

BREAKING DOWN THE BARRIERS OF RESEARCH COMPLIANCE - *A ROADMAP TO RESEARCH COMPLIANCE AT UNM FOR MAIN & BRANCH CAMPUS RESEARCHERS*

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Exec. Dir. of Research & Compliance on Main Campus
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Find more training opportunities at:
<http://research.unm.edu/research-training>

Presentation Objectives

- Provide basics of different areas of research compliance;
- Instruct how they may come into play with a research project;
- Inform which offices implement various facets of research compliance for UNM Main Campus or Branch Campus researcher.

Research Compliance Programs - the acronym map

Regardless of funding, your research and scholarly activities may involve engagement (such as submission, review and approval processes) with one or more of these programs

- [OIRB] HUMAN SUBJECTS RESEARCH
- [EC] EXPORT CONTROL ITEMS/ OBJECTS/ TECHNOLOGIES/ KNOWLEDGE/ ACTIVITIES
- [IS] CLASSIFIED PROJECTS/ ACTIVITIES/ CLEARANCES
- [COI] CONFLICT OF INTEREST IN RESEARCH
- [BCO] BIOHAZARDS AND NON-VERTEBRATE ANIMALS
- [OACC] VERTEBRATE ANIMAL CARE & USE IN RESEARCH AND TEACHING
- [RSO OR SRS] IONIZING OR NON-IONIZING RADIATION AND MEDICAL OR NON-MEDICAL LASERS
- [SRS] CHEMICAL & LABORATORY SAFETY

Understand & Plan

- Voluminous rules;
- Approvals take time (often involve committees);
- Help exists, seek it as early as possible.

■ Reviews, Clearances, Enforcement

+

■ Extra Services such as Consultations & Training

Regulatory Aspect

- Compliance impacts research activity, regardless if funded or not.
- Research investigators are held responsible under the regulations to ensure compliance with laws and rules.
- Compliance violations may result in sanctions (onto researchers & the institution):
 - *Civil*
 - *Criminal*
 - *Disbarment*
 - *Disciplinary measures...*

UNM Research Compliance Offices

Main Campus (MC)

Health Science Center (HSC)

Safety & Risk Services
(SRS)



UNM Research Compliance Programs

[Roadmap for MC Researcher]

- Conflict of Interest in Research [MC]
- Export Control (technology, knowledge, activity) [MC]
- Industrial Security (classified res., clearances) [MC]
- IRB/Institutional Review Board (human participants/subjects) [MC]
- Research Misconduct [MC]
- IACUC (vertebrate animals) [HSC OACC]
- Biohazards & non-vertebrate animals [HSC Biosafety Office]
- Chemical and Lab safety [SRS]
- Radiation & Lasers [HSC Radiation Office & SRS (non-medical, non-ionizing)]

Protection of Animals

- If non-vertebrate animals, contact HSC Biohazard Compliance Office -
- Timothy Muller; tmuller@salud.unm.edu
272-5993
- <http://hsc.unm.edu/som/biohazard/>

- If vertebrate animals, contact OACC office -
- Victoria Sugita Vsugita@salud.unm.edu; 272-6806
- <http://hsc.unm.edu/som/research/acc/>

Biohazards

- *Examples of Biohazards include:*
 - *Pathogens and potential pathogens of humans, animals, or plants;*
 - *Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines);*
 - *Recombinant DNA (and RNA), including creation or use of transgenic plants and animals;*
 - *Select agents and toxins (see <http://www.selectagents.gov/>) including strains and amounts exempted from the select agent regulations; or*
 - *Any material requiring a CDC import license, a USDA permit, or US FDA permit.*
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- HSC Biosafety Office -
 - Timothy Muller; tmuller@salud.unm.edu 272-5993
 - <http://hsc.unm.edu/som/biohazard/>

Radiation & Laser Safety

- *For non-medical lasers & non-ionizing radiation (radioactive materials and radiation-producing machines), contact Safety & Risk Services:*

ChemANJI Shu-Nyamboli, SRS Environmental Health Manager, 277-2753, cshu@unm.edu

Or

Carin Kelley, SRS Hazardous Materials Specialist, 277-2753, ckelley@unm.edu

- <http://srs.unm.edu>

- *For medical lasers, ionizing radiation (radioactive materials and radiation-producing machines), contact HSC Radiation Office:*

- Matt Eden, Safety Specialist at HSC Radiation Safety, 272-4607, MEden@salud.unm.edu

- http://hsc.unm.edu/som/research/radiation_safety/

Chemical and Lab Safety

- In addition to addressing chemical and lab compliance aspects, this office can provide consultation on shipping and receiving [comes into play, especially with Material Transfer Agreements]

