

Data Acquisition, Management, Sharing and Ownership

University of Ibadan MEPI-J program



What are data?

Research Data are

" . . the recorded factual material commonly accepted in the scientific community as necessary to validate research findings"

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part5.htm#_Access_to_Research



What are NOT research data?

- Drafts of scientific papers; peer reviews
- Communications with colleagues
- Physical objects (from which data are obtained)
- Trade secrets and other undisclosed intellectual property
- Information that could be used to identify a particular person in a research study

http://grants.nih.gov/grants/policy/nihgps_2003/
NIHGPS_Part5.htm#_Access_to_Research



Classes of Data-Related Issues

1. Issues related to **possession**
2. Issues related to **acquisition**
3. Issues related to **use**



Read Case of Rose & Discuss



Who Owns the Data ?

Relevant questions:

- Where is the research being performed?
- Who paid for the research, and under what arrangements?
- Who collected the data ?
- Who provided the intellectual guidance for the data collection?



Sharing: NIH encourages sharing of research data: What are the benefits?

- reinforces open scientific inquiry
- encourages diversity of analysis and opinion
- promotes new research, testing of new or alternative hypotheses and methods of analysis
- supports studies on data collection methods and measurement
- facilitates education of new researchers
- enables the exploration of topics not envisioned by the initial investigators
- permits the creation of new datasets by combining data from multiple sources.

http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm#a1



Are there other times when data should be shared?

- If you know that another lab is “barking up the wrong tree”, do you have an obligation to tell them?
- Are there ever instances in humans subjects research when preliminary data (or information) should be shared with subjects?



Case Study: Use of Data from Human Subjects

- Isaac, a graduate student in Prof's lab, obtains IRB approval for a protocol involving the collection of blood samples from 1000 Nigerians for a study of a certain metabolic disease. Two years after the conclusion of this study, another student in the lab wants to study the genetic risk factors for a cancer prevalent in the same population. The blood samples from Isaac's work are in the freezer.
- Is it OK for the student to use them for her research?



Sharing DNA – The Case of the Havasupai Indian Tribe in the US

- High incidence of Type 2 diabetes
- Tribe seeks help from university researchers (genetic risk factors had been found in another tribe)
- Researchers collect blood samples
- Consent form is fairly broad
 - Many tribe members uneducated
 - Language issues
- Diabetes research unproductive, but . .
- Scientists pursue other lines of research
 - Depression and schizophrenia
 - Interbreeding among population
 - Origination studies
- Tribe felt exploited, embarrassed; cultural myths challenged; rights to land threatened
- The university destroyed the remaining samples and settled with tribe.



NY Times 21 April 2010

Data Access and Security

- Data represents considerable investment of time and money
- Want to protect data from physical destruction and inappropriate dissemination
- Human subjects research can generate substantial private data
- Physical data should be kept locked up -- with only limited access
- Biologicals may need special consideration (power backups etc.)
- Electronic data needs special protection (firewalls, password security etc.)
- Univ of California in the US lost substantial amounts of private data to hackers in 2005
- **Best practice is to limit access to data (physical and electronic)**

Discussion: In labs you have been associated with, how is safety and integrity of data ensured?



Data Destruction

Discussion: Why destroy data ?

- Data retention guidelines vary among fields
- NIH requires data to be saved for 3 years beyond the funding period
- Destruction should be complete (physical or electronic shredding)



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Record Keeping

Discussion: Many different standards exist for maintaining lab "notebooks". In groups of 3-4 discuss:

- What are the characteristics of a good lab notebook?
- Kinds of lab "notebooks" used in labs you have been part of. Compare pros and cons.
- How you learned to keep a lab notebook?
- How will you handle laboratory notebooks when you are in charge?



Ensuring Reliability and Validity of Data

Discussion: In the same groups as before discuss:

- When you were a graduate student, how long did it take for you to gain the confidence of your Prof with regard to data you collected? What was that process like? How did that confidence evolve?
- How is the **validity** and **reliability** of data ensured in your current lab?
- How raw vs. processed data is handled in labs you have been associated with
- How is data communicated to the PI and other lab members?
- Does your lab have an effective chain of command (lab management) ?



Calibration and Equipment Maintenance

Discussion: The reliability and validity of data depends critically on properly working and calibrated equipment. How are these responsibilities distributed in your lab? Does the Prof have ultimate responsibility? What about work done in core facilities?



