTA Survey
- NIH/COGR MTA Discussion Group
- Charge from AUTM Board
  - No MTA Initiative
  - Use of UBMTA
- AUTM MTA Working Group – call for members at 2011 AUTM meeting

AUTM MTA Working Group

- Laurie Tzodikov, Princeton University
- Wendy Streitz, University of California
- Cherry Joy Beysselance, Howard Hughes Medical Institute
- Svetlana Shtrom, University of Central Florida
- Mike Mowatt, National Institutes of Health
- Chikako Saotome, Kyoto University
- Rupinder Grewal, MIT
- Jaysen Rajkomar, Stanford University
- Shawn Hawkins, St. Jude Children's Research Hospital
- Steve Harsy, University of Wisconsin -Madison
- Eric Paulson, University of Utah

NIH Research Tools Sharing Guidelines 1999

Minimize Administrative Impediments to Academic Research

Each iteration in a negotiation over the terms of a license agreement or materials transfer agreement delays the moment when a research tool may be put to use in the laboratory.

NIH Research Tools Sharing Guidelines 1999

Recipients should take every reasonable step to streamline the process of transferring their own research tools freely to other academic research institutions using either no formal agreement, a cover letter, the Simple Letter Agreement … or the UBMTA itself.

NIH Research Tools Sharing Guidelines 1999

The majority of transfers to not-for-profit entities should be implemented under terms no more restrictive than the UBMTA. In particular, Recipients are expected to use the Simple Letter Agreement provided below, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other Recipients for use in NIH-funded projects.

National Academies Report

National Research Council
of the National Academies
October 2010

Recommendation 8: To facilitate the exchange of scientific materials among investigators, especially those engaged in non-profit sector research, research sponsors should explicitly encourage and monitor compliance with requests for materials.

