

UD RESEARCH ORIENTATION

Engaging in Research at UD



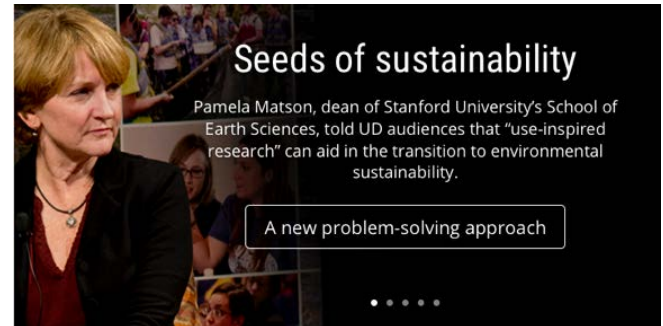
November 7, 2017

A Shared Vision

- Enhancing the success of our students
- Building an environment of inclusive excellence
- Investing in our intellectual and physical capital
- Fostering a spirit of innovation and entrepreneurship
- Strengthening our interdisciplinary and global programs



Operational Excellence



What We Will Do

A Pre-Eminent Learner-Centered Research University

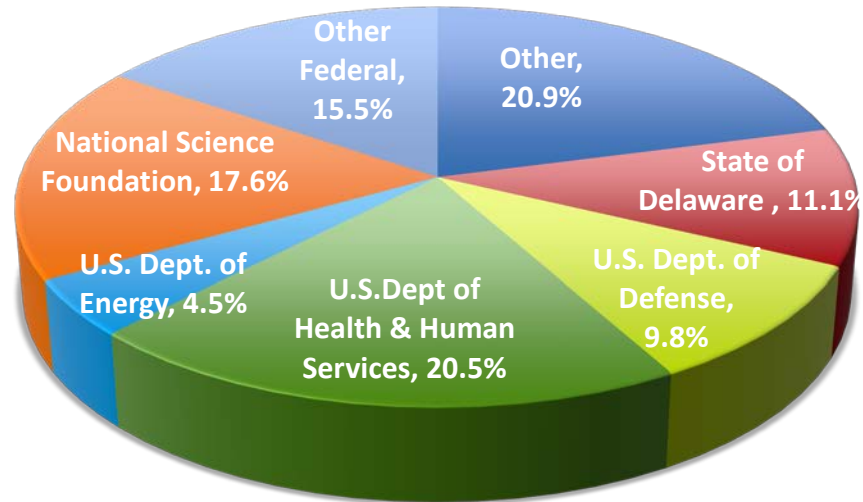
To focus and prioritize our aspiration to be counted among the world's premiere research universities, the University of Delaware sets the goal of achieving scholarly productivity, breadth and impact on a per capita basis that will be on par with the top half of the Association of American Universities (AAU) public universities by 2025.



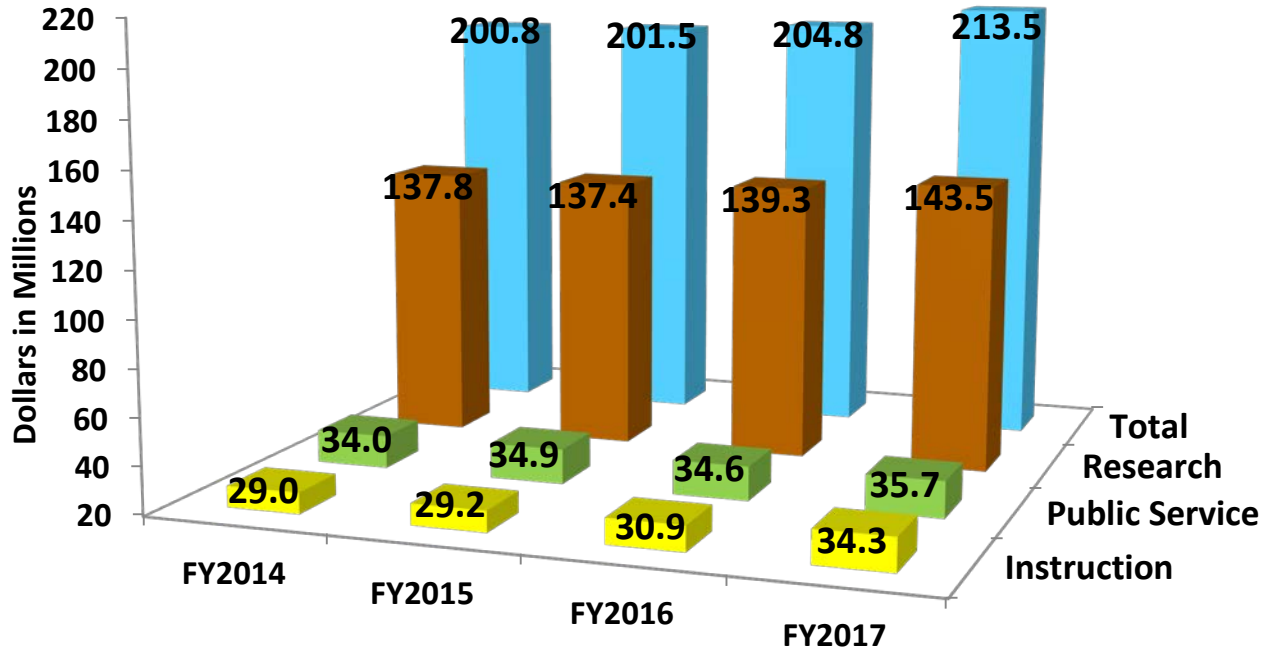
UD: A major research university

- Among **108 Carnegie Foundation “Research Universities with Very High Research Activity.”**
- Among **Top 100 institutions for Federal Science and Engineering Obligations** (without our own medical school).
- **71st nationally in total R&D expenditures** (excluding medical school expenditures)—**Ahead of a dozen AAU institutions** including Yale, NYU, Rice, Stony Brook.

FY 2017 Research Expenditures by Sponsor



Sponsored Expenditures



UD: A major research university

- **>\$210 million** in Sponsored Program Expenditures in FY17.
- Delaware faculty rank **#2 in publications per doctoral holder** and **#3 in articles produced per \$1 million in R&D funding**.
- **Faculty of excellence:** Members of National Academy of Engineering; National Academy of Sciences; National Academy of Inventors. 19 recipients of NSF CAREER awards since 2014.
- Research Institutes: **Biotechnology, Energy, Environment, Photovoltaics, Rehabilitation.**
- **Major grants from NSF, NIH, NEH, Department of Defense, Commerce:** Environmental Science and Policy (\$25 million); Colored Conventions Project (\$75K); Biomedical Research Infrastructure (\$25 million); Clinical Translational Research (\$28 million); Wounded Warrior Rehabilitation Consortium (\$19.7 million); Biopharmaceutical Manufacturing Innovation (\$199M).

