

THE USE OF FEDERAL FUNDED RESEARCH RESULTS

Information on Data Ownership, Patents and
Copyrights



Use of Research Results

- UR and PIs have a responsibility to **use** the results of federally funded research
- Use can be accomplished through
 - Publication and other types of academic exchanges
 - Intellectual Property Transfer
 - Patents
 - Copyrights



What are Research Data?

- Results of original observations
- Notebooks
- Gels, blots
- Photographs
- Computer files
- Video recordings, sound recordings
- Clinical records
- Instrument printouts
- Laboratory strains
- Cell lines, clones, antibodies



Who Owns Research Data?

- Research data is normally controlled by the research investigator, but
- The institution may have ownership rights
- Under sponsored agreements, vesting of ownership is often specified
- Commercial sponsors may have differing provisions with respect to ownership and rights to data (basic research vs. testing)



Rights under Federal Grants

- The federal government has the right to:
 - Obtain, reproduce, publish or otherwise use the data first produced under an award; and
 - Authorize others to receive, reproduce, publish or otherwise use such data for federal purposes



NSF's Expectations

“[NSF] expects investigators to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections, and other supporting materials created or gathered in the course of the research. It also encourages awardees to share software and inventions or otherwise act to make such items or products derived from them widely useful and usable.”

Important Notice 106 April 17, 1989



NSF Requirement

- Effective January 11, 2011, NSF requires applicants to submit data management/sharing plans in all proposals (or to assert the absence of the need for such plans)
- The data management plan should be described in the Special Information and Supplementary Documentation section. The data management plan will be reviewed as part of the intellectual merit or broader impacts of the proposal or both, as appropriate for the scientific community of relevance



Guidance on Data Sharing Plans

- See

<http://www.rochester.edu/orpa/policies/URGuidanceDataSharingPlans.pdf>



Research Data

What are responsibilities of the PI?

- Ensure integrity of scientific data
- Ensure proper documentation, storage and retention of data
- Allow access to data to institution and Government
- Submit correction/retraction of affected data



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Patents



Bayh Dole Act

- Universities are given the right to retain title to inventions funded with federal \$\$ and right to control licensing
- University must share royalty revenue with inventors (see University IP Policy handout)
- University has reporting obligations to funding agency
 - Whether an invention was created
 - Whether University will take title to it



Bayh Dole Act

- The general impact of the Bayh-Dole Act was to put into law the societal responsibility of the University in bringing inventions to public use.
- Government's role in funding innovations is only worthwhile if innovation results in benefit to public. Thus Universities must optimize the transfer of their inventions to public use. Patents are one way of doing this



What is a Patentable Invention

Processes, Machines, Compositions of Matter or
any new or useful improvement to them

Must be **novel**, **useful** and **not obvious** to one
skilled in the art

Simple rule is if you work to solve a problem,
your invention is probably patentable

If in doubt, call UR Ventures (Formerly OTT)



How to Obtain a Patent

- Patent application is filed by URVentures through close collaboration with PI. URVentures uses law firms with expertise in applicable field of science to draft applications.
- Application contains a written description of the invention that typically includes specifications, claims and drawings
- Inventors on a patent are more strictly defined than authors on a publication
- Patent application is “prosecuted” through the US Patent and Trademark Office



Why Protect Research Results that is Intellectual Property?

- Patenting protects our right to continue to research
 - First to file rule
 - Despite common misconception, there is no “experimental use” right to practice another’s patent
- Patenting makes the technology more marketable



What Do We Do with Patents

- Patents are marketed for license to companies for commercial use
- Inventors share in the royalties that come from licenses
- Part of the scheme of Bayh Dole/federal law and policy
- Over 100 patentable inventions are disclosed here per year



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Copyrights



Copyright - Coverage

- Protects original works of authorship
 - Photos, software, charts, written prose
 - Not ideas, or facts; only their expression
 - Does not cover works in the public domain and government works
 - Exists automatically when work is fixed in a tangible medium
 - Registration unnecessary, although useful