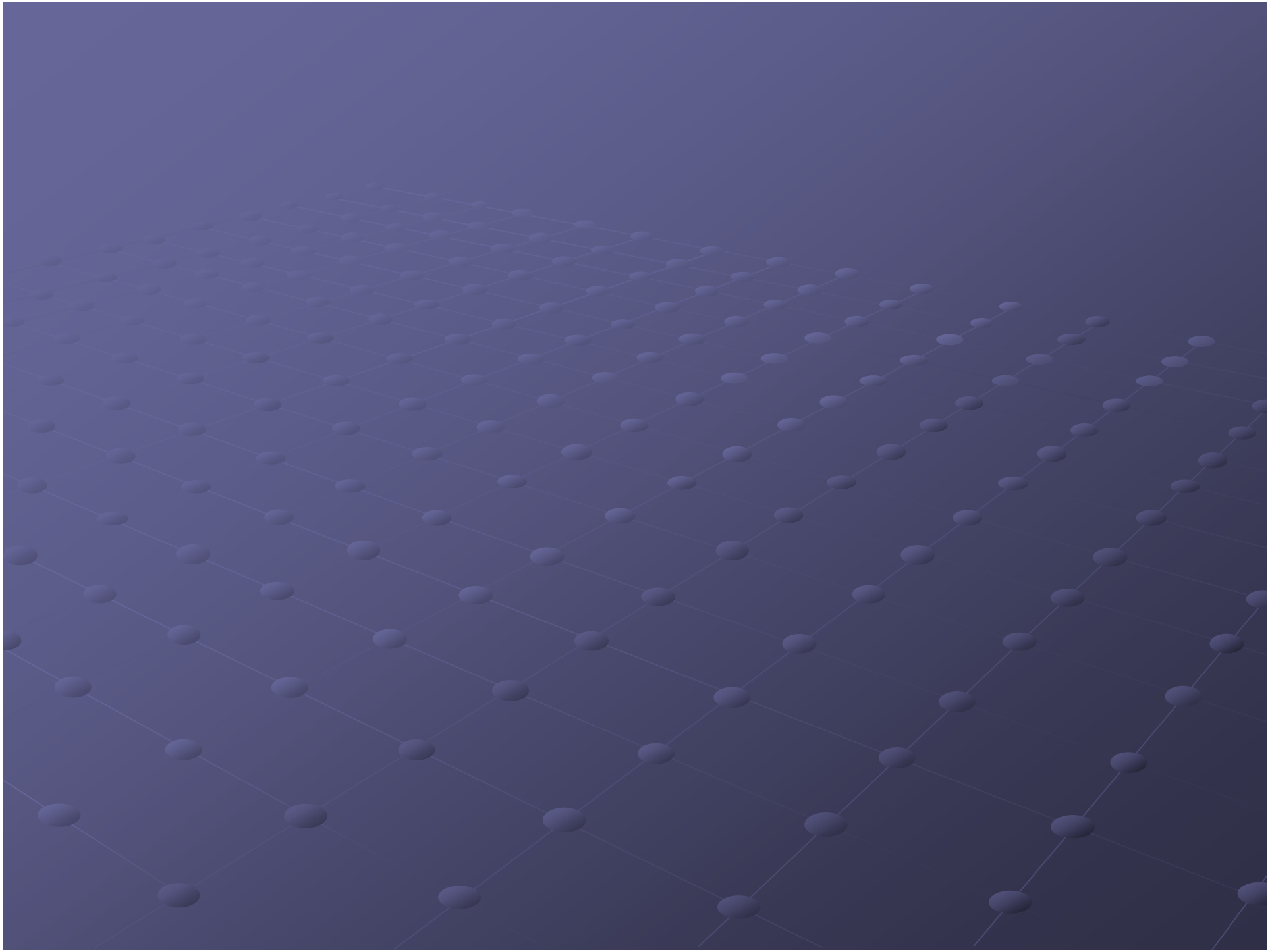
National Academies Report

Moreover, technology transfer offices should in the future either

- cease requiring use of Material Transfer Agreements when their investigators and colleagues at other nonprofit research institutions are exchanging non-hazardous or non-human biological material for in vitro research, or
- use only the Uniform Biological Material Transfer Agreement (UBMTA) or the Simple Letter Agreement (SLA) recommended by the National Institutes of Health.

Working Group Goals

1. Identify barriers that hinder the use of the UBMTA and NIH SLA and propose solutions
2. Develop guidance for institutions in transferring research materials
3. Review the “No-MTA” initiative and determine what role AUTM might play
4. Develop recommendations for promoting the use of standardized agreements



