RESEARCH OVERSIGHT AT TULANE UNIVERSITY

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Objectives of Presentation

- What is the role of the Research Compliance Officer?
- Why do certain types of activities have to be reviewed and approved before they commence?
- What are the different compliance oversight committees at Tulane?
- What type of activities trigger oversight by these committees, and who do I contact at each committee?
- Answer any questions you may have.
Role of Research Compliance Officer

- Resource to Tulane community regarding compliance with regulations and university policies that relate to the conduct of research
- Policy development, training, and auditing
- Open-door policy for questions from university community
- 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
  - Conducts for-cause and not-for-cause audits
Why do certain types of activities have to be reviewed and approved before they commence?

- **Federal Regulations**
  - Certain activities, regardless of who is conducting the activity, are regulated, primarily by federal statues but also by state statues.
    - Examples: Human subject research; animal research on certain species; activities involving recombinant DNA (rDNA); activities involving certain infectious agents; activities involving radiation; and international activities
  
- **Why?**
  - In the interest of public safety, either due to past abuses or to prevent harm to the public if the activity is inherently risky, such as research involving infectious agents.
Research Oversight Committees at Tulane

- Institutional Animal Care and Use Committee (IACUC) – vertebrate animals: http://tulane.edu/asvpr/iacuc/index.cfm
- Institutional Biosafety Committee (IBC) – rDNA and infectious agents: http://tulane.edu/asvpr/biosafety/committee/index.cfm
- Radiation Safety Committee: http://tulane.edu/oehs/radiation/radiationsafety.cfm
- International Review Group (IRG) – activities with an international component: http://tulane.edu/asvpr/ora/upload/IPPQ.pdf
Regulation of research – why is it needed?

- People imprisoned in Nazi Germany during Holocaust were forced to participate in human experiments – no informed consent.
- Total number of deaths uncertain, but death toll was very high. For example, experiments on twins resulted in 1,300 deaths out of 1,500 forced to participate.
- Other experiments: freezing point of the human body, malaria, mustard gas, sterilization, and effects of high altitude.
- Led to the passage of the Nuremberg Code: guidance (non-binding) on informed consent, minimization of risk and harm, and the freedom to withdraw.
Regulation of research – why is it needed?

- Tuskegee Syphilis Study (1932-1972):
  - No informed consent
  - Participants were not informed of all known dangers.
  - Participants were never told that Penicillin was an effective treatment for Syphilis, even though Penicillin became widely known as an effective treatment beginning in 1947.
  - Public outcry following an exposé led to the passage in 1974 of the National Research Act, which contained the first mandatory human subject protection provisions.
Regulation of research – why is it needed?

- Similar abuses occurred regarding animal research.
  - Prior to passage of Animal Welfare Act, 30% to 40% of monkeys and 40% to 50% of cats and dogs received by research laboratories died before labs could use them in research.
  - Previous attempts to pass Animal Welfare Act had failed; however, a 1966 Life article detailed abuses and cruelty of dogs by dealers who specialized in selling to research laboratories, which led to a public outcry and subsequent passage of the Act.
Human Subjects Research Regulations

- 5 CFR 46: known as the “Common Rule”. Main body of regulations for protection of human subjects participating in research

- FDA Regulations:
  - 21 CFR 50: protection of human subjects
  - 21 CFR 56: FDA IRB Regulations
  - 21 CFR 312: FDA Investigational Drug Regulations
  - 21 CFR 812: FDA Investigational Device Regulations
  - 45 CFR 164.508-514: HIPAA Regulations

- State-specific regulations
Human Research Protection at Tulane

- Tulane’s Human Research Protection Program ("HRPP") includes SOPs that incorporate state and federal regulations and the standards of the IRB’s accrediting body, AAHRPP. These regulations and standards:
  - govern all aspects of human subject research protections
  - mandates use of IRB to review all human subjects research occurring under the auspices of the university
  - govern the composition of the IRB

- Tulane HRPP SOPs are published at: http://tulane.edu/asvpr/irb/policies.cfm

- The Tulane Human Research Protection Office ("HRPO") administers the IRB.
Role of the IRB

- Investigators are responsible for the initial determination of whether the planned activity comprises human subjects research (Tulane SOPs 3.3). However, the university, as well as sponsors, hold the investigator accountable for wrong determinations.

