Does Your Project Require an Application to the Southwestern Institutional Review Board (IRB)?

**DECISION TREE #1**

Will you, a member of your research team or a collaborator, observe, interact with, or intervene with individuals to gather information that will be used for research? Examples:
- Surveys, questionnaires, focus groups, interviews
- Games, experiments in physical or in electronic environments
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures
- Diet, nutrition studies, taste tests
- Studies examining effectiveness of educational tools or curricula
- Use of instruments or devices, including phones, to collect data or monitor or influence behavior
- Observation of public behavior in physical or online environments in which there is an expectation of privacy
- Studies examining individuals’ responses to manipulation of their physical or online environment
- Another activity that involves observation of, or interaction with, individuals to gather information for research

**DECISION TREE #2 on Existing / Secondary data - page 2**

Does the research expose participants to greater than minimal risk, or do the proposed participants include vulnerable populations (prisoners, pregnant women, people under 18 years of age, or other vulnerable groups), or does the project involve sensitive information (such as sexual activity, drug use, illegal behaviors, etc.)?

The project may lead to use of the results outside of the course (e.g., for a publication, or a Capstone, Student Works Symposium or conference presentation).

**NOTES**

- YES: **Applicaton to the IRB is needed.**
- NO: **Not human participant research. No application to the IRB is needed.**

Project is research with human subjects. An applications to the IRB and written notice of approval required before the study can begin. Forms available at [http://www.southwestern.edu/offices/dean/IRB/](http://www.southwestern.edu/offices/dean/IRB/) Questions irb@southwestern.edu
Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require Review by the Southwestern IRB

**DECISION TREE #2**

**Are the data/specimens about or from individuals who are or may be still living?**

- **NO**, Materials are from cadavers, or data is about deceased individuals
  - **YES**
    - **• Are the specimens (human cell lines, tissue, etc.) obtained from a producer or supplier of public use data; or**
    - **• Is all the information about the specimens/data available in the public domain?**
      - **NO**
        - **Yes**
          - **Project is Not Human Subjects Research**
            - No application to the SU IRB needed.
          - **NO. Data is de-identified**
            - Can the **provider** (researcher or organization that originally collected the data/specimens) link the specimens/data, directly or indirectly, to identifiable living individuals?
              - **NO. Provider is solely providing, with no role in the research.**
              - **YES**
                - **Can the **recipient** (you and/or your research team) link the specimens/data directly to identifiable living individuals either directly or through a code?**
                  - **NO**
                    - **Is the **provider a collaborator in the **recipient's research?** i.e. involved in the design, conduct or reporting of the research and/or listed as collaborator and/or author on research proposals or protocols.**
                      - **YES.**
                        - Recipient and Provider are collaborators on the research
                      - **NO**
                        - Forms at [http://www.southwestern.edu/offices/dean/IRB/](http://www.southwestern.edu/offices/dean/IRB/)
                        - IRB/Questions? Contact irb@southwestern.edu
                - **YES**
                  - **Project is Human Subjects Research**
                    - Application to the IRB and written notice of approval or notice of exemption required before research can begin.
                    - Forms at [http://www.southwestern.edu/offices/dean/IRB/](http://www.southwestern.edu/offices/dean/IRB/)
                    - IRB/Questions? Contact irb@southwestern.edu

All Forms at [http://www.southwestern.edu/offices/dean/IRB/](http://www.southwestern.edu/offices/dean/IRB/)
Questions? Contact irb@southwestern.edu
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