USE OF HUMAN SUBJECTS IN RESEARCH

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Objectives of Presentation

- What is the role of the Research Compliance Officer?
- Why does it matter if human subjects research is involved?
- Does my research involve human subjects?
- Is IRB review of my research required?
- What does it mean when your research is subject to exempt, expedited, or full-board review?
Role of Research Compliance Officer

- Compliance role on the following committees:
  - IRB: [http://tulane.edu/asvpr/irb/index.cfm](http://tulane.edu/asvpr/irb/index.cfm)
  - Institutional Animal Care and Use Committee (IACUC): [http://tulane.edu/asvpr/iacuc/index.cfm](http://tulane.edu/asvpr/iacuc/index.cfm)
  - Institutional Biosafety Committee (IBC): [http://tulane.edu/asvpr/biosafety/committee/index.cfm](http://tulane.edu/asvpr/biosafety/committee/index.cfm)
  - Radiation Safety Committee: [http://tulane.edu/oehs/radiation/radiationsafety.cfm](http://tulane.edu/oehs/radiation/radiationsafety.cfm)
  - Conflicts of Interest Committee: [http://tulane.edu/counsel/conflict-of-interest-policy.cfm](http://tulane.edu/counsel/conflict-of-interest-policy.cfm)
Role of Research Compliance Officer

- Resource to students, faculty, and staff 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 IRB:
- Conducting for-cause and not-for-cause audits
- Assist with questions regarding research compliance
- Review and investigate research noncompliance
Regulation of human subjects research – why is it needed?

- People imprisoned by Nazis during Holocaust were forced to participate in human experiments – no informed consent.

- Total 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 on informed consent, minimization of risk and harm, and freedom to withdraw.
Regulation of human subjects research – why is it needed?

- Tuskegee Syphilis Study (1932-1972):
  - No informed consent
  - Participants 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.
Tulane’s Human Research Protection Program (“HRPP”) includes SOPs that incorporate state and federal regulations, including the DHHS regulations located at 45 CRR 46 (known as “The Common Rule”) and FDA human subjects regulations. These regulations:

- govern all aspects of human subject research protections
- mandates use of IRB to review research proposals and 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

- The university has charged the IRB with monitoring all human subject research occurring at the university.

- 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 HRPO (irbmain@tulane.edu) for guidance regarding whether the activity constitutes human subjects research before commencing their research.
Role of the IRB

- Possible Repercussions for failure to obtain IRB approval of human subjects research:
  - Prohibition from using data;
  - Prohibition from publishing;
  - Reporting to federal oversight agencies
  - Subject to filing of a research misconduct allegation, which can lead to a range of penalties, including expulsion.

- The research misconduct policies are located in the faculty handbook
2-Step process for review of 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 Subject 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 readily be ascertained

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Essential Questions

- Ask yourself the following:
  - Am I trying to answer a question?
  - Am I collecting data from or about individual human beings?
  - Am I using systematic methods to collect my data?
  - Does the data include individually identifiable info?
  - Will I write up the results?
  - Will the results be available to others?
Who can serve as Principal Investigator?

- Faculty, Staff, Residents, and Postdocs
- Students if a faculty member has agreed to serve as the students’ faculty advisor for submission to IRB
  - It is the faculty sponsor’s responsibility to
    - assure that the research is conducted consistent with regulations and Tulane SOPs; and
    - assure closeout of the study
- CITI training must be taken prior to submission to IRB
CITI Training

- All associated with Tulane are eligible for CITI Training: https://www.citiprogram.org/Default.asp

- Before a submission may be made to IRB, you must complete CITI Training:
  - https://www.citiprogram.org/
  - Biomedical researchers should complete the “Biomedical (group 1) Research for Investigators and Key Personnel” module

- A module for use of animals in research is also available.
Is it human subjects research?

