Collaborative Research
Mentoring
Conflicts of Interest
Financial Responsibility
Data management
Publication and Authorship

WHAT IS A RESEARCH COLLATION?

Normally, a significant intellectual contribution by each potential collaborator is necessary for the interaction to be considered a collaboration.

However, perceptions of what constitutes a "significant intellectual contribution" vary.
TYPES OF COLLABORATIVE RESEARCH PARTNERSHIPS

Within the Institution
- Same lab or department
- Interdisciplinary

Between Institutions
- Domestic
- International
- Multi-site clinical trials

Between academia and industry
- Public vs. Private interests

Skills based
- Techniques

Materials based
- Chemical compound
- Cell line
- Genetically altered animals

Equipment based

ASPECTS OF A COLLABORATION:
- Authorship and credit
- Research Accountability
- Intellectual Property
- Use of Data
- Data Retention and Preservation

WRITTEN AGREEMENTS
- Set forth each party’s rights and responsibilities in writing.
- Set forth rights and responsibilities of the researchers’ institutions.
- Are often required by employing institutions or sponsors.

TYPES OF WRITTEN AGREEMENTS
- Sub-award/sub-agreement
- Teaming agreement
- Collaboration agreement
- Intellectual property agreement
- Facility use agreement
- Consulting agreement
- Material transfer agreements

WHAT IS MENTORING?
- The social foundation of research
- One of the primary means for one generation of researchers to impart their knowledge to the next generations
- Teaching by example, being a role model
ROLE OF THE MENTOR
The role of the mentor is often complex and can take on many forms. A true mentor is typically someone who possesses:

- Experience with the research and challenges that trainees face.
- The ability and willingness to communicate that experience.
- An interest in helping another person develop into a successful professional.

A mentor might be a faculty adviser or another faculty member, a project leader, a fellow student, a wise friend, or simply another person with experience.

WIDE RANGE OF NEEDS
There is a wide range of needs to be met. Mentors should:

- help trainees develop as capable researchers
- support trainees’ career development and preparation for the job market
- Steward the socialization of trainees, including guiding ethical development, fostering an understanding of the political, economic, and social elements of interacting within the academic community, and instilling a sense of collegiality.
- Serve as an advocate for trainees. There are times when the mentor has to step forward and support the trainee.

The “truly complete mentor” needed by every trainee actually may be a composite of more than one individual.

RESPONSIBILITIES OF MENTOR
- Be Available
- Listen Carefully
- Keep In Touch
- Allow for Differences
- Let Trainees Make Decisions
- Teach by Words and Example
- Keep Learning about Effective Mentoring

RESPONSIBILITIES OF TRAINEES
- Identify Career Plans
- Locate Prospective Mentors
  Qualities to look for in potential mentors include:
  - Experience in areas relevant to the trainee's personal and career development,
  - An interest in the trainee's career,
  - A willingness to make the time to meet with the trainee, and
  - An ability to provide the trainee with useful advice.
- Distinguish between Supervisors and Mentors
- Be Clear about Needs and Expectations
- Keep Learning about Effective Mentoring

CONCERNS FOR MENTORS AND TRAINEES
- Inherent imbalance of power between mentor and trainee
  - A mentor can use this power to exploit the trainee.
  - A common complaint of trainees is that they are required to spend so much time working on the adviser’s research that they have little time left for their own work.
- The trainee’s fear of jeopardizing the mentor’s support further imbalances the relationship.
  - Mentor’s research vs. trainee’s research

EFFECTIVE MENTORS
The most effective mentors typically take actions that:

- Ensure that the trainee gets the maximum appropriate credit for any joint publications.
- Encourage the trainee to attend and present at national or international conferences, workshops, and symposiums.
- Promote the trainee’s work among colleagues.
- Help the trainee create important professional networks.
- The guiding principle of mentoring should be protecting the interests of the trainee.
Loki has signed an agreement stating that he will avoid contact with felines throughout the duration of his study. He is unaware that his previous agreement to share the kennel with Mr. Woo is a conflict of interest.

**WHAT IS A CONFLICT OF INTEREST?**

- Conflicts of Interest occur when researchers or other members of the institution find themselves in situations in which their responsibilities to the institution are, or may be, compromised by their relationship with outside entities.
- This typically occurs when a researcher (or immediate family member) has a financial interest in a company that is either sponsoring the research project or could benefit from the results of the project.

**WHAT IS A COI, FED STYLE?**

**NSF:**
Investigators must disclose if they have received $10,000 or more in payments during a twelve-month period or if they or their immediate family owns greater than or equal to $10,000 or 5% equity holdings in a company that is sponsoring the research project or that could be affected by the results of the research.

