RESEARCH OVERSIGHT AT TULANE UNIVERSITY

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TULANE UNIVERSITY RESEARCH COMPLIANCE OFFICER

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Role of Research Compliance Officer

- Resource to Tulane community regarding compliance with regulations and university policies that relate to the conduct of research – please contact me with your questions!

- Policy development

- Role on the compliance oversight committees:
  - Review proposals for compliance with SOPs and regulations
  - Assist with questions regarding regulations and policies
  - Review and investigate research noncompliance
  - Conduct for-cause and not-for-cause audits

- Assist researchers with questions regarding the compliance oversight committees
Role of the Research Compliance Officer (cont.)

- Respond to Freedom of Information Act ("FOIA") and public records requests related to research
  - Contact me before responding to any such request!
- Training:
  - Responsible Conduct of Research ("RCR") Seminar Series (begins March 4th)
  - Research Town Hall Series
- Assist investigators in preparing for audits of research studies by sponsors or regulatory bodies (FDA, OHRP, USDA, etc.)
- Serves as the University’s Research Integrity Officer to process allegations of Research Misconduct
Research Oversight Committees at Tulane

- Institutional Review Board (IRB) – must approve all human subjects research:  
  [http://tulane.edu/asvpr/irb/index.cfm](http://tulane.edu/asvpr/irb/index.cfm)

- Institutional Animal Care and Use Committee (IACUC) – must approve all activities involving vertebrate animals:  
  [http://tulane.edu/asvpr/iacuc/index.cfm](http://tulane.edu/asvpr/iacuc/index.cfm)

- Institutional Biosafety Committee (IBC) – must approve all activities involving rDNA and infectious agents:  
  [http://tulane.edu/asvpr/biosafety/committee/index.cfm](http://tulane.edu/asvpr/biosafety/committee/index.cfm)
Research Oversight Committees (cont.)

- Conflicts of Interest (COI) Committee – reviews and manages potential conflicts of interest of researchers based on the COI disclosure forms: 
  http://tulane.edu/counsel/conflict-of-interest-policies.cfm

- International Review Group (IRG) – reviews all activities with an international component: 
  http://tulane.edu/asvpr/ora/upload/IPPQ.pdf

- Radiation Safety – activities involving radiation: 
  http://tulane.edu/oehs/radiation/radiationsafety.cfm
IRB

- Tulane’s Human Research Protection Office (HRPO): 504.988.2665; irbmain@tulane.edu; http://tulane.edu/asvpr/irb/index.cfm; 1440 Canal Street, Suite 1705
- Tulane Human Research Protection Program SOPs: http://tulane.edu/asvpr/irb/policies.cfm
  - Apply to all activities that meet the definition of human subjects research
- Roxanne Johnson, Director: 504.988.2665; rjohnson@tulane.edu
- Ellen Dauchy, Assistant Director: 504.988.2642; edauchy2@tulane.edu
- Roberta McDuffie, IRB Chair, 504.988.0299; rmcduffi@tulane.edu
IRB - Definition of Human Subjects Research (45 CFR 46 & Tulane HRPP SOP 1.4)

- Any **systematic investigation** (including research development, testing, and evaluation)
- On a **living individual** about whom the investigation is being conducted
- Where the investigator obtains
  - **Data** through *intervention or interaction* with the individual; or
  - *Individually identifiable private information*
- That is designed to develop or contribute to **generalizable knowledge**.

When in doubt, complete and submit the IRB’s “Human Subjects Research Determination Form”
IACUC

- IACUC SOPs: [http://tulane.edu/asvpr/iacuc/index.cfm](http://tulane.edu/asvpr/iacuc/index.cfm)
  - Apply to all activities involving vertebrate animals

- Sheila Garrison, IACUC Director and Chair; 504.988.6868; sgarriso@tulane.edu

- Georgina Dobek, DVM, Director of Department of Comparative Medicine; 504.988.5214; gdobek@tulane.edu
  - Operate Tulane Vivariums
  - Animal Procurement
  - Animal husbandry
  - Regularly scheduled monthly training programs and by request: [https://adobeformscentral.com/?f=fzIdAPAmwdGnLWKp2LNROA](https://adobeformscentral.com/?f=fzIdAPAmwdGnLWKp2LNROA)
Institutional Biosafety Committee (IBC)

- The IBC reviews all activities involving rDNA and infectious agents, and assesses decontamination and biocontainment levels.

