WHEN A STUDENT BECOMES A RESEARCHER ENGAGED IN HUMAN SUBJECTS RESEARCH

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Objectives of Presentation

- What is the role of the Research Compliance Officer and the IRB?
- 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

- 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:
  - ex-officio
  - 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 human body, malaria, mustard gas, sterilization, effects high altitude.
- Led to passage of 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 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.

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

The IRB is the decision making body of Tulane’s HRPP.

The Tulane Human Research Protection Office (“HRPO”) administers the HRPP.
Why does it matter if human subject research is involved?

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

- Faculty and students 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.
Why does it matter if human subject research is involved?

Possible Repercussions for failure to obtain IRB approval of human subjects research:

- Prohibition from using data;
- Prohibition from publishing;
- Reporting to federal oversight agencies (ex: FDA, OHRP; OIG);
- Subject to filing of a research misconduct allegation, which can lead to a range of penalties, including expulsion.
2-Step process for review of research

- Step 1: Does the activity constitute human subjects 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*
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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Practical Interpretations

- 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.
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?
  - Is the data private and individually identifiable?
  - Will I write up the results?
  - Will the results be available to others?
Who can serve as Principal Investigator?

- Students must have a faculty advisor in order to submit proposals to the IRB for review.
- 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
- Students must take CITI training online prior to submitting proposals to the IRB
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
- Research results that will not be published outside the classroom.
What is publishing?

- Look to intent to make the results public.
- Information used within a class does not constitute publishing and does not require IRB review.
- Sharing the information with individuals outside the classroom likely constitutes publishing, therefore necessitating review.
- For example, 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. This is not human subjects research.
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 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. However, if the collected data later will be published or presented publically, human subjects research may exist.
Question: May we hire a student to work on a research project?

Answer: Yes. However, the student is considered to be conducting human subject research and should undergo CITI training if:

- The student is developing research questions
- The student is testing hypotheses
- The student has contact with participants
- The student has access to participants’ individually identifiable information.
Example: Thesis or Dissertation

- **Question:** Is a student’s research for a thesis or dissertation considered 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 being collected and analyzed from live human subjects. If so, then research likely exists. The student would need a faculty advisor and approval from the IRB to conduct the research.
Example: Pilot Studies

Question: A student 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 by a student 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.

Thus, no institutional review is required.
Example: Interviews for Publications

- **Question:** Does a student’s interview of prisoners for a magazine article on prison life constitute human subjects research?

- **Answer:**
  - It depends. If the goal is not the production of generalizable or universal knowledge, the information generated is specific to the people interviewed in their current situation. Thus, no institutional review is required.
  - If the goal is to inform policies or generalize findings in an evidence based way, then it is research.
Assuming Human Subjects Research Exits, three levels of IRB review:

- Exempt Review; Expedited Review; Full-Board Review.
- Each level requires a different application.
- If unsure of what level is required for your activity, submit query to irbmain@tulane.edu prior to submitting application to IRB.
What is exempt research?

- Minimal risk studies that fall within set categories listed in Tulane SOPs 3.4.2.
- Shortened application.
- 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 meet 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:

- **Category 2**: collections of blood samples by finger stick, heel stick, ear stick, or venipuncture
- **Category 3**: prospective collection of biological specimens for research purposes by noninvasive means.
- **Category 6**: Collection of data from voice, video, digital, or image recordings made for research purposes
- **Category 7**: Research on individual or group characteristics or behavior (including research on perception, cognition, motivation, identify, language, cultural beliefs, social behavior, etc.)
How long does the IRB take to review a submission?

- **Exempt Review:**
  - 1-2 weeks
  - Must fall within exempt categories listed in SOPs 3.4.2

- **Expedited Review:**
  - 2-3 weeks
  - Must be no more than minimal risk and fit within categories of SOP 3.5

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

- All filings must be made via IRBNet.
Critical Points to Remember

- Be cognizant of the lead time needed for the IRB to review a submission (including requested changes).
- CITI training is required for anyone involved with human subject research.
- Register with IRBNet in order to submit a protocol to IRB.
- The student must have a faculty advisor in order to submit a protocol to the IRB.
- Be cognizant of expiration dates for approval of the study and for approval of the informed consent document.
- If you are unsure about whether your proposal requires exempt, expedited, or full-board review, contact the HRPO.
Critical Points to Remember

- Refer to the HRPP SOPs, which are available at [http://tulane.edu/asvpr/irb/policies.cfm](http://tulane.edu/asvpr/irb/policies.cfm).
- If you have questions that you or your faculty advisor can’t resolve, contact HRPO.
- File an amendment via IRBNet if any changes are made to the study.
- If your activity originally does not involve human subjects research but your intent changes to include human subjects research, then make a submission to IRB.
Seek clarification from the IRB regarding whether activity is human subjects research. If yes, seek clarification regarding what type of review is required.

If the activity does not meet the definition of human subjects research, the need for institutional review is eliminated.

Alternatively, tailor the research so that it qualifies for exempt review:
- Benefits: shortened initial application, may be granted up to 3 years approval, and review by IRB chair (or designee) rather than full board.

Alternatively, tailor the research so that it qualifies for expedited review:
- Benefits: review by IRB chair (or designee) rather than full board.
Contact Information

- 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
- Research Compliance (Brian Weimer): 504.988.1147; bweimer@tulane.edu; Room 2425 of Tidewater Bldg; http://tulane.edu/asvpr/research-compliance.cfm
- Instructions for taking CITI Training: http://tulane.edu/asvpr/responsible-conduct-in-research-training.cfm