A Few Facts from FY16

1717
Proposals

679 Active
Awards

\$910M
Requested in
Funding

1950 Human
Subjects
Protocols

105 Animal
Subjects
Protocols

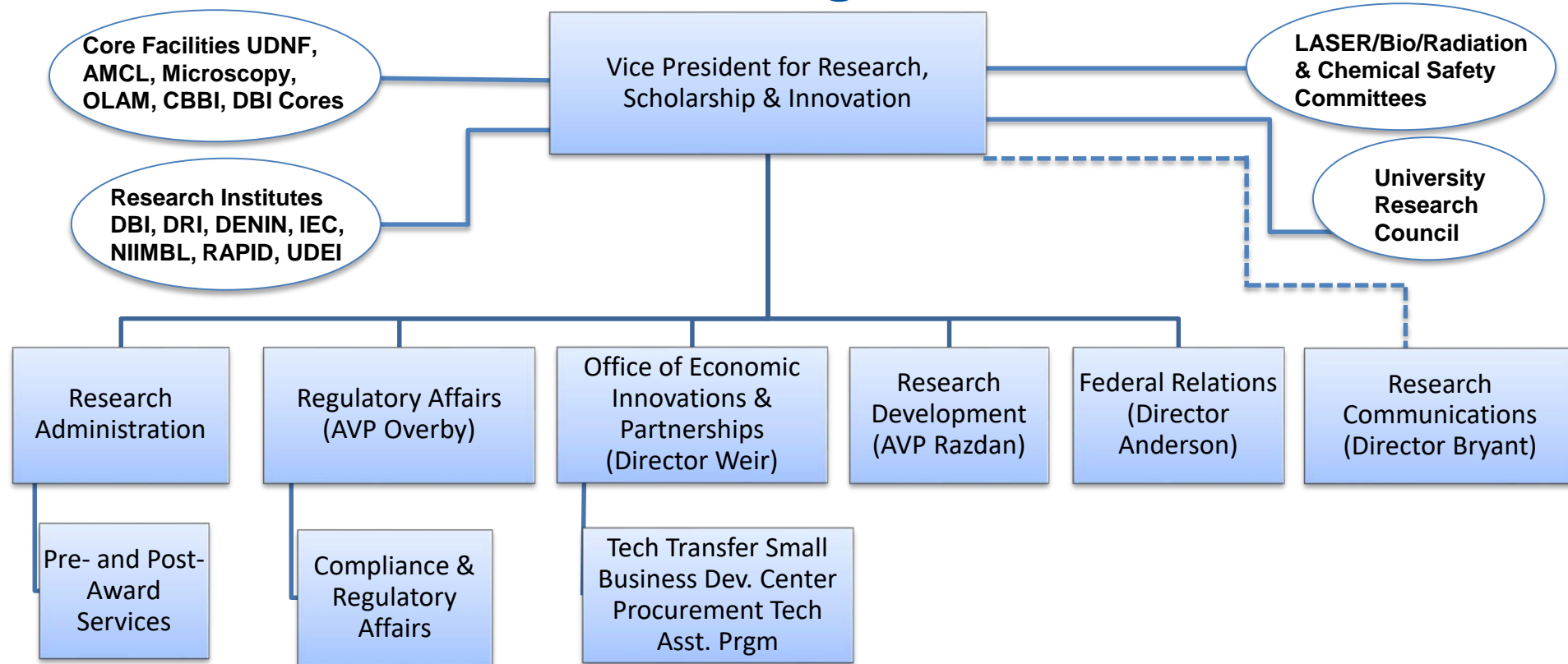
19 Audits

Research Office Mission

- Advance the University's Research Enterprise
- Build leading-edge research programs from existing strengths
- Develop new strengths aligned with UD's Strategic Plan
- Promote the application, impact and awareness of UD research and creative endeavors

**Vice President for Research, Scholarship & Innovation
is the "Chief Research Officer & Advocate"**

Research Office Organizational Chart



Research Institutes

Delaware Biotechnology Institute (DBI)

Delaware Environmental Institute (DENIN)

Institute of Energy Conversion (IEC)

University of Delaware Energy Institute (UDEI)

Delaware Rehabilitation Institute (DRI)

Interdisciplinary Humanities Research Center (IHRC)

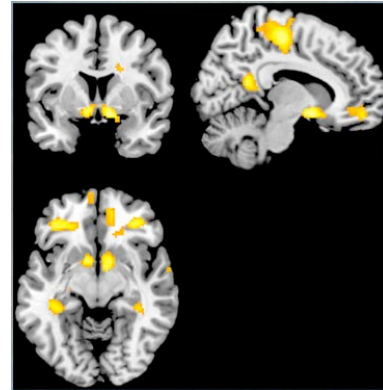


Clinical and Translational Research Center (CTR)

BADER Consortium (Wounded Warrior Project)



Center for Brain and Biomedical Imaging



Opened spring 2016

Research Communications



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2. [News Briefs](#)
3. [Coming Events](#)
4. [Recent Award Recipients](#)
5. [Funding Opportunities](#)
6. [For Research Administrators](#)



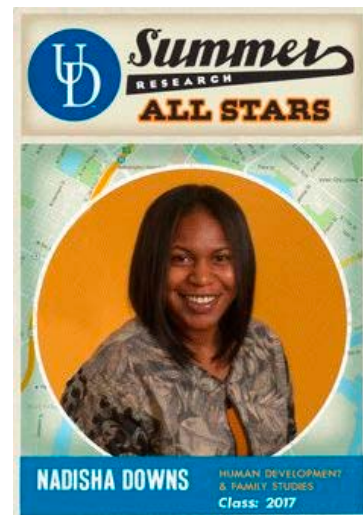
Charlie Riordan Retweeted



#UDel professor Rodrigo Vargas wins @NSF Faculty Early Career Award to investigate blue carbon
[@UDcanr ow.ly/Kf1m30g5N2n](https://www.udel.edu/research/2017/08/21/rodrigo-vargas-wins-nsf-faculty-early-career-award-to-investigate-blue-carbon/)



INSIDE
WHEN THE WORLD TURNS UPSIDE DOWN
Climate researchers serve as messengers for recovery
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WHAT SCIENCE WRITING CAN TEACH US
Keri Dunbar shows the path to clear thinking
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WHERE AMERICAN ATTITUDES TOWARD ISLAM BEGAN
The country lays its roots in a nation
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Research
Office

Cordell Overby

Assoc. VP, Research & Regulatory Affairs

Research &
Regulatory Affairs

Cordell Overby, Sc.D., Ext. 2383
Diane Hess, Adm. Asst., Ext. 2136

Animal Care
Program

Gwen Talham, D.V.M.
Ext. 2980

Frank Warren, C.L.A.T.
Ext. 2400

Human
Research
Protection
Program

Maria Palazuelos, Ph.D.
Ext. 8619

Nicole Farnese-McFarlane, M.S.
Ext. 1119

Export
Controls &
Secured
Programs

Sean Hayes, J.D., Ph.D.
Ext. 7445

Research
Related
Matters

- COI
- MTA/NDA
- RCR
- Agreement Questions
- FOIA



Research
Office

Anshuman Razdan “AR”

