RESEARCH POLICIES

Cert Class # 12
Wednesday, May 4, 2016
Presenters

Debra Murray  
Assistant Director for Compliance  
Sponsored Program Accounting & Compliance  
ext. 52618, dmurray@umd.edu

Monique Anderson  
Assistant Director, Office of Research Administration  
ext. 56272, manders1@umd.edu

Joe Smith  
IRB Manager, COI Administrator  
ext. 50678, jsmith54@umd.edu
Objectives

- Highlight selected Board of Regents (BOR) and UMD policies relating to research, training and service
- Discuss compliance with BOR/UMD policies and understand the processes necessary for compliance
- Campus resources to assist with compliance
Why are Board of Regents Policies Created?

- Federal Regulation & Law Changes
- State Law
- Campus Needs
Where Can I Find Board of Regents Policies?

www.president.umd.edu/policies

www.ora.umd.edu/resources/um-policies
Is it Board of Regents Policy or University of Maryland College Park Implementation?

**Board of Regents Policies**
- Purely numerical designation
- General principles and framework

**Campus Policies/Implementations**
- Numerical designation + (A), (B) etc.
- Individualized for College Park
VIII-10.40(a) University Of Maryland Policy For Direct Charging Of Costs To Federal Grants, Contracts, And Cooperative Agreements

- Policy provides the institutional standard for determining how costs are charged to federally sponsored agreements
- Follow the general guidelines in sections D & E of 2 CFR 200 in determining treatment of costs as direct or indirect.
New Direct Charging Changes under Uniform Guidance

- Direct charging of administrative costs must be explicitly budgeted and approved by the sponsor.
- Determination on allowability of administrative costs will be made centrally (ORA & SPAC) BEFORE a proposal is submitted.
- Allow time in routing process if admin costs are budgeted and follow guidelines.
New Direct Charging Changes under Uniform Guidance

2 CFR 200.413, Direct Costs

(c) The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

(1) Administrative or clerical services are integral to a project or activity;

(2) Individuals involved can be specifically identified with the project or activity;

(3) Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and

(4) The costs are not also recovered as indirect costs.
ORU & SP

There is a process (and a form!):

http://www.ora.umd.edu/proposal-development/administrative-cost-designations

Proposals that include administrative or clerical costs in the budget will only be submitted if:

(1) ORU or SP status has been requested and approved; or
(2) sponsor guidelines allow administrative or clerical costs; or
(3) the project is not supported in any way by Federal funds
ORU & SP
Organized Research Unit (ORU)

- large, complex program—such as an engineering research center, clinical research center, or other program—that manages large teams of investigators and/or service providers. The designation as an ORU will allow such units to bypass the award-by-award approval process for charging administrative expenses.

- Characteristics:
  i. Expected to be supported largely by external funding and not exert significant claims on State or UMD resources;
  ii. Likely to have been initially established as a result of federal funding with the goal of obtaining alternative funding sources;
  iii. May be located off campus;
  iv. Does not generally offer courses or oversee degree programs; and/or
  v. May report to a Dean's office or other central division, such as the VPR or Provost, but will typically not report to a department chair or director.
ORU & SP

Significant Project (SP)

• Projects that require an extensive amount of administrative or clerical support considerably greater than the routine level of such services provided by a department, institute, or center. Determination of what constitutes a Significant Project will be conducted on an award-by-award basis.

• Examples:
  i. extensive data accumulation, analysis and entry, surveying, tabulation, cataloging, searching literature, and reporting (such as epidemiological studies, clinical trials, and retrospective clinical records studies);
  ii. travel and meeting arrangements for large numbers of participants, such as conferences and seminars;
  v. project-specific database management; management of multiple human or animal protocols across several researchers, and/or multiple project-related investigator coordination and communications.
ORU & SP

- In order to ensure compliance with the federal regulations, the final determination on the allowability of administrative or clerical charges will be made centrally by ORA and SPAC, either BEFORE a proposal is submitted or at the time of a rebudget request to add administrative costs.

- If granted, approval will be noted in KFS so that after-the-fact compliance reports can be generated.

- Projects that receive the designation of “Significant Project” (SP) or units that receive the designation of “Organized Research Unit” (ORU) will be permitted to charge administrative costs. These units would still be responsible for following federal regulations and UMD policies.
IV-4.00(a) University Of Maryland Policy And Procedures For Cost Sharing

- University makes cost sharing commitments only when required by the sponsor or by the competitive nature of the program,
- Cost sharing must follow requirements of OMB Circulars A-21 and A-110
- Cost sharing must be documented and tracked in accounting system
The cost sharing policy has changed

• Any specific mention of effort on a project without salary will be considered cost sharing that requires documentation (i.e. a cost share account)

• Computer equipment under $5k is defined as a supply and will incur F&A costs.
VIII-10.50(A) University Of Maryland College Park Policy Governing Specialized Service Facilities

• **Definition:** A specialized service facility is broadly defined as any major recharge activity that provides specific measurable services to users with total annual revenues in excess of $500,000, or at least $200,000 derived from charges to sponsored contracts and grants.