**DHHS:**
"A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000."

The NSF policy and the DHHS both aim to stop or mitigate through disclosure and effective management, the negative effects of financial conflicts of interest.

The FDA regulation is directed toward clinical trials and is somewhat different from the approaches taken by NSF and DHHS.

**WHAT IS A COI, UNR STYLE?**

"Significant financial interest" means:

1. **With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

2. **With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the investigator (or the investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

3. **Intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests.

4. **On behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available.

The full Conflict of Interest policy is located in the Administrative Manual, section 2.691.

**ARE YOU SAYING I CAN’T DO RESEARCH IF I HAVE A RELATIONSHIP WITH A COMPANY?**

- NO! This does not mean that researchers cannot have relationships with companies or other external entities. The involvement of researchers with companies can be beneficial to the researchers, companies and/or the institution. For the most part, this is not a problem.

- On the other hand, when researchers or members of their immediate families have a significant financial interest in a company, the institution needs to be informed of the situation then determine how best to handle the conflict.

**DISCLOSING A COI**

- Disclosure of these relationships is key!
- The INSTITUTION must review each case and make a determination as to whether or not a conflict exists.
- Each case has its unique characteristics and must be evaluated on its own merits.
CONSEQUENCES

• Uphold the public's trust

• An institution that has a reputation for being indifferent to conflicts of interest can suffer from a number of bad consequences

  Examples:
  • loss of prestige
  • lessening of respect for faculty
  • suspicion that research findings are tainted
  • loss of sponsored funding and private donations.

CONFLICTS OF COMMITMENT

• Outside activities in excess of the time permitted by institutional policy.

• Using graduate students on a personal consulting project or business venture.

GUIDELINES

Costs must be:

• ALLOWABLE under sponsor policies,

• properly ALLOCATED to the correct project,

• and are considered REASONABLE.

FINANCIAL RESPONSIBILITY, FED STYLE

• OMB Circular A-21: Sets forth the basic definitions and rules for both direct costs and Facilities and Administrative costs for federal awards.

• OMB Circular A-110: Sets forth the rules pertaining to the management of federal grants and cooperative agreements, but it does not apply to federal contracts.

These are guides. Check the sponsors' terms and conditions for rules.

COST-SHARING

Two central issues involved in cost-sharing:

• Shared costs must meet the same tests as those charged to the sponsored project,

• Shared costs must be effectively tracked in order to permit accurate reporting while meeting the sponsors requirements for record retention.

Compliance is difficult, if not impossible, to uphold if the tracking of cost-sharing is delayed until the end of the project.
EFFORT REPORTING
- Permits a portion of a person's salary to be charged to a sponsored project, based on the amount of time they spend working on the project.
- PIs are responsible for making sure that the payroll expenses charged to a project are an actual reflection of the work done on the project.
- Salary charges initially based on estimated levels of effort must be modified when necessary to reflect actual effort.
- Reports be prepared no less frequently than every six months for all effort by faculty members and staff charged to sponsored projects and other activities.

HOW EFFORT REPORTING WORKS AT UNR
1. Effort is estimated in the proposal.
2. Payroll set up based on PI's estimates of effort.
3. Employee gets paid, based on estimates.
4. After-the-fact certification of how time was ACTUALLY spent. ERS reports sent to departments.
5. Request labor cost transfer if Effort ≠ Payroll within +/- 5%
6. Submit new PAF if effort change will be long term.

WHAT CERTIFICATION MEANS
A legal document in which the certifier agrees that:
1. They have first hand knowledge of 100% of the activities in the report, and
2. The report represents an accurate and reasonable account of work performed.

WHO CAN CERTIFY AN EFFORT REPORT?
1. The employee
2. The employee's supervisor or PI with first hand knowledge of employee's effort
3. A responsible official who used a "Suitable Means of Verification"
   Examples of "Suitable Means of Verification"
   - Email from employee
   - Lab notes
   - Time cards
   - Calendars
   The suitable means of verification becomes part of the legal document.

COST TRANSFERS
- The transfer of costs associated with a sponsored program generally occurs for one of three reasons:
  - when it is discovered that a cost charged to a project is not allowable within the sponsor's policies.
  - when, upon review, it is found that a cost was charged inappropriately and is allocable to a different project.
  - when a project budget is overspent and the excess is charged back to an institutional account.
- Cost transfers should be the exception, not the rule.
- When transfers are required, they should be done as quickly as possible with detailed documentation as to the reason for the transfer.
OliFur testing the security of his data storage package.