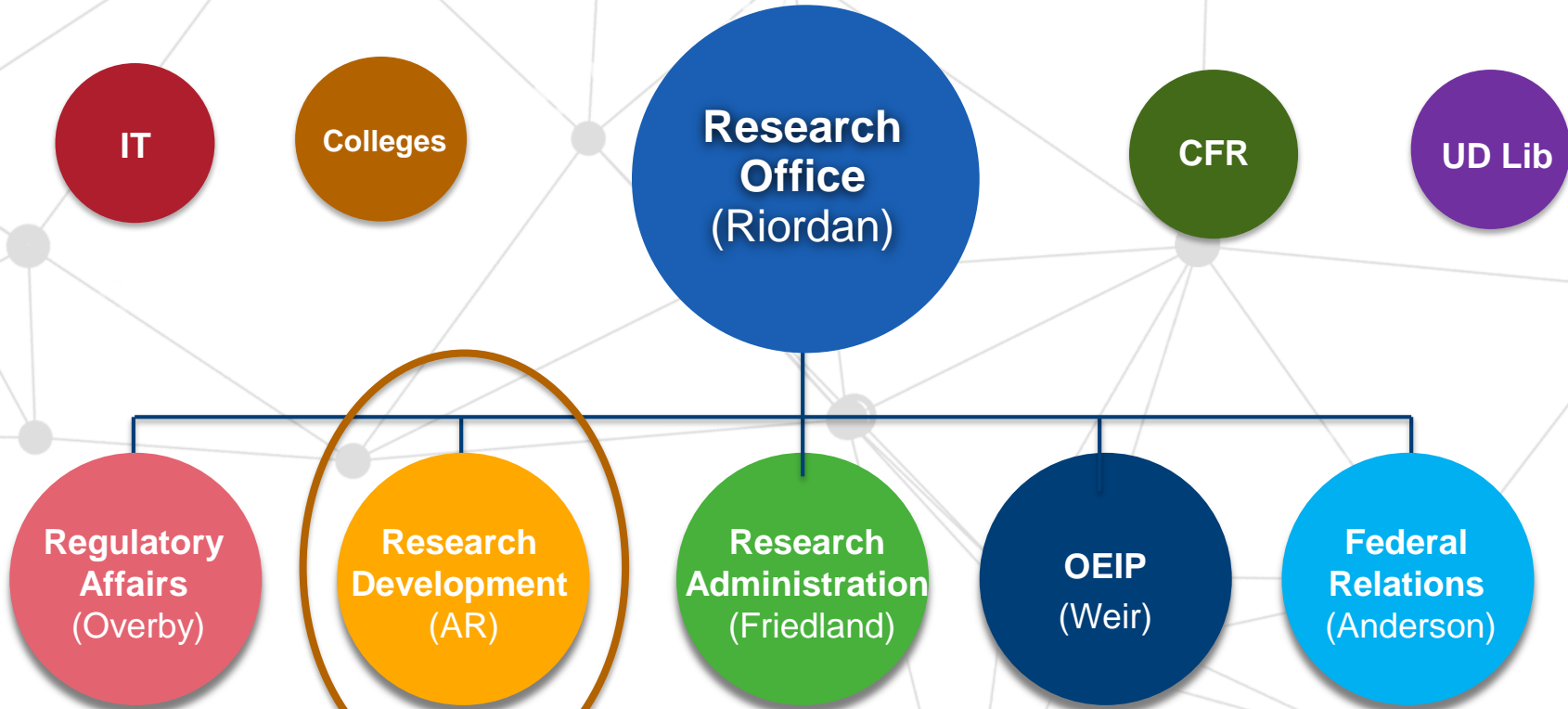
Assoc. VP *for* Research Development
(razdan@udel.edu)

Research @ UD

- Think bigger
- Think broad spectrum
- Think interdisciplinary
- Think collaboratively within and across organizations
- Impact socially, economically & globally



UD Research Office



RO Mission

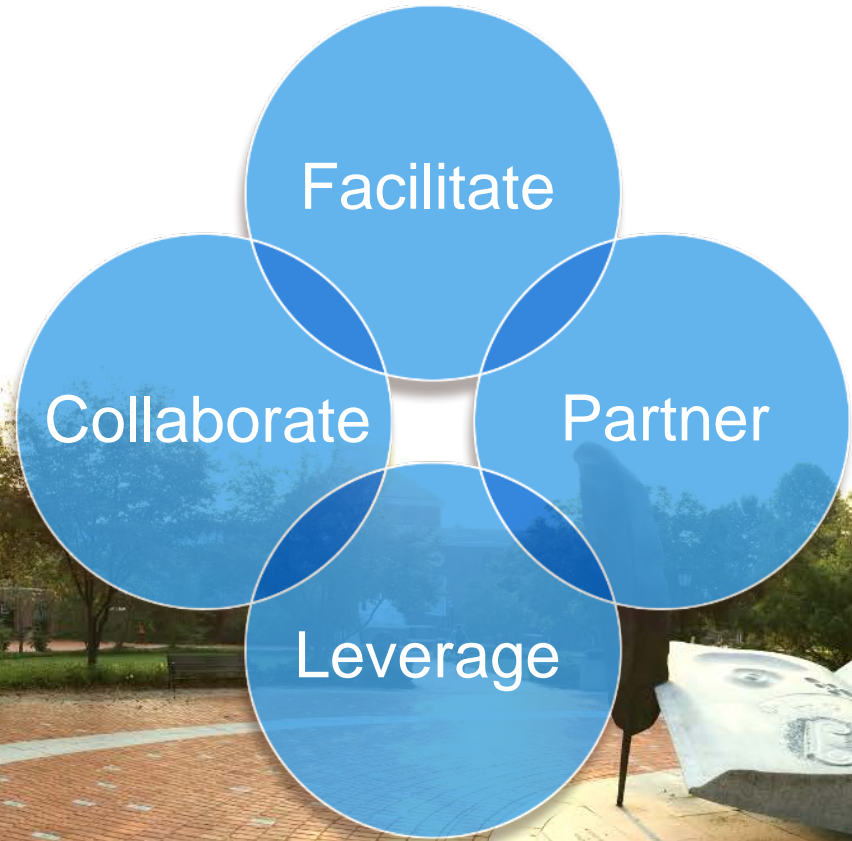
From Ideation to Submission and beyond!

- **Advance** the University's Research Enterprise
- **Serve** Faculty and Researchers in meeting their scholarly/research goals
- **Leverage** current strengths to build leading-edge research programs
- **Facilitate** development of new strengths aligned with UD's Strategic Plan
- **Enable** partnerships, innovation and entrepreneurship, and champion Tech Transfer
- **Promote** UD research and creative endeavors at local, state and federal level

Research Development

Research Development is a ***service oriented*** approach to strategic, proactive, catalytic, and capacity-building activities designed to facilitate individual faculty members, teams of researchers, and central research administrations in attracting extramural research funding, creating relationships, and developing and implementing strategies that ***increase institutional competitiveness.***

Research Development Strategic Cornerstones



Sponsored Activities

**Basic & Applied
Research**

Training

Service

Industry

Federal

State

Industry

Foundations

UD Strengths

RDO Strategic Activities

- Exploring and mapping new opportunities
- Large and/or Complex teams and proposal development, cost shares, LOS, etc.
- Research Dean's Council
- Communication
- Laisse with other UD/outside units
 - CFR, Libraries, IT, VA, CTR, INBRE
- Analytics: UD Capabilities, Capacities and Aspirations (CCA)

Training and Workshops



Grant Writing workshop had over 130 participants

Research Focused

- Grant writing
- Early Career
- **NIH 101 (coming spring 2018)**
- RCR
- Research Orientation
- COS Pivot
- Internal Funding Opps.
- Faculty leadership/mentoring

Training and Workshops



Water workshop had over 70 participants

Thematic Research

- Water
- International (2 so far)
- Data Sc. (May 12th)

Research Communications



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In the Spotlight



Building the future with biopharmaceuticals

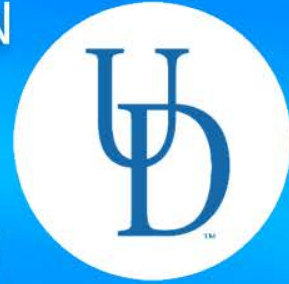
Fourteen shovels plunged into a symbolic mound of dirt on UD's

Research Development Excellence Goals

- **Increase expenditures with a focus on medium and large awards (as a ratio of total)**
- **Number of medium (>2M), large (>5M) and super large (>20M) proposal submissions**
- **New Initiatives (Data, Manufacturing, One Health, Water, ...)**
 - supported by external funding/ philanthropic donations(?)
- **Serious run at one or more NSF ERC, STC, Mission Agency large center(s), NIH Pxx**
 - Build upon successes of Manf. Institutes (NIIMBL, RAPID)
- **Increase number of RO1 funded researchers, career/young investigators**
- **Renewal of or new infrastructure grants**
 - CTR, INBRE, COBREs, EPSCoR and other (NIH/NSF MRI)
- **Sustained branding of the institution (UD) and Research Office w.r.t. research marketing**

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PARTNER INTRODUCTIONS

Office of Economic Innovation & Partnerships (OEIP)

- **Technology Transfer**
 - Invention disclosure, patentability & marketability analysis
 - Patent procurement & commercialization
- **Small Business Development Center**
 - Start-up assistance, business advisory services
 - SBIR training & assistance
- **Corporate Partnerships**
 - Industry liaison, sponsored research



Research Communications: A Partnership with You!