• **Examples** of specialized service facilities may include: computer centers, animal facilities, wind tunnels, major reproduction facilities, motor pools, and telecommunication systems.
VIII-10.50(A) University Of Maryland College Park Policy Governing Specialized Service Facilities

- Rate proposals are to be submitted to the Contract and Grant Accounting Office at least annually for a formal analysis of costs and recharge rates.

- Specialized service facilities must retain documentation showing how user rates were calculated, the rate review letter from the Comptroller's Office, supporting documents relating to expenses incurred including payroll expenses, records supporting utilization (level of activity), records supporting the amount and basis for user billings, monthly ledgers and annual financial statements of the center.
IV-2.00 - Policy On Solicitation And Acceptance Of Sponsored Projects

- Proposals & Awards reviewed at the institutional level
- Applications may be submitted and awards accepted directly by the designated officer on each campus
- Designated Officer = ORA
IV-3.20 (A) University of Maryland Policy on Intellectual Property

- Sponsored research agreements shall provide that all intellectual property developed by Personnel or Students under such agreements shall belong to the University;

- The University, on a case-by-case basis (as circumstances warrant, and consistent with applicable private use restrictions e.g., under bond covenants), may agree to assign ownership or licensing rights to the sponsor, subject to the University's right to use and reproduce the intellectual property for research and educational purposes.
Intellectual Property and Federally Funded Research

- Research funded, in whole or in part, by a federal agency is subject to specific federal statutes and regulations (37 CFR 401 or the “Bayh-Dole Act”).

- These regulations generally allow the University to elect title to any invention that is conceived of or first actually reduced to practice in the performance of federally-funded research with the purpose of commercializing the invention, subject to the government's rights which include reservation of a nonexclusive license to use the invention world-wide for government purposes.
Revenue Sharing

• Patents: The University shall remit to the inventors or their assignees or heirs, their share of Revenue from inventions as specified in the policy.

• Computer Programs and Software: The University shall remit to the creators or their assignees or heirs, their share of Revenue from computer programs or software as specified in the policy.

• Copyrights: The University shall remit to creators or their assignees or heirs, their share of Revenue from copyrights as specified in the policy.
IV-2.20-Policy On Classified And Proprietary Work

UMD may not conduct classified work at any of its campuses nor may UMD permit the use of its facilities or resources for classified work.

UMD may not accept any agreement that restricts the disclosure of:

- Existence of agreement
- Nature of work
- Identity of sponsor
IV-2.20-Policy On Classified And Proprietary Work (cont)

UMD may accept a sponsor’s proprietary information or materials

- To extent permitted by law, UMD may agree to reasonable efforts to protect information
- Cannot accept liability for proprietary information if efforts fail
IV-2.20-Policy On Classified And Proprietary Work (cont)

UMD may not accept any agreement that prohibits publishing or publicly disclosing the results, however UMD may agree to delay publication by 90 days.

A further 90 day delay may be negotiated with PI’s agreement to reach the maximum of 180 days delay (only to seek patent protection).

This policy does not apply to:

- Consulting or other activities conducted off-campus
- Work conducted without University resources or facilities
VIII-7.10 - Policy On Reporting Suspected Or Known Fiscal Irregularities

Fiscal irregularities include:
- Embezzlement
- Theft
- Falsification of documents
- Financial conflict of interest
- Misuse of University property

General Principles:
- UMD must have comprehensive internal control structure that ensures financial accountability
- Any known, or suspected, fiscal irregularities must be reported immediately to the VP for Administrative Affairs or System Internal Audit Office
Conflicts - Defining and Identifying

Financial Conflict of Interest
• Significant financial interest ($0)

Individual Conflict of Interest
• Supervision of students
• Selection of award recipients
• Knowledge provides competitive edge (example: on detail to agency that is releasing a Broad Agency Announcement)
• Can involve ownership in a company
  - For example, cannot be owner/consultant of company receiving funds and UMD PI.
• Effort is a separate, but related issue
Conflict of Interest

May arise when a UMD employee is in a position to gain financial advantage or personal benefit from his/her position, either through:

• outside professional activities (consulting/ownership) or
• actions or decisions at UMD (PI/Supervision of students/etc)

COI may also arise in context of State Ethics Law

• Restricts the relationships (employment, consulting and other) and financial interests that UMD employees may have with outsiders
  - Under UMD authority or
  - That do or seek to do business with UMD or the State

Prohibits other things like:

• Using prestige of office or confidential information for private gain
• Asking for or accepting certain gifts
• Representing parties in State matters for contingent compensation
COI Policy & Procedures

http://www.president.umd.edu/policies/

II-3.10(A) University Of Maryland Policy On Conflict Of Interest and Conflict Of Commitment

II-3.10(B) University Of Maryland Procedures On Conflict Of Interest And Conflict Of Commitment
COI Policy
University System and State