- Safety & Risk Services -

Chemaji Shu-Nyamboli, SRS
Environmental Health Manager, 277-2753,
cshu@unm.edu

or

Carin Kelley, SRS Hazardous Materials
Specialist, 277-2753, ckelley@unm.edu

- <http://srs.unm.edu>

RESEARCH COMPLIANCE PROGRAMS @ MC

For details, visit the web sites of or contact
UNM Office of the Vice President for Research (OVPR)
<http://research.unm.edu>

or
UNM Office of Research Compliance
<http://researchcompliance.unm.edu>

Conflict of Interest in Research

- ... addresses if outside professional or financial relationships may compete with research obligations to UNM.
- COI need not be eliminated, so long as it can be managed or reduced.
- Researchers/Investigators who have to disclose include individuals who are responsible for a task that could have a significant or direct effect on the design, conduct or reporting of UNM research.
 - *All persons, including faculty, staff and students, regardless of UNM affiliation (includes UNM and non-UNM investigators), who are engaged in research activity at UNM Main and Branch Campuses and who are responsible for tasks that can have a significant or direct impact on the design, conduct or reporting of research are required to submit an annual disclosure and to report any material changes or new conflicts which arise after the submittal of their annual disclosure.*
- For more information, see UNM *Faculty Handbook* Policy E:110: <http://handbook.unm.edu/policies/section-e/e110.html>

Conflict of Interest in Research

- MC Research Compliance -
- Office of Research & Compliance
- coiresearch@unm.edu
- Tel: 505.277.5358 & 505.277.1045
Fax: 505.277.2697
- Office Hours: 8 am – noon & 1 pm – 5 pm
- Monday through Friday
- <http://researchcompliance.unm.edu/coi>

Protection of Human Participants

- Human subjects/participants & HIPAA-related issues
 - *Relevant research activity spans from body invasive studies to interview-type studies.*
 - *Institutional Review Board reviews studies, hence the IRB acronym.*
 - *The IRB and the researchers are assisted by the Office of the IRB.*

Office of the Institutional Review Board

- MC Research Compliance -
- Office of the IRB:
- IRBMainCampus@unm.edu
- Tel: 505.277.2644
- Fax: 505.277.2697
- Office Hours: 8:00 am - 5:00pm
- Monday through Friday
- <http://irb.unm.edu/>

Industrial Security

- Classified research
- Clearances
- Travel and Security consultations and trainings
- Clean computers and cell phones

Industrial Security

- MC Research Compliance -
 - *Industrial Security Office*
 - *Office of Research & Compliance*

 - *Audrey Pineda, Compliance Specialist*
 - *Deb Kuidis, Industrial Security Manager & FSO*

- pinedaa@unm.edu & dkuidis@unm.edu

- Tel: 505.277.2968 & 505.277.2058
- Fax: (505) 277-2697

- Office Hours: 8 am – noon & 1 pm – 5 pm
- Monday through Friday

- <http://researchcompliance.unm.edu/industrialsecurity-home>

Export Control

- Control of exports from and imports into the U.S.
 - Control of goods, information & services/activities.
 - Typical triggers: Publication restrictions, Restrictions on foreign nationals' participation, Detailed export control clauses, Certain activities such as consulting on items or processes that can have military applications or can otherwise confer disadvantages to the U.S.
 - Certain goods and technology such as: Semiconductors, Lasers, Sensors, & Optics, Robotics, UAV's (Unmanned Aerial Vehicles), Information Systems, Navigation Systems, Aeronautics, Marine and Space Systems, Cryptography/Encryption technology, Nuclear research, Anything that can have military use...
 - Technology Control Plans may need to be implemented
 - Travel and Security consultations and trainings
- *Caution: illegal export may be deemed to have occurred even if there was not an actual transfer of goods or information across the U.S. border [typical example is disclosure of controlled information within the U.S. territory to certain non-U.S. persons]*

Export Control

- MC Research Compliance -
 - *Export Control Office*
 - *Office of Research & Compliance*

 - *Audrey Pineda, Compliance Specialist*
 - *Deb Kuidis, Industrial Security Manager & FSO*

- pinedaa@unm.edu & dkuidis@unm.edu

- Tel: 505.277.2968 & 505.277.2058
- Fax: (505) 277-2697

- Office Hours: 8 am – noon & 1 pm – 5 pm
- Monday through Friday

- <http://researchcompliance.unm.edu/exportcontrol>

Responsible Conduct of Research

- Research Integrity [aspirational + training] vs. Research Misconduct [formal investigations]

- Research Misconduct investigations address:

- *Plagiarism*
- *Falsification*
- *Fabrication*

[For further information, see UNM Faculty Handbook Policy E:40: <http://handbook.unm.edu/policies/section-e/e40.html>]

- Research Misconduct proceedings are formal proceedings that result in binding administrative decisions.
- AIRE Training is a program required for all student researchers and for certain other researchers (see subsequent slides for more information).
- There are 2 types of plagiarism detecting software available *gratis* to UNM faculty, staff and students:
 - iThenticate [<http://ithenticate.unm.edu>]
 - SafeAssign [<http://online.unm.edu/help/learn/faculty/assessments/safeassign/index.html>]

