Data Sharing Policies and Procedures in ADC/ADRCs

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Sometimes sharing information is NOT "a good thing"…

Outline

- History (intellectual property)

- Current rules and policies affecting sharing

- Current procedures in ADC/ADRCs for sharing

- Conclusions

Science advances through…

Intellectual Property (IP) = Products of the Human Mind

- Examples of IP for ADCs:

  - Development of research tools like transgenic mice, PIB, etc. or perhaps unique measurement tools like CDR, NPI, etc.

  - Our research itself, the concept, execution and statement of findings

- Property implies ownership – How do you protect ownership of ideas?

Balance of Protection versus Dissemination

Competition

Commercialization

Development

Protection of Ideas
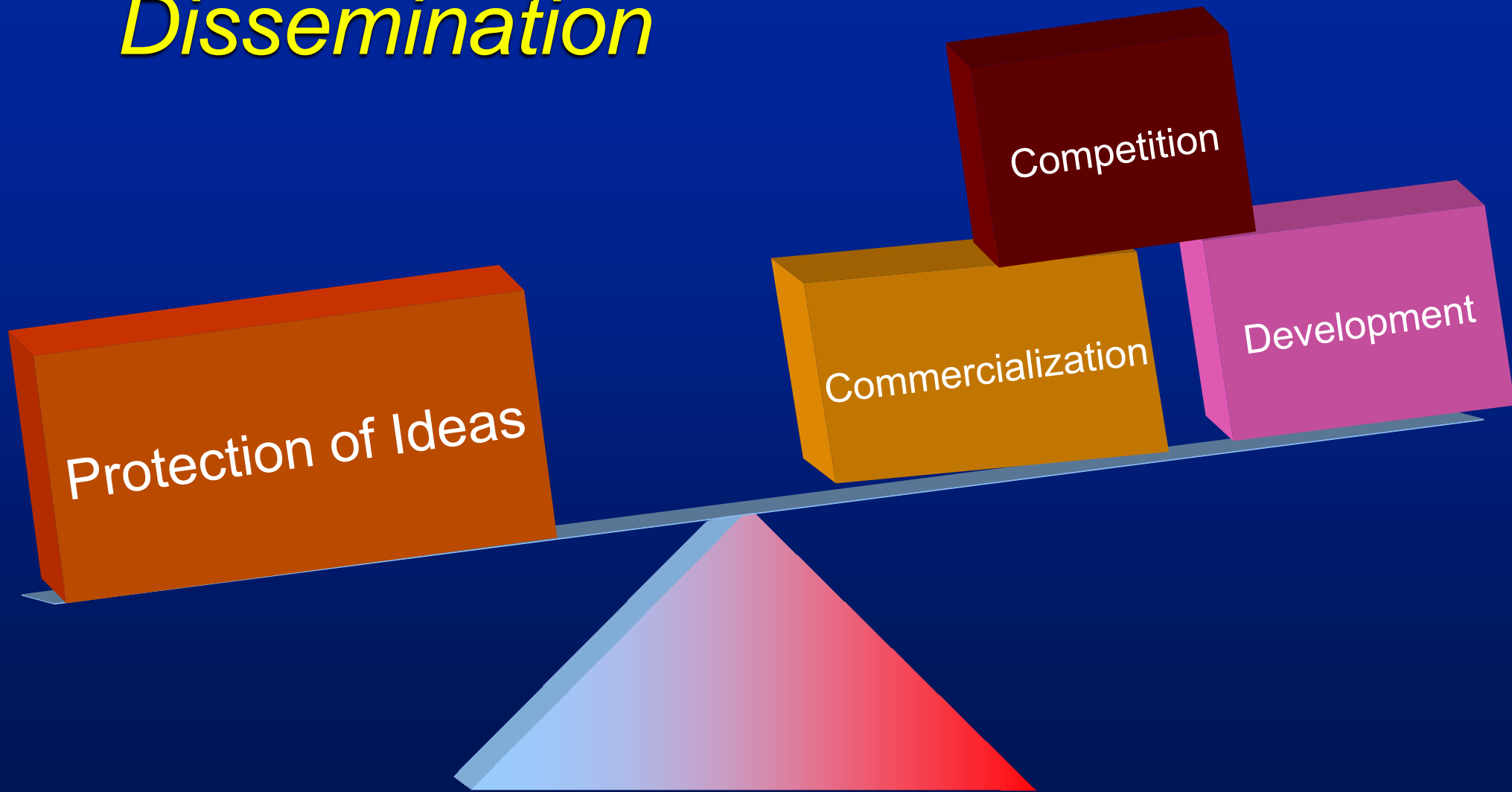
Protection vs Dissemination

- One way to protect intellectual property is to keep it a secret.