- IBC Policies: http://tulane.edu/asypr/biosafety/committee/policies.cfm

- Lucy C. Freytag, PhD; IBC Chair; (504) 988-6772; lfreyta@tulane.edu

- Don Sibley, PhD; Biosafety Officer; (504) 988-0300; dsibley@tulane.edu
Conflicts of Interest (COI)

- COI Committee reviews potential financial conflicts of interest of researchers based on the COI disclosure forms submitted by researchers at least annually.
  - Where a potential conflict exists, the COI Committee institutes a conflicts management plan when possible.

- [http://tulane.edu/counsel/conflict-of-interest-policies.cfm](http://tulane.edu/counsel/conflict-of-interest-policies.cfm)

- Genean Mathieu, Administrative Compliance Specialist; 504.247.1286; gmathieu@tulane.edu
International Review Group (IRG)

- The IRG meets bi-weekly and reviews the following activities:
  - Sponsored international research
  - Un-sponsored international research
  - Academic activities with an international component, including:
    - TU faculty, staff, and students going abroad
    - Foreign nationals coming to Tulane as students, faculty, or staff.

- The IRG members consist of a swath of administrators and faculty to facilitate international activities.
The IRG facilitates the following activities:

- International travel & personal baggage
- Project staffing
- **Hiring foreign employees**
- Deployment of University staff abroad
- Use of vehicles, equipment & assets abroad
- Establishing Tulane office overseas
- Licensing requirements for foreign nationals who will have access to controlled technology
- Opening in-country bank account
- Formal collaboration, services or cooperation with foreign governments
- International shipment of goods
- **Export controls**
- Research
- Independent Contractor Agreements
- Purchased Services Agreements
Before undertaking international activity:

- Complete and submit an International Preliminary Project Questionnaire ("IPPQ"): [http://tulane.edu/asvpr/ora/upload/IPPQ.pdf](http://tulane.edu/asvpr/ora/upload/IPPQ.pdf)

- Completion of the form allows the IRG to facilitate the international activity, such as ensuring compliance with export control regulations.

- **IRG Chair**: Wade Wootan, JD; Global Affairs & Regulatory Compliance; [wwootan@tulane.edu](mailto:wwootan@tulane.edu); 504.988.0598
Any activity involving the use of radiation must obtain a license from the Radiation Safety Committee prior to the start of the activity.

- License application: [http://tulane.edu/oehs/radiation-material-licenses.cfm](http://tulane.edu/oehs/radiation-material-licenses.cfm)

- Radiation Safety Policies are online at [http://tulane.edu/oehs/radiation/radiationsafety.cfm](http://tulane.edu/oehs/radiation/radiationsafety.cfm)

- Natalie Lonsberry, Radiation Safety Officer, 504.988.2867; nlonsber@tulane.edu
Research Misconduct

- Policies listed in the faculty handbook and on Research Compliance website: http://tulane.edu/asvpr/research-compliance.cfm
- Research Misconduct is defined as fabrication of data, falsification of data, and/or plagiarism.
- If you discover research misconduct, you are obligated to report it – contact the RCO for guidance.
- If you are accused of research misconduct, you are entitled to due process rights – contact the RCO for guidance.
Conclusions

- I can be contacted with questions involving all research compliance areas
- If human subjects research involved = IRB
- If animals are involved = IACUC
- If rDNA and/or infectious agents involved = IBC
- If international component = fill out IPPQ
- If radiation involved = Radiation Safety Committee
- FOIA requests = contact RCO
- Research Misconduct guidance = contact RCO
Questions?

- Research Compliance and Research Integrity Officer, Brian Weimer: 504.988.1147 (office) 504.261.6579 (mobile); bweimer1@tulane.edu; Suite 2425 of Tidewater Bldg. (1440 Canal Street); http://tulane.edu/asvpr/research-compliance.cfm

- Office Hours: 8:00 AM to 5:00 PM, M-F