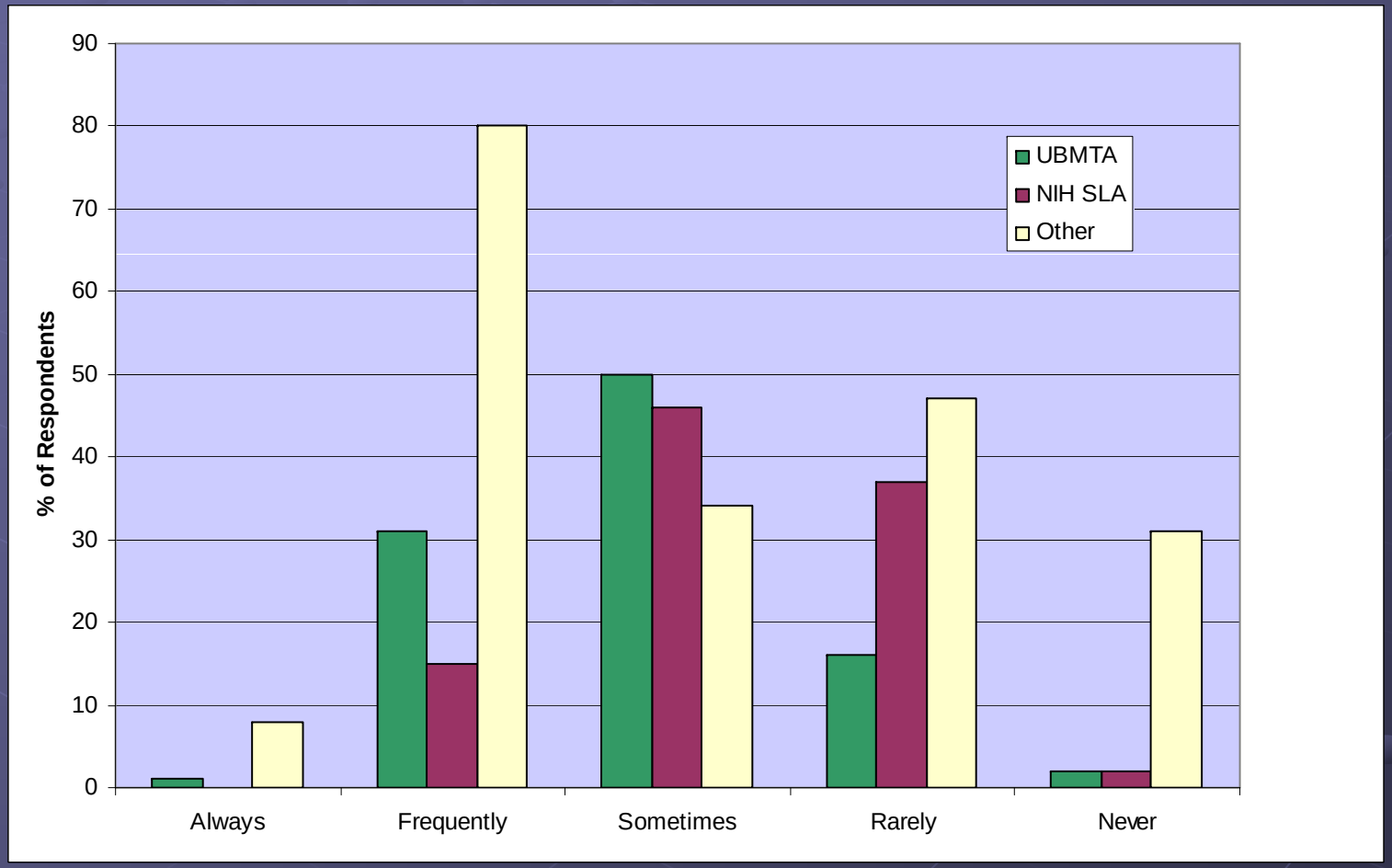
Barriers to Sharing

1. Finding and requesting materials
2. *Negotiating the terms of transfer*
3. Managing the paperwork

Minimizing Transaction Costs

- Customized terms and conditions
- Standardized terms and conditions
- No terms and conditions

Incoming MTAs from Non-profits



AUTM 2011 MTA Survey, Sec. 3 Q11

Why Not Use the UBMTA?

17	Prefer our own template, which is UBMTA-like
13	Additional terms needed (confidentiality, pre-publication review, scope of work, export control, etc)
12	UBMTA not comprehensive enough or different terms needed (no specifics)
11	Not a signatory
11	Material is either patented or licensed
8	Material not biological as defined in the UBMTA
7	Third party involvement complicates things
3	State/country law issues
1	No MTA required

MTA Working Group Approach

- Identify academic institutions with which members have experienced “MTA challenges” – include UBMTA signatories and non-signatories
- Develop questionnaire for informal telephone interviews: Why not UBMTA or SLA?
- Gather responses and analyze
- Devise possible approaches to improve UBMTA utilization

Feedback from a dozen institutions

Not so helpful

"It's them not us."

"The PI doesn't like it."

"We like ours better."

Helpful

"It has some specific deficiencies, e.g., …."

"It doesn't work for things like chemicals, human materials, and iPS cells."

What Modifications Would Increase the Use of the UBMTA?

- The ability to modify or add terms – open it up?
- Add description of work scope
- Address transfer of confidential information
- Deal with some liability issues
- Add an export control provision

Transfers of “Non-UBMTA Materials”

UBMTA used as a model for MTAs to transfer other materials:

- Chemicals
- Human Tissue
- iPS Cells
- Living organisms, stem cells to be developed

Model Agreements Based on UBMTA

- Human Tissues
  - Reference to IRB, HIPAA
  - Specification of research plan
- Chemicals
  - Deletion of references to biological materials
- iPS Cells
  - Definition of progeny/derivatives

Next Steps

- Continue to gather feedback on proposed MTAs and MTA principles
- Present principles, model MTAs to AUTM board
- Work with NIH on options to modify UBMTA

So, we will have the tools… How the do the barriers to use come down?

- Advocacy – AUTM, COGR, other organizations
- “Encouragement” by granting agencies
  - Guidance and policy
  - Tools that promote use of standard agreements, discourage use of custom agreements
- Institutions must individually take responsibility