- But how do you, or society, benefit or profit from the IP?

- Another way is to patent or copyright it where the owner can control who can use the IP.

- But if the US government supported the development of the idea/invention/process/substance, who owns the IP?

The Bayh-Dole Act of 1980

- Promotes competition by guaranteeing "ownership" to the organizations and individuals producing research tools funded by federal sources (albeit with some reporting requirements and privileges to the US government).

- Intellectual property strategies (e.g. MTAs) for research resources should enhance availability, not limit it.

- Institutions have offices to manage material and technology transfers. Usually your center can influence the transfer language somewhat to assure least restricted use.

Patent/copyright laws are a way of encouraging BOTH competition and sharing

How else can the government promote sharing if science is not moving toward it fast enough?

Require it.

History of data sharing for Centers

- *"In the beginning..."* Wording in RFAs ("Centers are expected to share…") and informal discussion that encouraged sharing

- 1994-6 First formal NIH requirements for sharing of unique resources (e.g. synthetic compounds, cell lines, viruses, cell products, cloned DNA, DNA sequences, nucleic acid and protein sequences; transgenic mice; and intellectual property such as computer programs)

- 1997 ADC Executive Committee and NIA established the interim data center at Rush and asked all centers to contribute to the Minimum Data Set (MDS)

- 1999 NACC established

- 1998-9 Data sharing clauses added to RFAs and Notice of Grant Awards for ADCs

- 2003 Data sharing policy for NIH as a whole implemented

NIH Final Statement on Sharing Research Data (2-26-03)

- Applies to all applicants (not just ADCs) seeking $500,000 or more in direct costs in any year of the project period

- Applies to "final research data" (NIH considers grantees the 'owners' of data they generate)

- Requires timely release of data (no later than the acceptance for publication of the main findings from the final data set)

- Requires that if you cannot share data, explain why not (e.g. sample too small to protect confidentiality)

NIH Final Statement on Sharing Research Data (2-26-03) Cont'd.

Ways to share:

- Publications

- Investigator-specific distribution

- Public archives

- Web site (with privacy protections)

- Restricted access data centers or data enclaves

An investigator can request funds to achieve the sharing or archiving of data in the original application or as a supplement.

NIH Requirements for ADC/ADRCs
(from the RFA)

All competing ADC/ADRCs must submit a data-sharing plan that should address:

- Procedures and policies for sharing research resources (data and biological specimens) with qualified individuals within the scientific community

- Where necessary, issues of intellectual property

- Sharing language must be included in consent documents

Recommend discussion with Institute staff.

Special Policies on AD Genetics Studies

- Sharing is required for all research on genetics of AD regardless of dollar amount
- Specimens and associated phenotypic data for the genetics of late onset AD will be deposited with NCRAD
  - Using the NIA-approved MTA (copies of all such MTAs to NIA)
  - Signed sharing plan agreement (to NIA)
- Sharing with others (not NCRAD) use a Simple Letter of Agreement (SLA; copies of pre-existing and existing agreements to NIA)
- Consent forms should contain appropriate sharing language
- Data/material should be shared no later than 1 year after project period or immediately upon publication, public disclosure or patent
- Report <u>all</u> requests and their outcomes in progress report

Current Data Sharing in ADCs

- ADCs
  - Promote, enhance and support research of many sorts
  - From many sources (internal, external, funded, unfunded, not-for-profit, for-profit, etc.).

- Reporting the sharing of data, tissue and subjects has been a part of our progress reports for some time.
  - Tables for standardizing how we report this information have been provided to and required from all Centers by NIA.

- Projects are more likely to have intellectual property issues.

Procedures for this Report

- Survey of administrators on the ADCAdministrators Listserv

- Requested policies and procedures describing how their centers handle requests for research resources (data, tissue, etc.)

- Of 32 centers, received responses from 27

- May have been some confusion on what was being asked. Some responded that they "didn't have one" (procedures for data sharing)

Overview of Results

- The bureaucracy for requesting resources increases

  – With the size and or maturity of the Center

  – With the value of the resource (e.g. requesting data is simpler than requesting tissue or subjects).

- First contact is the Administrator, sometimes the Data Manager, and in a few cases, the Director.