- Investigators should err on the side of caution and contact the IRB (irbmain@tulane.edu) for guidance regarding whether the activity constitutes human subjects research before commencing their research.
2-Step process for review of human subject research

- Step 1: Does the activity constitute human subjects research?
  - Look to prospective intent of the investigator and the definition of research

- Step 2: If so, does the research qualify for exempt review, expedited review, or convened (i.e., full) board review?
Definition of *Human Subjects Research*
(45 CFR 46 & Tulane SOPs 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*
A "systematic investigation" is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.

“Generalizable knowledge” involves studies that are designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside the specific study population), inform policy, or generalize findings.
What is Individually Identifiable Information? (SOP 3.7.5)

- Information where the identity of the subject is or may be readily ascertained, such as:
  - Name
  - Address
  - SSN
  - Phone No.
  - Email address
  - Full Face Photo
  - Account Number
  - Finger Print
Essential Questions

- Ask yourself the following:
  - Am I trying to answer a research question?
  - Am I collecting data through intervention or interaction with a living individual or collecting identifiable private information about a living individual?
  - Am I using systematic methods to collect my data?
  - Will I write up the results?
  - Will the results be available to others?

- If yes to all, then the activity likely involves human subjects research subject to review/oversight by Tulane’s IRB.
Now we will look at examples. As you will see, it is not always a clear cut answer.

The answers to each of these questions depends upon the facts and whether the researcher is engaging in a systematic investigation 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.

If the activity is part of a class project only, the activity usually does not meet the generalizable knowledge test.
Is it human subjects research?

- A study comparing cognitive behavior therapy to medication in treating depression?
  - Yes, this is research, unless the investigator is not doing anything with the data.

- Focus group study of parenting practices?
  - Maybe. What is the planned use of the data? If it is a systematic investigation and designed for generalizable knowledge, then yes. If presented solely in class, then no. If conducted for quality improvement within group, then no.
Is it human subjects research?

- Biomedical research on cadavers?
  - No, as this would not involve living human subjects.

- Study that counts the number of Hispanic surnames in the list of registered voters in New Orleans?
  - No. Counting names in the voter registry is not a "systematic investigation", i.e., an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.
What is *not* research?

- Training exercises that do not produce generalizable results
- Activities designed for educational purposes only
- Results of class projects that will *not* be published outside the classroom
  - Examples of publishing outside of the classroom: magazine articles, master’s thesis, doctoral dissertation, poster session, abstract, or any other publication or public presentation.
- Quality Improvement studies
- Research involving dead people
What is publishing?

- Look to intent to make the results public.
- Information used only within a class and not provided outside of the class setting does not constitute publishing.
- Sharing the information openly with individuals outside the classroom likely constitutes publishing, therefore necessitating review.
Is this publishing?

- As part of a class project, a School of Medicine class collects data from 10 human subjects to answer a research question. The results are not intended to be shared outside the classroom, is this publishing?
  - No

- If the results are shared via the department’s intranet that is password protected, does this constitute “publishing?”
  - Generally, if the results are confined to limited audience, this is not considered a systematic investigation that is designed to develop or contribute to generalizable knowledge
Example: Research Practica

- **Question:** A course requires students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these class projects is to train students on research methods and to provide them with an opportunity to practice various research methods. Is this human subjects research?

- **Answer:** No. The purpose of the activity is to train students to conduct research, not for generalizable knowledge. Research Practica are designed to offer students opportunities to learn various research methodologies through practice.
Question: Is research for a thesis or dissertation considered human subjects research?

Answer: It depends. A thesis ordinarily involves a systematic investigation that is published or made generally available. The analysis turns on whether data is obtained through intervention or interaction with individuals or whether individually identifiable private information is obtained.
Example: Video Interviews

- Question: Are video recordings of interviews with Hurricane Katrina survivors created to preserve or describe individual experiences to be viewed at a museum considered “human subject research”?

- Answer:
  - No. The creation of the video recording does NOT intend to draw conclusions, inform policy, or generalize findings.
  - The sole purpose is to create a historical record of specific personal events related to experiencing the hurricane and to provide a venue for survivors to tell their stories.
  - What if the purpose of the interviews is to create an archive for future research? Since the intent is to collect data for future research, IRB review would be needed.
Assuming Human Subjects Research Exists, three levels of IRB review

- **Exempt** Review; **Expedited** Review; **Full-Board** Review (as provided for in federal regulations).