1. Study comparing cognitive behavior therapy to medication in treating depression?
2. Focus group study of parenting practices?
3. Research in historic archives to learn about what the pioneers ate?
4. Study that counts the number of Hispanic surnames in the Nashville telephone directory?
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
- 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.
- For example, if a School of Medicine class collects data as part of a class project from 10 human subjects and the results are not intended to be shared outside the classroom, is this publishing?
Question: A course requires students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these course projects is to train students and provide them with a closer view of social, educational, or psychological processes, and 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. However, if the collected data later will be published or presented publically, human subjects research may exist.
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 the individual or the data contains individually identifiable private information.
Example: Pilot Studies

Question: An investigator plans to undertake a preliminary investigation of the feasibility of a study on a small scale (i.e., fewer than 10 subjects), which will be exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments to prepare a better, more precise research design. Is this research?

Answer: No. This study focuses on data collection procedures and research design. This is akin to quality assurance and is not human subject research. Pilot studies intended to lead to generalizable knowledge are considered human subjects research.
Question: Are video recording 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 Exits, three levels of IRB review

- **Exempt Review**; **Expedited Review**; **Full-Board Review**.
- Each level requires a different application.
- Application forms are available on IRBNet, the IRB’s electronic submission system.
- If unsure of what level is required for your activity, submit query to irbmain@tulane.edu prior to submitting application to the IRB.
What is exempt research?

- Minimal risk studies that fall within set categories listed in Tulane SOPs 3.4.2.
- Shortened application – exempt from further review
- Exempt studies do not require convened IRB review and are reviewed by the IRB chair (or designee).
- Exempt research can not include research involving children or prisoners or that is international in nature [Tulane SOPs 3.4.1].
- Approval period can be for up to three years, unlike expedited or full-board review approval periods, which are for a maximum of one year.
Common exempt studies (SOP 3.4.2)

1. Research involving the collection or study of existing data, documents, or records where the sources are publicly available or de-identified (i.e., the participants can not be identified directly or through identifiers linked to the subject)

2. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless:
   - Information obtained is recorded in such a manner that Human Subjects can be identified directly or through identifiers linked to the subjects; and
   - Any disclosure of the Human Subjects responses outside the Research could reasonably place the subjects at risk
What is expedited research?

- Research that is **no more than minimal risk** to subjects and that meets the categories listed in Tualne SOPs 3.5

- The identification of participants will not place them at risk of criminal or civil liability or be otherwise damaging

- Review is conducted by the IRB Chair or designee

- Approval period is for up to one year
The research must fit into one of several specific categories to qualify as expedited research (see Tulane SOPs 3.5.1). Common categories include:

- Collections of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data from voice, video, digital, or image recordings made for research purposes
- Research on individual or group characteristics or behavior (including research on perception, cognition, motivation, identity, language, cultural beliefs, social behavior, etc.)

Any research not exempt or expedited is full-board review.
How long does the IRB take to review a submission?

- **Exempt Review:**
  - 1-2 weeks

- **Expedited Review:**
  - 2-3 weeks

- **Full Board Review:**
  - 4-5 weeks if approved as submitted
  - 6-8 weeks if modifications are required by board and the PI submits appropriate modifications

- The IRB approval letter will contain an expiration date for IRB approval of the research. Be sure to submit your continuing review application well in advance of the expiration date.
Critical Points to Remember

- Register with IRBNet in order to submit a protocol to IRB (all submissions are via IRBNet)
- Complete CITI training prior to submission to IRB. All personnel involved in the project must complete CITI training.
- Be cognizant of the lead time needed for review by the IRB.
- Students need a faculty advisor in order to submit a protocol.
- Do not begin research until you receive the IRB approval letter.
Critical Points to Remember (cont.)

- Be cognizant of expiration dates for approval of the study and for approval of the informed consent document.
- Most studies are approved for a maximum of one year. A continuing review application must be submitted far enough in advance of the expiration date to allow for IRB review of the continuing review application.
- File an amendment if any changes are made to the study.
- If activity originally does not involve human subjects research but your intent changes to include human subjects research, then make a submission to IRB.
Contact Information

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

- Tulane’s Human Research Protection Office (HRPO): 504.988.2665; irbmain@tulane.edu; http://tulane.edu/asvpr/irb/index.cfm

- Tulane human subjects protection policies: http://tulane.edu/asvpr/irb/policies.cfm

- Instructions for taking CITI Training: http://tulane.edu/asvpr/responsible-conduct-in-research-training.cfm