*Increasing UD's visibility as a
leading research institution*

Office of Communications & Marketing

Contact us when ...

- You're doing something really cool
- Your journal article is accepted for publication
- You've won a grant, patent, award or honor
- You'll be doing fieldwork in an interesting/remote location
- Your student/postdoc has made a major achievement
- A reporter has contacted you to do an interview



CONTACT US

Have a UDaily story idea?

ocm@udel.edu



Doctoral student Desiree Narango has a new paper that shows how native trees provide more caterpillars for birds than their non-native counterparts.

DOCTORAL STUDENT INVESTIGATES FOOD WEBS

Article by Adam Thomas | Photos courtesy of Desiree Narango and Doug Tallamy | October 27, 2017

UD's Desiree Narango looks at how residential yards impact food webs

University of Delaware doctoral student Desiree Narango is researching trees and shrubs planted in the lawns of homeowners throughout the Washington, D.C., Maryland and northern Virginia areas to assess how those choices are impacting food webs.

Narango, who is working with Doug Tallamy, professor of entomology in UD's Department of Entomology and Wildlife Ecology, is also associated with the Smithsonian Migratory Bird Center and works through a citizen-science program called "Neighborhood Nest Watch." Narango is co-advised by Pete Marra, director of the Smithsonian Migratory Bird Center.

EXPERTS AT THE UNIVERSITY OF DELAWARE

[Experts Home](#) | [Help](#)



[DOWNLOAD HI-RES PHOTO](#)

Thomas H Epps III

Chemical & Biomolecular Engineering

Journalists: Andrea Boyle Tippet (UD Media Relations) can assist with interview requests for this expert. 302-831-1421, aboyle@udel.edu

- Research focuses primarily on designing, building and characterizing new polymers.
- Works in materials design and fabrication to create conducting membranes for current and next-generation energy generation and storage devices, such as batteries, fuel cells and solar cells.
- Winner of the Presidential Early Career Award for Scientists and Engineers and the Air Force Young Investigator Award.
- Can discuss block copolymers, solution assembly, nanostructured materials, scattering, electron microscopy and thermodynamics.

Curriculum Vitae:

<http://www.che.udel.edu/pdf/facultycv/21890cv.pdf>

Web Site:

<http://www.che.udel.edu/directory/facultyprofile.html?id=21890>

Titles:

Thomas and Kip Gutshall Associate Professor, Chemical & Biomolecular Engineering
Associate Professor, Materials Science

UDaily Articles:

[Epps, DuPont receive NSF funding to develop new approach to manufacture nanostructured arrays](#)
[UD researchers demonstrate that processing can affect size of nanocarriers for targeted drug delivery](#)





Research & Discovery [PLAY ALL](#)



Headquarters for National Institute for Innovation in
University of Delaware
464 views • 1 week ago



University of Delaware team brings Arctic to life using
University of Delaware
203 views • 1 month ago



UD invention may make spacesuits safer
University of Delaware
1.9K views • 1 month ago



Students explore hands-on research through Research
University of Delaware
58 views • 1 month ago



'Brain Camp' gives students intensive introduction to
University of Delaware
359 views • 1 month ago

UD RESEARCH ORIENTATION 2017

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Tweets	Following	Followers	Likes	Lists	Moments
2,175	859	1,396	871	0	0

UD Research

@UDResearch

Explore the latest research news and events from @UDelaware. Follow us for science, tech, humanities and other cool stuff.

Newark, DE, USA

udel.edu/research

Joined April 2009

615 Photos and videos

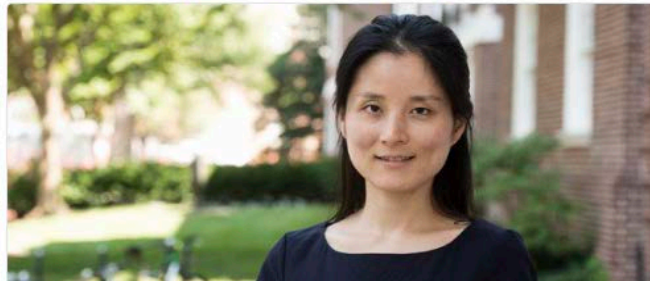


Tweets Tweets & replies Media



UD Research @UDResearch · 2h

#UDel's Tingyi Gu wins @AFOSR Young Investigator Award to build light-speed communications ow.ly/yQpO30goclJ @UDEngineering #UDNanofab



Who to contact ...

- Tracey Bryant, Director for Research Communications
tbryant@udel.edu / 302-831-8185
- Your College Communications Leader

We work together!

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RESEARCH OFFICE OVERVIEW

Research Development Office

Services include:

- Resource and infrastructure development
- Identification and dissemination of funding opportunities
- Management of the limited submission process
- Assistance and coordination of large and complex proposal efforts
- Proposal development and campus outreach activities
- Management of UD's internal UDRF, GUR and Fraunhofer-UD programs
- Assistance with the creation and maintenance of collaborative partnerships

General University Research (GUR)

Mission: The budget of the "*University of Delaware*" provides for assistance to full-time faculty for individual research and professional development through "*General University Research Grants*." These merit-based grants are administered by the Vice President for Research, Scholarship and Innovation and Grant Program, who is advised by the Research Committee of the Faculty Senate. The Research Committee recommends allocation of the funds available for the year, evaluates applications, and recommends those to be supported. **GUR grants** are awarded primarily in the arts, humanities, and social sciences. Proposals involving interdisciplinary research are especially encouraged.

Grants vary in amounts and are capped at **\$15,000**. Proposals are approved on the basis of individual merit, and support such costs as technical assistance, equipment, supplies, travel, and graduate student salaries. The maximum total budget allocation for PI salaries is \$5,000.

University of Delaware Research Foundation (UDRF)

Mission: The **University of Delaware Research Foundation, Inc. (UDRF)** is a nonprofit, tax- exempt organization for the support of fundamental research in all fields of science. Although an independent corporation, it is chartered primarily to support the University's research mission. In 1994, the UDRF Board of Trustees redefined its mission as follows to focus on assisting only early-career permanent faculty as follows:

“The Mission of UDRF is to support the research mission of the University of Delaware in strengthening research and increasing national and international distinction of select graduate programs. In so doing, we will:

- Provide grants supporting the highest quality engineering and scientific research;*
- Focus on assisting early-career, untenured, tenure-track faculty in areas of primary interest to the University, and*
- Provide funds that supplement, but do not supplant, funds available from the University or other sources.”*

The typical **project budget is \$35,000** of which \$25,000 can be requested from the sponsor with an additional \$5,000 each in match from the Provost and the respective College Dean. Special Circumstances that warrant additional personnel may be addressed and larger budget amounts will be considered on rare occasions.

UDRF- Strategic Initiatives

Mission: Established in 2008, the **UDRF- Strategic Initiatives** program supports high-quality, collaborative, scientific research projects in alignment with the University's new strategic plan, *Delaware Will Shine* (DWS). Proposals should address one or more of the seven grand challenges in DWS. In addition, the UDRF- SI program requires a joint proposal from an untenured, tenure-track faculty member and a tenured faculty member.

The typical UDRF- SI project **budget is \$45,000** of which \$30,000 can be requested from the sponsor with an additional \$5,000 in match from the College Dean and \$10,000 from the Provost. If a larger amount is requested (up to \$60,000) the proposal should specifically address the need, benefits, and impact of a larger project.