Copyright - Rights

- Gives exclusive rights to copyright owner (reproduction, display, performance, eg.)
- Rights last for a limited time – but a long one
 - Currently - life of author plus 70 years
- Copyright duration of older works is complicated; most of what you are likely to use is probably still protected
- See http://www.proquest.com/assets/literature/services/copyright_dissthesis_ownership.pdf



Using Copyrighted Works

- In general, you need the owner's permission
 - Even with attribution!
 - The “owner” may be the publisher, not the author (even for your own work)
- Exception: Creative Commons License
- Exception: Fair Use
 - Do not need permission to make limited use of copyrighted work if the factors are met
 - See UR copyright policy on Library web site



Fair Use

- Balance 4 factors
- 1. Purpose of the Use
 - Educational or Commercial?
- 2. Nature of Work
 - Creative or factual?
- 3. Amount of Work Used
 - Small portion or whole work?
- 4. Market Effect (usually most important)



International Issues

- Generally, when in U.S., apply U.S. law
- Most foreign works will be protected by Berne convention and other treaties
- In other words, treat foreign works as you would U.S. works



Take Aways

- Assume copyright protects a work unless you know for sure that it does not
- Don't assume every “educational” use is Fair Use – think it through
- Seek advice when unsure
 - Library (see copyright policy on website)
 - University Counsel
- Seek permission from copyright holder if in doubt



CONFLICT OF INTEREST



What is a Conflict of Interest?

- When an individual's private interests (usually, but not always, financial) conflicts with, or can be perceived to conflict with, his or her professional obligations (usually, but not always, related to unbiased research) to the University



What is a Conflict of Commitment?

- When outside activities (e.g., consulting, pro bono or public service work) interferes with a faculty member's ability to meet the research, educational, service, and administrative responsibilities of his/her appointment



Federal Policies

- Federal Policies
 - PHS “Objectivity in Research” Final Rule, 45 CFR 94, July 11, 1995. Revised August 25, 2011
 - NSF Conflict of Interest Policy, Grants Policy Manual Section 510, July 11, 1995
- These policies deal with financial interests that would reasonably affect research



UR Faculty COI Policy

- Definitions
 - Faculty: All individuals holding a paid academic, clinical or research appointment with the UR
 - Investigator: Any individual who is responsible for the design, conduct and reporting of research



UR Faculty COI Policy

- Significant Financial Interest:
 - Anything of monetary value, including but not limited to, salary or other payments for services, equity interests, and intellectual property rights, when aggregated for the investigator and the investigator's spouse and dependent children are greater than or equal to \$5,000 in value
 - Exclusions include royalties from applicant organization, financial remuneration from institutions of higher education and governmental entities, etc



UR Faculty COI Policy

- Financial Conflict of Interest
 - A Financial Interest or Significant Financial Interest that the University reasonably determines could directly and significantly affect the design, conduct or reporting of University research



What types of “special interests” might interfere with the proper exercise of judgment on behalf of research?

- Financial
 - Consulting, Advisory Boards, etc
 - Equity
 - Intellectual property (patents, royalties, etc)

- Non-financial



Do Special Interests Influence Research?

Industry sponsorship a/w...	Reference
More favorable study designs	JAMA 2003;289:454
Selective reporting of outcomes	BMJ 2003;326:1171
Omission/suppression of data	NEJM 2006;354:1193
Favorable results repeatedly published	JAMA 1999;282:1752 BMJ 2007;335:1202
Interpretation of the results	JAMA 2003; 290:921 BMJ 2002;325:249 NEJM 1998; 338



How Can COIs in Research Be Managed?

- Disclosure
- Reduce one's interest
- Eliminate one's interest
- Modify one's role in research
- Third-party oversight



Why is COI Such a Big Deal?

- Jesse Gelsinger (1999)
- Changed focus from objectivity of research to endangerment of human subjects
- Several negative OIG audit reports on COI management by NIH and universities
- LOTS of scrutiny from Congress and the public at large



Finally,

- Refer to “Guidelines on Research Integrity and Conflict of Interest: Graduate Students and Postdoctoral Appointees”