Research Misconduct

- MC Research Compliance -
 - *Office of the Vice President for Research*
 - *& Office of Research & Compliance*

- rcgeneral@unm.edu

- Tel: 505.277.6128 (OVPR) & 505.277.5358 (R&C)
- Fax: 505.277.5271 (OVPR) & 505.277.2697 (R&C)

- Office Hours: 8 am – noon & 1 pm – 5 pm
- Monday through Friday

- <http://researchcompliance.unm.edu/responsible-conduct-of-research>

AIRE Training

- MC Research Compliance -

- *Office of Graduate Studies*

- *William L. Gannon, Ph.D*

- wgannon@unm.edu

- Tel: (505) 277-3488

- Tel: (505) 249-7906

- <http://researchcompliance.unm.edu/responsible-conduct-of-research>



AIRE

ACADEMIC INTEGRITY + RESEARCH ETHICS

- UNM has a comprehensive, campus-wide program aimed at enhancing integrity and ethical attitudes in research for graduate students and for all faculty and other researchers.
- The Academic Integrity & Research Ethics program (AIRE) is housed in Graduate Studies and strongly supported by the Provost's Office and the Office of the Vice President for Research.
- We provide university-wide services for the community of scholars in research ethics and academic integrity in support of our reputation as an institution of research excellence. Courses, workshops, special presentation (for instance in a research methods class) commonly offered.
- AIRE oversees compliance in training and certification in the responsible conduct of research (RCR) as required of all researchers (grad students, postdocs, others) supported by federal funding (NSF, NIH). Contact us today and get research ethics certification soon!

RCR CERTIFICATION

Responsible conduct of research (RCR) is federally prescribed education for researchers and scholars to ensure that the newest generation of scientist produce work that is original, honest, and well-intended. AIRE offers multiple opportunities to participants for RCR certification each semester.

Who needs certification?

■ Those funded by certain federal agencies need to obtain RCR certification within a year of the award.

- Funded by NSF: Undergraduates, graduate students, and postdoctoral researchers
- Funded by NIH: All trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, or dissertation research grant
- Funded by NIFA: Program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in the research project

AIRE and Graduate Studies recommends that all members of the academic community who are engaged in research or who support the practice of scholarly inquiry participate in some level of research ethics education

12 CORE RCR AREAS

**More than just knowing
human subject protection
(CITI) training!**

- Conflicts of interest
- Ethical use of human and other animal subjects in research
- Authorship and publication
- Peer review
- Data acquisition, management, ownership and sharing
- Data reproducibility
- Mentoring
- Research misconduct policies
- Financial management
- Whistleblower ethics
- Collaborative research
- The scientist as a responsible member of society

OUR SERVICES ALSO INCLUDE

CONSULTATION

- Confidential individual or departmental **consultations**

INSTRUCTION

- **Tailored presentations** for students, faculty, staff, or research groups and coordination with research methods course instructors to include AIRE into their syllabi

RESEARCH ON RESEARCH ETHICS

- Staff are involved in studies of “deep learning” and effective RCR instruction especially in cross-cultural and “normal misbehavior” contexts.

CURRICULUM GUIDANCE

- Development and guidance for faculty (and other instructors) in the creation of their own **discipline-specific academic integrity and research ethics**

curriculum

COMPLIANCE

- **Tracking** of participants who are supported by federal funds requiring RCR certification
- Keep informed on issues of human and animal institutional committees; assist as needed with issues of research misconduct.

MARKETING

- Communication with UNM community on upcoming workshops, courses, or symposia on research ethics and opportunities for certification; **PAW series**

COMING SOON:

MODULES TO HELP YOU BETTER UNDERSTAND HOW TO HANDLE CASES OF **PLAGIARISM, RESEARCH MISCONDUCT, PREDATORY PUBLISHERS, AND REPRODUCIBILITY!**

WATCH FOR ANNOUNCEMENTS ON THE AIRE WEBSITE.

Director: William L. Gannon, Ph.D. Graduate Studies wgannon@unm.edu 505-249-7906 or 505-277-3488

Graduate Assistants: Sue Wilder: Instructional Design, Learning Objects, and Process Improvement swilder@unm.edu

Christine Shell: Graphic Design, Marketing, and Web Design and Maintenance shellc@unm.edu

LEARN MORE AT AIRE.UNM.EDU

THANKS FOR YOUR ATTENTION TO THIS INFORMATION!

Our offices stand ready to assist you in ensuring research compliance at UNM and to help you navigate various facets of research compliance at UNM.

Sincerely,

Ana Andzic Tomlinson

Exec. Dir. of Research & Compliance on Main Campus

aandzict@unm.edu

505.277.5358

Thanks for fostering
UNM research activity
and for strengthening
UNM research
enterprise!

To further advance your knowledge & skills in research development, administration & compliance and to learn more about additional training opportunities, go to: <http://research.unm.edu/research-training>