- Last contact is usually the Data Manager or other appropriate Core (Neuropath Core for autopsy material, Genetics Core for blood, buffy, plasma, DNA; Imaging Core for scans)

Overview of Results

Data sharing in ADCs takes the following forms:

- Sending Core data/tissue to NACC, NCRAD and other collaborative projects that represent a formal agreement through a grant or contract

- Sharing Core data/tiss~~~ investigators through a~~~

- Publishing

- Placing data in a publi~~~

Data placement in a public archive creates one dilemma for us: Can't track closely who uses the data and therefore how productive the data is (not like looking for grant # in PubMed)

Request Process

Initial Request	Review and Decision Process	Resource Conferred

Investigator submits a request: Form & research plan

Resource-specific review committee (e.g. Tissue Committee)

N=~11

Director

Executive or Steering Committee

N=~10

Investigator receives resource

Initial Request

Investigator submits a request: Form & research plan

The requirements for this process varied greatly

- Some ... inform... iables, samp...

- Some ... includ... ges long... to NIA (fund... period, etc.)

- Instru... from "subr... more than a 2 p...

- Some Centers also required PI CV or biosketch (to evaluate whether the requestor is a "qualified investigator")

Some centers provided investigators with background information to assist in making the request and in interpreting the results. These documents might contain a description of the sample, the diagnostic categories, the instruments used, key citations for writing up the data, etc.

Review and Decision Process

Director

Relevant Core Leader (s)

Resource-specific review committee (e.g. Tissue Committee)

Executive or Steering Committee

- In a few centers, reviews and decisions are made by the Director and/or Core Leaders

- Some centers had resource-specific review committees that made recommendations to the Director and/or Executive/Steering Committees

What about rejected requests?

- Most centers relied on their Executive/Steering Committees for reviews and decisions

- One Center sent resource requests for formal review by 2 reviewers prior to Executive Committee consideration

Decision Criteria *(in no particular order)*

Not all centers stated their criteria for evaluation requests, but of those who did, one or more of the following were listed:

- Scientific Merit
- Funding source (e.g., priority given to Center-funded investigators, then University investigators, then outside investigators. No distinction)
- Availability of resource
- Appropriateness of PI qualifications
- Feasibility and IRB issues
- Burden on resources, staff and subjects
- Appropriateness to ADRC goals/themes

Resource Conferred

If request is approved, there might be many 'hoops' and 'strings' attached to the sharing of resources:

Hoops

- IRB approval
- HIPPA documents-limited data use agreement
- Material transfer agreements

Strings

- Acknowledgment in publications and presentations
- Progress reports on the project
- Productivity reports on publications or funding that were derived from the project
- No second-party sharing
- No cost unless the request required effort beyond what could be supported by Center funding (e.g. lots of tissue preparation quickly, complicated data extraction)

Investigator receives resource

What we learned in Kindergarten …still applies.

Conclusions

- Have a plan that deals with
  - Intellectual Property (work with responsible institutional office)
  - Sharing of resources to qualified investigators
    - » Specify procedures for
      - The request process
      - The review process
      - The approval process
      - The distribution process
      - The tracking process (including protections)
  - Appropriate informed consent language
  - Identify collaborative agreements and/or databases to which you contribute

NIH websites on sharing

- NIH Data Sharing documents
  - http://grants2.nih.gov/grants/policy/data_sharing/
- Obtaining &Disseminating Biomedical Research Resources: Final Notice
  - http://ott.od.nih.gov/NewPages/RTguide_final.html
- NIH Final Statement on Sharing Research Data (2-26-03)
  - http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html
- AD Genetics data sharing policies
  - http://www.nia.nih.gov/funding/policies/geneticspolicy.htm
- Sample AD Genetics sharing agreement
  - http://www.nia.nih.gov/funding/policies/geneticsguidance.doc

Add New Investigator Information

INSTRUCTIONS: Please take the time to carefully fill out all of the fields below. Once you click "Submit", your information will be stored in the Resource Database and you will be able to make resource requests from the ADRC. You will only need to enter your information this one time.

Name: `Last Name, First Name`   *e.g. Smith, John*

Institution:

Department:

Street:

City: State: `Select One`

Zip/Postal Code:

Country: `Select One`

Phone:

Fax:

Email:

Submit Investigator to Database (click only once)   Clear the Form

Washington University St. Louis — Alzheimer's Disease Research Center

Tissue Request Form

Investigator: [(Select Investigator Name) ▼]

Date of Request: [_____] *e.g. 1-1-2002 or 1/1/2002*

Project Title: [_____]

Source of Support - *Required*

* Type of Funding: [(Select One) ▼]

* Sponsor: [_____]

* Grant Number: [_____]
* Dates: [_____] to [_____] *e.g. 1-1-2002 or 1/1/2002*
* Total Amount (for entire period): [_____] *e.g. $20,000, $20000, or $20 thousand*
* Primary Investigator (if other than requestor above): [_____]

Purpose

☐ Current or planned research
☐ Abstract submission
☐ Progress report
☐ Journal publication