USM III-1.11 Conflict of Interest in Research or Development
http://www.usmh.usmd.edu/regents/bylaws/SectionIII/III111.html

State Ethics Law Sections 15-501 et seq. of the State Government Article of the Annotated Code of Maryland
http://ethics.gov.state.md.us/
General Policy Overview

- UMD faculty/students/staff have an obligation to **report** actual or potential ethical, legal, financial, or other conflicts of interest and commitment

- Working with supervisors/department chairs/deans, UMD faculty/students/staff must either find means to **resolve or to manage** any conflicts, **or** they must **not participate** in the activities that give rise to them
Disclosure

Disclosure is always good

- Allow the COI Committee to make the final determination

- Significant professional activities outside UMD or the unit
  “significant” to be determined by Unit Head, in consultation with unit faculty and approval by Dean or other appropriate administrator

- Other situations where a conflict or perception of conflict may occur
Key Items: Full and Prompt Disclosure

When to Disclose

- As situations arise, inform Unit Head (defined as the chair or director in an academic department, or a similar official in a non-academic unit, unless a different individual is designated by proper authority)
- Complete COI Disclosure Form and obtain signatures of Unit Head and Dean
- Submit to COI Disclosure Form to ORA or Research Compliance Office
Form and Procedures

COI Submission:
http://www.umresearch.umd.edu/RCO/coi.html

When to file
• Initial Disclosure
• Annual Confirmation
• Change in circumstances
• When relationship ends

FCOI Submission:
http://www.umresearch.umd.edu/RCO/fcoi.html

• Must be submitted prior to proposal for PHS funded research
• Submit through IRBNet
• All “Key Personnel:” Anyone responsible for the design, conduct or reporting of the research.
  - Determined by the PI
• Annual Confirmation
• Change in circumstances
Form and Procedures

COI Form
• full description
• supporting documentation (proposal)
• Ownership information, if applicable
• additional information as requested

Submit
• To Unit Head
  Include proposed management plan to reduce or eliminate real or potential COI
  Unit Head may help develop a management plan with the discloser
• To Dean, then to COI Administrator

FCOI Form
• Follow the IRBNet Smart Form
• Click Sign and Submit
• Disclosure only needs to be submitted in order to have the proposal submitted. Must be reviewed and acknowledged/approved prior to/at time of award
Requirements for Approval

Relationship may not:

• Give improper advantage
• Lead to misuse of students or employees
• Interfere with employees’ responsibilities
• Constitute a harmful interest (an interest found to impair impartiality in the conduct of research, the interpretation of results and/or the determination of research, professional or employment priorities)
• Otherwise violate policies, procedures or best interest of UMCP
Review and Approval

- COI Committee reviews and makes recommendation to President (through the VP for Research)
- Restrictions may be imposed to manage, reduce, or eliminate, any actual, or potential COI
  - May include modifications to investigator’s proposed management plan
- President’s decision is final
- Approval may be withdrawn
  - Misrepresentation
  - Change in circumstances
- Management Plan Approval is filed with Chancellor and State Ethics Commission
Examples

PI & Co-I Married

- In same department, report to the same Chair
- Management Plan
  - Recuse themselves from discussions related to each others’ performance reviews
  - Inform those working on the grant of the potential COI in writing and have them sign indicating their acknowledgement
  - Any concerns or issues of grant employees will be referred to Department Chair or Director of Graduate Studies
Examples

Hiring of a Consultant

• Dr. Jones Consulting w/ Acme, Inc.

• Acme, Inc. awarded MIPS grant
  – Part of work to be conducted at UMD, with Dr. Smith (UMD Faculty) as PI on Joint Project
  – Dr. Smith wants to hire Dr. Jones as a UMD post-doc on Acme, Inc. grant.

• Management Plan: Dr. Jones can be UMD post-doc or Acme, Inc. consultant, but not both.
Examples

Company Ownership

• Dr. Johnson, UMD Faculty, is CEO of ABC, LLC and applies for a MIPS grant as CEO
  – Dr. Johnson is not eligible to be UMD PI of MIPS proposal or to supervise/advise UMD students/postdocs on MIPS project and also be CEO of ABC, LLC
  – Dr. Johnson cedes PI role to a UMD faculty member in her lab as well as supervision of this UMD faculty member to the Department Chair.

• In certain cases, the link cannot be cleanly broken. When this happens, the COI Committee may appoint an Oversight Official.
Questions or concerns?

Who to consult for guidance

- Other Colleagues
- Department Chair
- College Dean
- College Business Officer
- Legal Affairs
- Office of Research Administration
- Sponsored Program Accounting & Compliance
Presenters

Debra Murray
Assistant Director for Compliance
Sponsored Program Accounting & Compliance
ext. 52618, dmurray@umd.edu

Monique Anderson
Assistant Director, Office of Research Administration
ext. 56272, manders1@umd.edu

Joe Smith
IRB Manager, COI Administrator
ext. 50678, jsmith54@umd.edu