Examples of Previously Funded

May be found at <http://www1.udel.edu/research/preparing/funding.html> along with guidelines, deadlines and FAQs

- Call for proposals & guidelines typically released in July
- UDRF overview meeting in early September
- UDRF- SI grant deadline is typically the end of September
- GUR overview meeting typically in mid- October with grant deadline in mid- November
- UDRF grant deadline is typically in mid- January

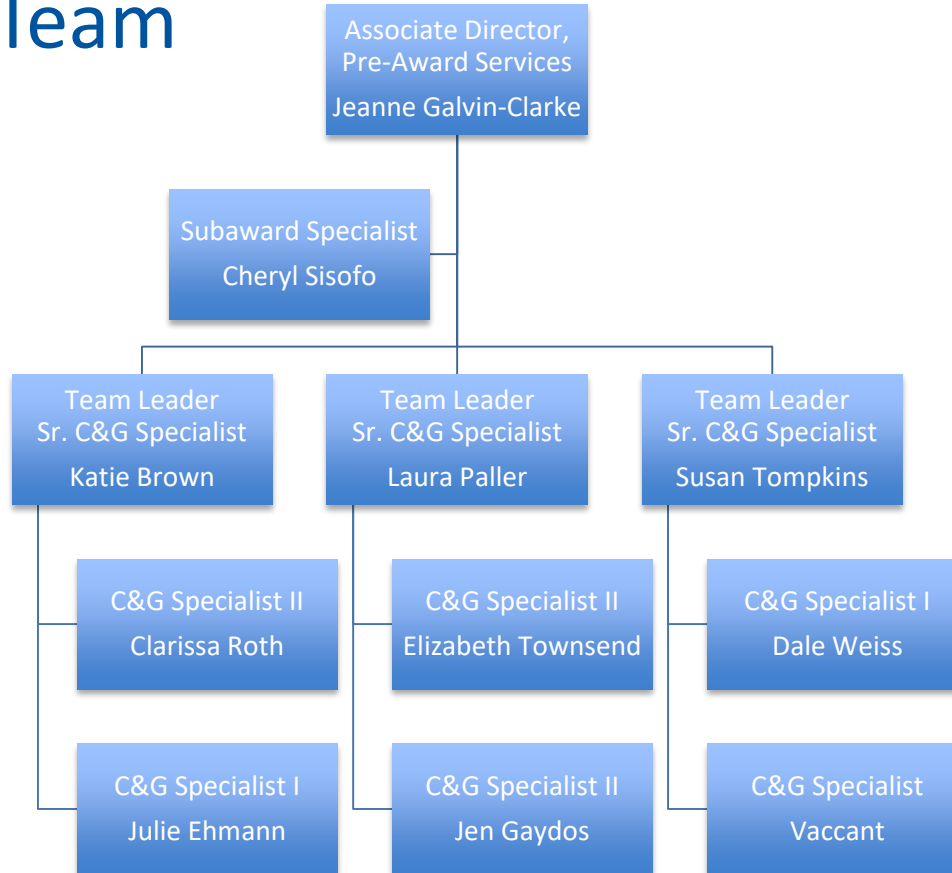


research.udel.edu

Best way to reach us: researchdev@udel.edu

- **Leigh Botner**, *Research Development Director*
 - lbotner@udel.edu – 831-7088
- **Dr. Anshuman Razdan “AR”**, *Associate Deputy Provost, Research Development*
 - razdan@udel.edu – 831-4717

Pre-Award Team



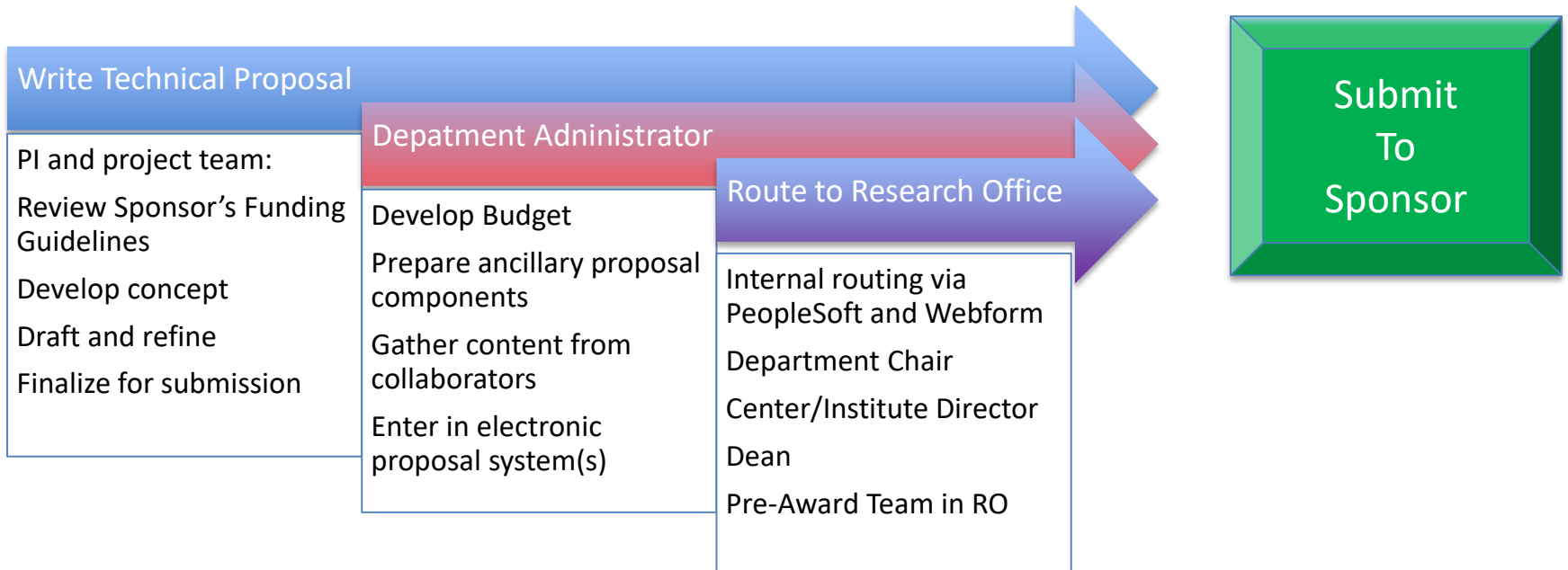
Pre-Award Team

- Proposal Review and Submission
- Negotiation of Grant and Contract terms and conditions
- Award Acceptance and Initiation in Accounting System
- Subawards
- Award Management: contractual changes, approvals, interpretation of policies and regulations
- Annual non-competing applications, Supplements, Project extensions

UD Policies re: Proposals

- **External Sponsorship and Grants**
 - ALL proposals and awards ... must be approved and signed by the Vice Provost for Research or his or her designee
 - UD's "Authorized Official" for externally funded awards
- **72-hour policy**
 - UD researchers need to have their proposals to UD Research Office **by 8:00 a.m. three business days prior to the sponsor's deadline** — or they will not be submitted to the sponsor.
- Why? We want to help your proposal be successful!

How Do I Submit a Grant Proposal?



Electronic Research Administration

- PeopleSoft Proposals & Award Financial Management
- Cayuse for submission to Federal Agencies via Grants.gov
- Sponsor-specific systems: NSF Fastlane, NIH eRA Commons, DOE , USDA, NASA, CDMRP, ONR, AFRO Proposal Central, AHA, and the list goes on...
- UD-at-a-Glance (portal into UD's financial system)
- Webforms – UD's e-routing system

Welcome to the Researcher's Toolbox

The Research Office is committed to encouraging and supporting the research activity of UD faculty and staff. Whether you're a first-timer or a veteran at developing research proposals, you will find the tools you need here to prepare your proposal, manage your grant, protect your great ideas and inventions, and present your results to the scientific community and the public.