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Issues Relating to Data Use

- Misrepresentation of preliminary results
 - Oversell prelim data
- Analysis vs. Manipulation
 - Suspect methods: Filtering, normalizing, thresholding, discarding
 - "Data analysis becomes data manipulation when finding what you want takes precedence over representing what is in the data."-Clinical Tools Inc.
- Outliers and statistical analysis
 - Establish statistically appropriate analysis methods *before* experiments are conducted



Issues Relating to Data Use

- **Discussion:** In labs you have been associated with, have there been “standard” analysis methods? Standard statistical methods? How were these “norms” passed on and enforced? Have you had experiences with anyone trying to circumvent these norms?



Issues Relating to Data Use

cont'd

- Sharing data among projects in the lab
 - Ties into authorship issues
- Deciding what data (and lines of research) can leave the lab with graduating students and postdocs

Has anyone had this discussion with their Prof?



Intellectual Property



Commercializing Research Discoveries

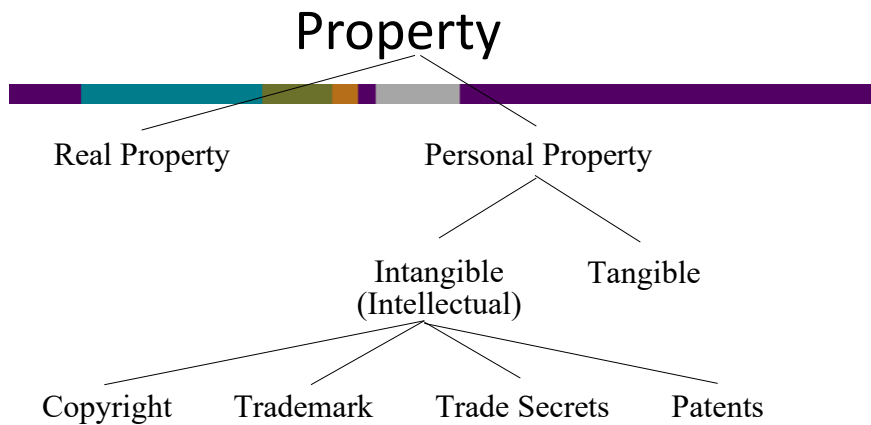
- Problem: US government had lots of patents but little commercial development (poor tech transfer!)
- Solution:
 - Allow universities to retain ownership of inventions from fed funded projects
 - Create uniform rules for tech transfer involving federal agencies
- Universities' obligation:
 - Protect intellectual property with patents and pursue commercialization
 - Share royalties with inventor(s) and institution
- Result: Acceleration of University-owned patents



Commercializing Research Discoveries

- Potential Problems
 - Tighter control of data, publications, and research directions that adversely impact PhD students and junior faculty
 - Conflict Of Interest between PI's lab and company
- How are research discoveries handled in Nigeria?





Patent



- Legal document conferring to the inventors a ***monopoly*** over their invention
- Gives inventors right to ***prevent others*** from making, using, or selling (or offering for sale), the invention in the country that issues the patent without permission
- In return, inventors fully ***disclose*** the invention (in a patent)

A patent is a tradeoff



Criteria for Utility Patent

- Subject matter
 - A process, machine, something that is manufactured, a composition of matter
- Usefulness
 - Typically not a problem- A use can be found for anything!
- Novelty
 - Invention must differ in an important way from existing products in the field (i.e. *prior art*)
- Non-obvious
 - Invention cannot be “obvious” to somebody in the field



What Cannot Be Patented

- Laws of nature and physical phenomena
- An abstract idea (for a new process, machine, manufacture, etc.)

Only an actual invention can be patented.
Must be **reduced to practice**, or so described that another could reduce it to practice



Novelty Criterion

- In US, patent rights go to the ***first inventor*** (not to the first ***to file*** as in many countries)
- To claim novelty, the inventor must demonstrate:
 - First to conceive of the invention
 - Diligence to reduce it to practice (must not have abandoned the invention)

Keep good lab notebooks!!



When Can a Patent Application Be Filed?

- Patent applications must be filed ***within 1 year of disclosure*** to retain rights in the US
- Patent applications (regular or provisional) must be filed ***before disclosure*** to retain rights in most foreign countries
- Disclosure includes:
 - Discussing the invention with a party potentially interested in using it
 - Publishing a paper
 - ***Presenting a poster or paper at a conference***
- ***What are patent rules in Nigeria?***



University Policies and Procedures



Questions & Discussion

