

IRB Exclusion Decision Tool - My Project Needs Review

Instructions: Use this decision tool to determine whether a complete application should be submitted for your proposed project to the Institutional Review Board. This worksheet is designed to help investigators find out whether their project constitutes human subjects research according to the definitions provided by the regulations for the protection of human subjects. This worksheet is NOT designed to determine whether a research project involving human subjects is exempt. **Exclusion and Exemption are not the same thing.** Please enter the information in the exact prescribed order to ensure accuracy.

Students: Complete this worksheet ~~before~~

remainder of the worksheet. Projects that are not systematic investigations do not meet the federal regulatory criteria for o

Please note that you do not need to have direct interaction with individuals or collect identifying information from them in order for the activity to be an interaction involving humans

4. Will the research utilize existing or secondary data which contain individually identifiable private information?

Existing or secondary data include records as well as tissue, organs, fluids and other biospecimens that were not originally collected for the research or will not be collected specifically for the research in the future.

Individually identifiable private information is defined in #3 above.

Yes, or Not Sure? The research requires review and you may stop filling out 864e Tj -0.084 Tw () a t

Student Research: Faculty members should engage students in a discussion about whether their goals include conducting research that contributes to new scholarly knowledge. Students should only be routed to the IRB if they have indicated, using this worksheet, that their project is a systematic investigation designed to contribute to generalizable knowledge involving human subjects. No procedural requirement or verification with the Office of Research is needed if the work is determined to not meet the criteria for oversight. However, SJSU policy imposes limitations on student work that does not meet the federal definition of human subjects research:

- Student work must be minimal risk and may not target special populations or include sensitive subject matter. Minimal risk means that participants will encounter no harms or discomforts greater than those that are part of their daily lives.
- A project specific consent form may still be appropriate in many circumstances. While students may refer to the informed consent handbook posted on our website for information on best practices, the consent form used may not indicate that the University approved the work, and it may not include contact information for the Office of Research.
- Participants should not be led to believe that the project constitutes a formal

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