**What is Data?**
- Research data: information collected and generated in the course of a research project.
- Financial data: budget information and the record of expenditures incurred in the performance of a project.
- Administrative data: information related, for example, to project proposals, required approvals, and subawards, the inventory of equipment, the management of select agents, the documentation related to export controls, and the intellectual property records.

**Ownership of Data**
- In general, the institution owns financial and administrative data. Sponsored project agreements are executed between the sponsor and the institution.
- An institution may give its researchers some latitude with regard to the management and retention of research data, but with regard to sponsored funding the institution is considered to be the owner of such data.

**The Bayh-Dole Act**
The Bayh-Dole Act governs the rights to inventions discovered in the performance of federally sponsored projects. It allows universities to have control over the intellectual property from federally funded research.
- Responsibilities are given to the institution to comply with disclosure, reporting, and licensing requirements.
- Both the Federal Acquisition Regulations and agency specific grant regulations clearly reserve a royalty-free, nonexclusive license to copyrightable materials or research data generated with federal funds.
- Most institutional policies regard the principal investigator (PI) as the "gatekeeper" of the data but this does not connote a transfer of ownership.
- Since the awards are made to the institution rather than to individual researchers, the clear implication is that the institution retains the responsibility for complying with the requirement to ensure that federal rights are preserved.

**PI Changes Institutions**
There are two basic options for institutional policies:
- Either the researcher may take a copy of the data to the new institution and leave the original data, or
- the researcher may take the original data and leave a complete copy that is identical to the original.

In the latter case, though not necessarily the preferred option, at the very least there needs to be a written agreement that the researcher will retain the original data for the required retention period and will permit authorized individuals to have access to that data.

**Access to Data**

**Research Data**
- Funding Sponsor
- Intellectual Property Licensees
- Institution
- Others: If the research is supported by federal funds, members of the public may seek access to research data by making a FOIA request.

**Financial Data**
- Sponsor
- Institution: Within an institution, access to financial data is generally limited to those having a need for access.

**Administrative Data**
- Sponsor
- Institution
DATA SHARING CONCERNS

Publication vs. Protecting Intellectual Property
- Must balance the need to protect intellectual property rights and interests with provisions that preserve the institution's and researcher's academic freedom.
- Examples: rights to inventions in countries other than the U.S. can be destroyed if publication occurs prior to the submission of a patent application.
- U.S. invention rights can be destroyed if a public disclosure of the invention occurs more than a year before the submission of a U.S. patent application.

Commercialization of Academic Research Enterprise
- Perception that public good is sacrificed for the benefit of private interests
- Perception that researchers are in competition with each other for corporate funding and refuse to share their data with competitor researchers

GUIDANCE ON DATA SHARING

NIH Guidance on Data Sharing
- Researchers supported by NIH funds shall, to the greatest extent and as freely as possible, share data and the results of their research subject to legitimate intellectual property rights. In addition, for large proposals exceeding budget requests in excess of $500,000 in any year, applicants must submit a data sharing plan in which they indicate how the data resulting from the project, if funded, will be disseminated and shared with others.

NSF Guidance on Data Sharing
- "It (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."
- "Section 2, Policies for Openness, recognizes the importance of commercializing the results of research, but the retention of intellectual property rights... does not reduce the responsibility of researchers and institutions to make research results and supporting materials openly accessible."

RETENTION OF DATA

- The OMB Circular A-110 states that the retention period is at least three years from the date the final financial report is submitted.
- If there is research misconduct involving NIH funding, records must be retained for six years after the final resolution date of the case.
- It is important to should check the record retention requirements for each sponsor.

POTENTIAL PROBLEMS

The following are some of the problems that might arise in the management of research, financial, or administrative data.
- Technical data not recorded properly.
- Technical data management not supervised by PI.
- Data not maintained at the institution.
- Financial or administrative data not maintained properly.
- Data not stored properly.
- Data not held in accordance with retention requirements.
- Data not retained by the institution.

PRACTICES THAT CHARACTERIZE RESPONSIBLE CONDUCT OF RESEARCH

- Honesty and fairness in proposing, performing, and reporting research.
- Accuracy and fairness in representing contributions to research proposals and reports.

Office of Research Integrity, U.S. Department of Health and Human Services
RESEARCH MISCONDUCT INCLUDES:

• Fabrication
• Falsification
• Plagiarism

AUTHORSHIP

Who should be credited as an author?

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS GUIDELINES:

Authorship credit should be based on:

1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) drafting the article or revising it critically for important intellectual content; AND
3) final approval of the version to be published.

UNETHICAL AUTHORSHIP PRACTICES

• Authorship by authority
• Gift, courtesy, or honorary authorship
• Political authorship
• Ghost authorship

QUESTIONS?