- [Compliance Hotline](#)
- [Reporting Misconduct](#)
- [Conflict of Interest](#)
- [Roles and Responsibilities](#)
- [Web Resources](#)
- [Research Administrator's E-Newsletter](#)



Preparing your research proposal



Open List ▶

Managing your grant



Open List ▶

Protecting your results



Open List ▶

Presenting your results



Open List ▶

Research Office interactive Staff Directory

MECHANICAL ENGINEERING

Your Contract and Grant Administrator is:

Elizabeth Townsend
302/831-7274
TOWNSEND@UDEL.EDU

Your Department Administrator is:

Michele Jennings
302/831-7700
MICHELEJ@UDEL.EDU

Your Effort Administrator is:

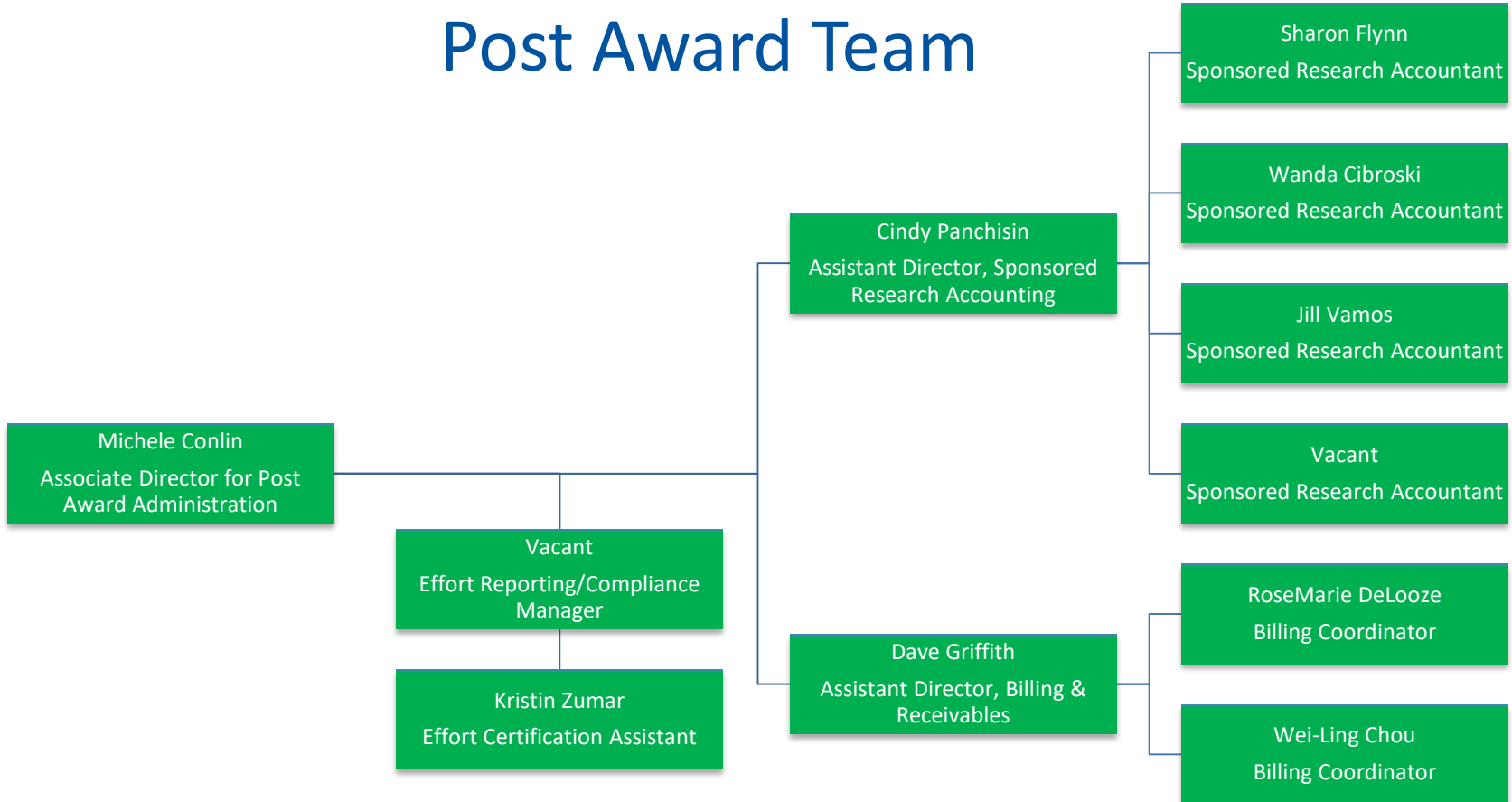
Tyrese Cason
302/831-0535
TYRESEJ@UDEL.EDU

Your Award is Funded

Pre-Award Team assistance

- Award Acceptance and Initiation in Accounting System
- Subawards:
 - Issue subcontracts to other parties
 - Manage changes, invoices and Close-out
- Award Management:
 - Changes to budgets, scope of work, terms of the award
 - Submitting requests to and obtaining approvals from Sponsors
 - Interpretation of Sponsor regulations, award terms, University policies
- Annual non-competing applications, Supplements, Project extensions

Post Award Team



Post-Award Team

- Financial Reports
- Allowability of Costs
- Cost Transfers
- Billing and Collections
- Close-out
- Audits
- Effort Reporting

Getting Started

Maintaining the Award

Closing the Award

During the life of an award, there is no substitute for good practices in tracking and reconciling your transactions. If you keep good records, are proactive in reconciling your transactions, and prompt in making corrections, your close-out audit should be trouble-free. Knowing the financials data and how to get it is the key to success.

There are several tools that will prove invaluable to this process.



Resources (Click on subject to expand or collapse it's contents.)

- Useful Tools
- Administrative Salaries
- Budget Revisions
- Capitalizing Fabrications
- Cash and Billing
- Cost Accounting Standards (CAS)
- Cost-Share
- Cost Transfer (Journal Vouchers)
- DHHS Salary Cap
- Effort

Web Resources

NEW 3-rd Party Cost Share Contribution Template

90-day Cost Transfer Job Aid

Automated Closeout Report (ACR) Job Aid

Automated Closeout Report (ACR) webform login

Cash Advance Worksheet

Problematic Charges on Grants

General Accounting

Effort Certification System

Human Resources

LAM/Obligations (FIPRD)

Procurement Services

UD Financials reporting (FIRPT)

UD Financials Systems Information

UD Grants System (FIPRD)

UD Webforms

UD Webviews

UDataGlance

Administrative Roles & Responsibilities

Principal Investigator

- Assume overall responsibility for all programmatic aspects and financial stewardship of an award
- Initiate proposal submission, create project plans
- Supervise project performance and ensure research integrity
- Complete and submit technical reports
- Initiate requests for award revisions
- Manage subaward performance
- Review and approve effort certification
- Ensure delivery of project results to Sponsor and timely close-out of award

You are not Alone

Department Administrators

Research Office Contract & Grant Specialists

Research Office Sponsored Research Accountants

Research Office Billing & Collections Team

Research Office Team for Compliance and Regulatory Affairs

Research Development Team

Research Office Executive Support Team

Research Data Management

Goals & Best Practices

Campus Resources

Aletia Morgan
Institutional Data Manager
ahmorgan@udel.edu

What is Research Data Management?

The processes by which a researcher plans for, describes and executes the handling of data throughout the research project lifecycle. A **Data Management Plan** describes how you plan to collect, store, organize, analyze, protect, share and archive the data produced as part of your research project.

Research Data Management Goals

- Conform to legal & ethical responsibilities
- Ensure the validity of your valuable research data
- Support the reuse of research data to validate and extend findings
- Manage risks inherent in the collection, storage, preservation and sharing of research data
- Enhance your visibility and impact
- Meet funder and publisher mandates

Getting Started with Data Management

Data Management Begins Before Your Research

Data Management should be part of the initial project planning. A clear understanding of how you will collect, protect and preserve your data will improve your proposal, your DMP and your research workflow.