- Application forms are available on [www.IRBNet.org](http://www.IRBNet.org), the IRB’s electronic submission system.

- If unsure of what level is required for your activity, submit query to [irbmain@tulane.edu](mailto:irbmain@tulane.edu) prior to submitting application to the IRB.

- If activity originally does not involve human subjects research but your intent changes to include human subjects research, then make a submission to the IRB.
IRB Contact Information

- 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 subjects protection policies: http://tulane.edu/asvpr/irb/policies.cfm
- Roxanne Johnson, Director: 504.988.2665; rjohnson@tulane.edu
- James “Jim” Outland, Assistant Director: 504.988.2665; joutland@tulane.edu
IACUC

- Institutional Animal Care and Use Committee
- The IACUC existence and functions are mandated by the PHS’s Office of Laboratory Animal Welfare (OLAW) and the USDA to ensure the humane care and use of animals used in research and compliance with guidelines and regulations
- IACUC is set up similarly to the IRB, with a Board to review research proposals and different levels of review based on the type and invasiveness of research.
IACUC SOPs, Guidelines and Policies

- The IACUC SOPs Guidelines, & Policies are located online at [http://tulane.edu/asvpr/iacuc/index.cfm](http://tulane.edu/asvpr/iacuc/index.cfm)
- The SOPs and Policies are campus-specific.
- The SOPs and Policies are based on laws, regulations, and policies from federal agencies and other accrediting organizations.
- Applies to all activities involving vertebrate animals, not just research (ex: applies to class projects such as live frog dissection).
IACUC Contact Information

- Sheila Garrison
  Tulane University IACUC Director
  sgarriso@tulane.edu
  504.988.6868
  1440 Canal Street, 17th floor.
Institutional Biosafety Committee (IBC)

- The IBC is responsible for assuring the safe conduct of activities involving rDNA and infectious agents, assessing decontamination and biocontainment levels, and ensuring research is done in compliance with government and institutional regulations.

- The use of rDNA or infectious agents has the potential of endangering the health of humans and animals and affecting the environment. Therefore, federal regulations require that all procedures involving the use of rDNA or infectious agents, which according to the "NIH Guidelines for Use of Recombinant R-DNA" that are Non-Exempt, undergo review by the IBC.
The IBC has a dual purpose:

- **Biosafety:** established programs/policies reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents.

- **Biosecurity:** protection of microbial agents from loss, theft, diversion or intentional misuse.

- **Why?** Research involving use of rDNA and/or infectious agents yields new technologies and/or information with the potential for both benevolent and malevolent applications.
IBC Contact Information

- IBC Policies: http://tulane.edu/asvpr/biosafety/committee/policies.cfm
- Chair of the IBC: Lucy C. Freytag, PhD; Dept. of Microbiology and Immunology with the School of Medicine; lfreyta@tulane.edu; (504) 988-6772; Room 5063 of the School of Medicine.
The IRG meets bi-weekly and reviews the following activities:

- Sponsored International Research
- Unsponsored International Research
- International Academic Activities. This includes:
  - TU faculty, staff, and students going abroad, and
  - Foreign Nationals coming to Tulane as students, faculty, or staff.

The IRG members are made up of a wide swath of faculty and staff from across the university.
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
- Memoranda of Understanding
- 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:

- Faculty, Staff, and Students are required to complete an International Preliminary Project Questionnaire (“IPPQ”) and submit it to the IRG for review and prior approval before beginning the international activity.
- The IPPQ Form can be found at: [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 Contact Information

- IRG Chair:
  Wade Wooten, Esq.
  Global Affairs & Regulatory Compliance
  Tulane University Office of General Counsel
  wwootan@tulane.edu
  504.988.0598
  1440 Canal Street, Suite 2425

Additionally, questions regarding export controls can be directed to me (Research Compliance Officer)
Radiation Safety Committee

- Any activity involving the use of radiation must obtain a license from the Radiation Safety Committee prior to the start of the activity. Request a license application form by calling 504.988.2867.

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

- Contact information: James Terry, PhD, Chair of Radiation Safety Committee; jterry@tulane.edu; 504.988.7567
Conclusions

- I can be contacted with questions involving all areas
- If human subjects research involved = IRB
- If animals are involved = IACUC
- If recombinant DNA (rDNA) involved = IBC
- If international component = fill out IPPQ
- If radiation involved = Radiation Safety Committee
Questions?

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