Review Funder Data Management Requirements

- By Directorate or Program
- Specific Solicitation Requirements

Use your UD Resources

- Departmental IT
- Research Office
- Campus IT
- University Library

Key Contacts:

Research Office

Aletia Morgan

Institutional Data Manager
(Joint appointment,
Research Office & IT Security Group)

ahmorgan@udel.edu

Information Technology

Anita Schwartz

Scientific App'l Consultant

anita@udel.edu

University Library

Monica McCormick

Associate University Librarian for Scholarly
Publishing and Research

mmcc@udel.edu

Tom Melvin

Reference Librarian
Research DMP Training Expert

tmel@udel.edu

Call Us early in your Project Planning!

Campus Web Links for RDM Guidance & Support:

Information Technology

[Data Management Principles](#)

Key considerations through each step of the research process

[Research Security & Risk Management](#)

Steps to assess the risks associated with your research data

[Secure UD Research Security Plan Documentation Tool](#)

Word document form that you can fill in to document your security practices – may be of use when responding to a required Data Use Agreement

[Research Computing Data Management Reference](#)

Examples of resources for Data Management activities, including the free [DMPTool](#)

[SecureUD Home Page](#)

Campus wide security policies and resource guidance

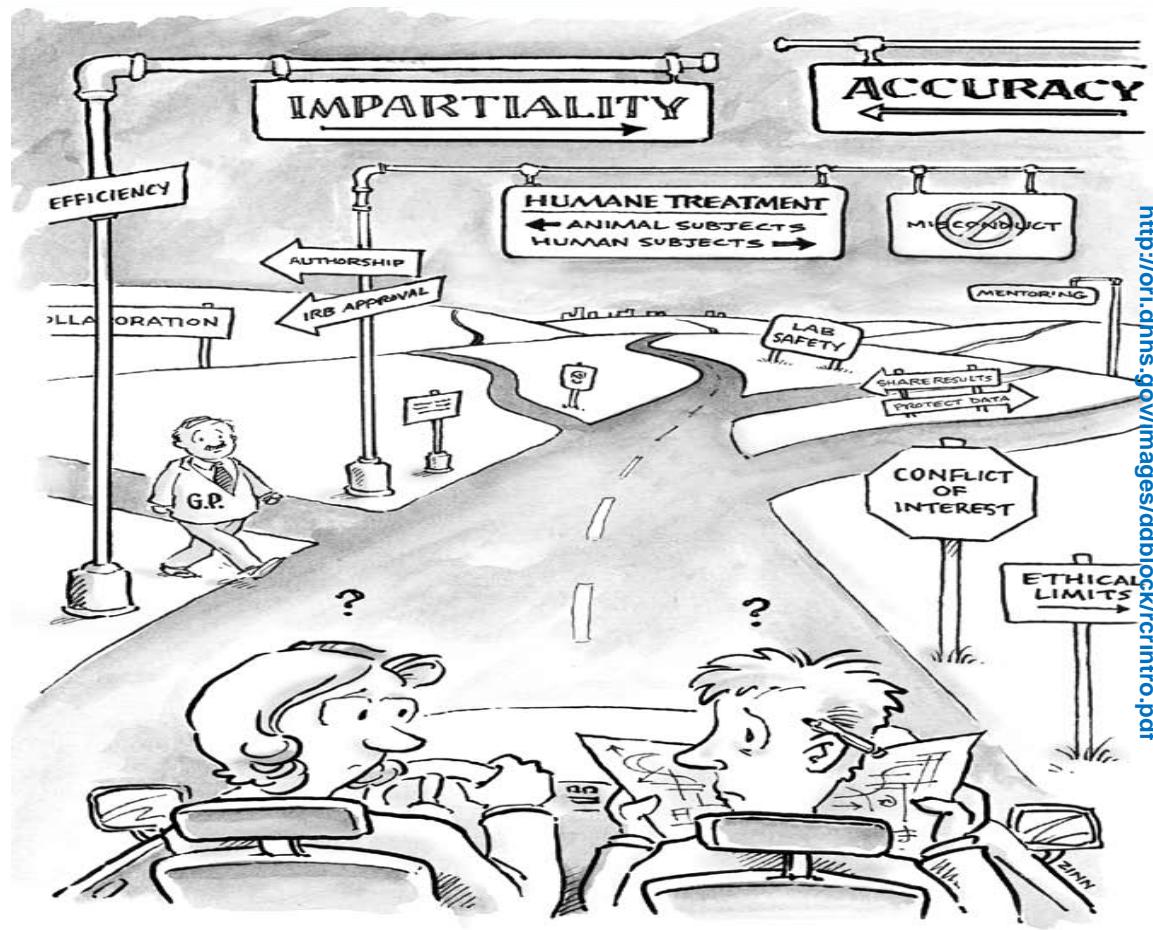
University Library

[Morris Library Guide to Research Data Management](#)

DMP development hints plus guidance on data preservation and sharing

Navigating Research Compliance: UD's GPS

Maria Palazuelos, Ph.D.
Director of Research Compliance
mariapj@udel.edu



<http://ori.dhhs.gov/images/ddblock/crintro.pdf>

Research Compliance – Why Does It Matter?



Proper stewardship of research activities is a **shared responsibility** of the **PIs and the Institution**.

Research Compliance - Areas of Focus

- ❖ Research Misconduct / Responsible Conduct of Research
- ❖ Conflict of Interest (COI)
- ❖ Human Subjects Protection: FWA (HHS)
- ❖ Animal Use in Research: AWA & PHS
- ❖ Agreements (NDAs, CAs, MTAs) / Intellectual Property
- ❖ Export Controls
- ❖ Safety in Research
- ❖ Financial Management

Research Integrity

<http://www.udel.edu/research/preparing/researchintegrity.html>

Research misconduct is defined as ***fabrication, falsification, or plagiarism*** in proposing, performing, or reviewing research, or in reporting research results.

U.S. Office of Science and
Technology Policy (OSTP)

Research misconduct does NOT include honest error or differences of opinion.

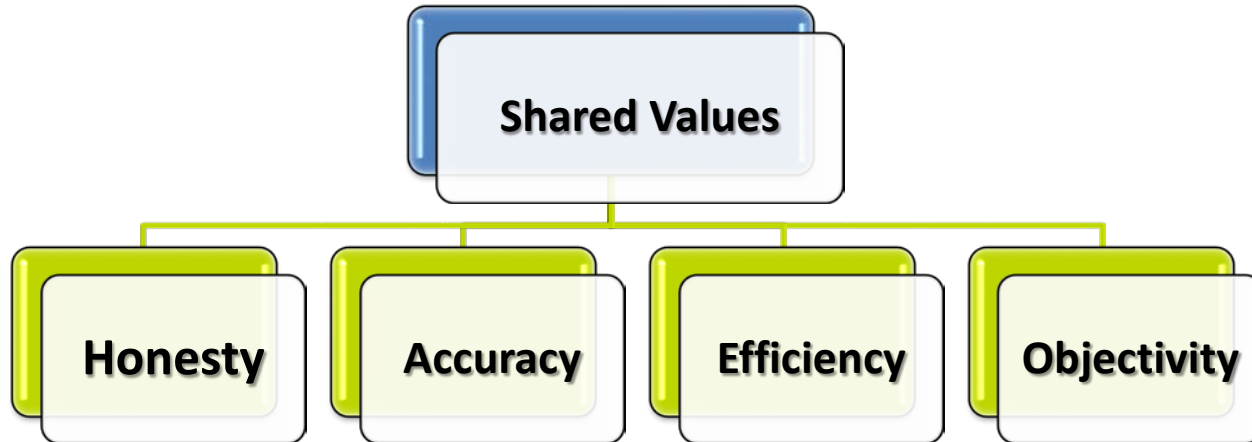
http://www.ostp.gov/cs/federal_policy_on_research_misconduct

Where to Report: Allegations of research misconduct may be reported to the, Associate Vice President for Research and Regulatory Affairs

Dr. Cordell Overby, overbyc@udel.edu

Responsible Conduct of Research (RCR)

To promote objectivity, protect research subjects, ensure proper use of funds, and minimize opportunities for wrongdoing.



**Required
training:**

<http://www1.udel.edu/research/training/training-responsible-conduct-research.html>

Conflict of Interest

<http://www.udel.edu/research/preparing/conflict.html>



UD Research Policy 6-11 "a potential conflict of interest occurs when there is a **divergence between an individual's private interests and his or her professional obligations...**"

- **All faculty and professional staff must disclose** all significant financial and commitment interests **every year** – At UD COI disclosures are done via Webform.
- If a COI exist within a project or institutional responsibility a management plan is to be developed and agreed wit the Chair, Dean and RO
- Awards are not set up if COI disclosure is no current

Human Subjects in Research

<http://www1.udel.edu/research/preparing/humansub.html>

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information

Does your NIH funded study...

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial

Training for the protection of human subjects in research (and GCP training if NIH funded clinical trial) **is required**. At UD training must be completed at www.CITIProgram.org

Clinical Trial Reforms & Initiatives

Enhancing Clinical Trial Stewardship at NIH



- ✓ Accountability
- ✓ Transparency
- ✓ Efficiency
- ✓ Dissemination

Use of Animals in Research

<http://www.udel.edu/research/preparing/animalcare.html>



www.npx.aufi
smspot.com

- ✓ **Refine** - consider alternatives to procedures causing more than momentary pain or distress
- ✓ **Reduce** - the number of animals used should be the minimum that is consistent with the aims of the experiment
- ✓ **Replace** - use non-animal models when possible (e.g., *in vitro* methods)

Russell, W.M.S. and Burch, R.L.. "The Removal of Inhumanity: The Three R's", 1959

UD Office of Laboratory Animal Medicine (OLAM)

- ❖ Dedicated to the care and well-being of research animals
- ❖ Provides specialized resources, services, consultation, information and training

Who to Contact?

Gwen Talham, DVM x2980, gtalham@udel.edu

Frank Warren x2400, fwarren@udel.edu

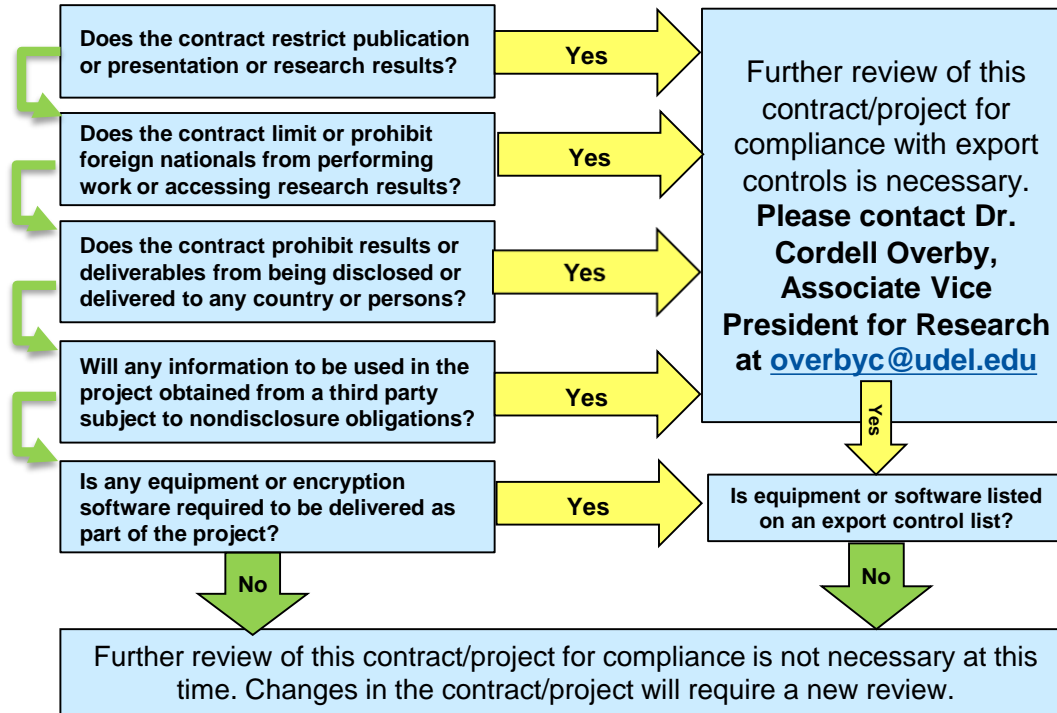


Compliance Frameworks: Agreements

- Non-Disclosure Agreements
- Material Transfer Agreements
- Data Use Agreements
- Invention Disclosures: Patent Law

Sean P. Hayes, J.D., Ph.D.
U.S. Registered Patent Attorney
Research Advisor

Compliance with Export Controls at UD



Safety in Research



EHS Mission is to maintain a safe and healthful campus environment while ensuring compliance with applicable federal, state and local regulations.

- Chemical
- Biological
- Radiological (Lasers, X-Rays)
- Environmental
- Fire and Life Safety
- General Safety
- Industrial Hygiene (occupational)

Prior Approval Needed

Environmental Health and Safety must be notified when certain operations or projects occur. The notification is required in order for EHS to help researchers and students safely perform the task or process. ...**when in doubt call EHS 302-831-8475 !!**

- Renovations to laboratory and research spaces
- Use of Class IIIB or IV lasers
- Explosive laboratory reactions or use of high explosives
- Use of highly toxic chemicals, radioactive materials, carcinogenic materials, reproductive toxins or materials of unknown toxicity
- Purchasing of refrigerators for chemical storage
- Purchasing, moving or installing a chemical fume hood, laboratory exhaust ventilation or laminar flow equipment
- Minors (under 18 years of age) working with hazardous materials or performing hazardous operations
- Experiment or process that impacts building or laboratory design, i.e. a large piece of equipment or apparatus that blocks sprinkler heads
- Purchase or use of a respirator.

<p>Cordell Overby, Sc.D. overbyc@udel.edu x2383</p>	<p>Sean Hayes, J.D., Ph.D. hayes@udel.edu x7445</p>	<p>Maria Palazuelos, Ph.D. mariapj@udel.edu x8619</p>	<p>Gwen Talham, D.V.M. gtalham@udel.edu x2980</p>	<p>Environmental Health & Safety (EHS)</p>
<ul style="list-style-type: none">• Export Controls• Conflict of Interest• Material Transfer & Non-Disclosure Agreements• Research Integrity• General Regulatory Affairs	<ul style="list-style-type: none">• Intellectual Property• Research-Related Legal• Material Transfer & Non-Disclosure Agreements	<ul style="list-style-type: none">• Conflict of Interest• Responsible Conduct of Research• Human Subjects• Clinical Trials <p>Nicole Farnese-McFarlane, BS, CRA nicolefm@udel.edu x1119</p> <ul style="list-style-type: none">• IRB Office x2137	<ul style="list-style-type: none">• Veterinary Care• Animal Regs <p>Frank Warren, L.A.T. fwarren@udel.edu x2400</p> <ul style="list-style-type: none">• Lab Animal Facility Mgt• Animal Ops	<p>Michael Gladle, M.P.H., C.I.H. mgladle@udel.edu x8475</p> <ul style="list-style-type: none">• Biosafety• Hazardous Substances• Radiation Safety• Laser Safety• Chemical Hygiene

General Questions:

If you're not sure who to call, contact your Contract & Grant Specialist!