IRB Exclusion Decision Tool: Does My Project Need IRB Review?

Instructions: Use this decision tool to determine whether a complete protocol application needs to be submitted for your proposed project to the Office of Research. This worksheet is designed to help investigators find out whether their project constitutes human subjects research, according to the definitions provided by the federal 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 fill out the information in the exact prescribed order to ensure accuracy. **Students:** Complete this worksheet in the exact prescribed order with your faculty supervisor. **All:** Retain this worksheet for your records. A copy of this worksheet does not need to be submitted to the Office of Research.

Completed By: _____

Date: _____

Signature of Faculty Supervisor (if applicable): _____

Date: _____

Project Title: | |

Does It Meet the Federal Definition of "Research"?

1. Is your project a *systematic investigation*, including research development, testing, and evaluation?

A ***systematic investigation*** refers to a strategy of study involving a methodical procedure or plan that is theoretically grounded, specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods. A study that is systematic allows conclusions to be drawn from the results. Although some qualitative research projects are exploratory in nature and may not have specific aims or hypotheses at the outset, these may still be systematic investigations if their purpose is to compare results to other assessments or to draw conclusions.

☐ Yes, or Not Sure? Continue to question #2.

☐ No → STOP. A protocol submission is not required even if you answer yes to questions on the remainder of the worksheet. Projects that are not systematic investigations do not meet the

federal regulatory criteria for oversight. **However, please read the section below "Not Human Subjects Research: Additional Information and Restrictions" prior to beginning your project**.

2. Is the project designed to develop or contribute to *generalizable knowledge*?

Generalizable knowledge means a set of conclusions, facts, or principles that enhances scientific or academic understanding by applying broadly to a whole category, such as a population or field of knowledge. Generalizable knowledge is produced when investigators make the components of their research design (procedures, methods, and instruments) as well as the analyzed findings/results available for other professionals or academics to peer review, replicate, and utilize. Traditionally this occurs when publishing or presenting at a professionally refereed venue, conference, or competition, but it may also occur through new media methods of discourse. In qualitative research, generalizable knowledge may emerge when the research generates detailed descriptions of phenomena which may be transferable to like situations or when new theories, principles, or statements of relationships are developed as a result of the data collection. Master's theses are published and made available outside SJSU and are usually considered research that contributes to generalizable knowledge. However, projects which are disseminated exclusively at SJSU and are not intended for dissemination beyond the instructional setting are *typically* not designed to contribute to generalizable knowledge. Likewise, research projects which are designed as common biographical research, oral histories, and journalism are *typically* not designed as a systematic investigation to contribute to generalizable knowledge. The purpose of these activities is often to create a record of specific historical events or persons, and findings are usually not generalized to a broader population or group.

☐ Yes, or Not Sure? Continue to question #3.

☐ No → STOP. A protocol submission is not required even if you answer yes to questions on the remainder of the worksheet. Projects that are not designed to develop or contribute to generalizable knowledge do not meet the federal regulatory criteria for oversight. **However, please read the section below "Not Human Subjects Research: Additional Information and Restrictions" prior to beginning your project**.

Does It Involve "Human Subjects"?

3. Will the research involve *interaction* or *intervention* with living individuals or the collection of *individually identifiable private information*?

Interaction includes communication or interpersonal contact between the investigator and the subject that solicits personal information. Examples of interaction may include collecting personal data through questionnaires, interviews, tests, and performance evaluations. Persons involved in a research activity are not considered to be human subjects when the person interviewed/surveyed is asked to provide information specific to his/her expertise or

institutional information as opposed to personal information (examples of personal information include opinions, thoughts, perceptions, performance metrics, and private data about the individual). For example, welders asked to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead are not disclosing information about themselves and, as such, are not research subjects in this context. Likewise, when investigators wish to collect information about institutions or social processes from individuals, such activities do not constitute research involving human subjects when the focus of the research is not on the characteristics or personal views of the informant. There is often a fine line between what is defined to be "human subjects research" and research that collects information from people in order to understand institutions or social processes. For example, asking the same welders in the above example how industry consolidation has affected the safety practices in their work environment would constitute research involving human subjects. Research on institutions or social processes, the purpose of which is to create generalizable knowledge about the attitudes, beliefs, or behaviors of individuals or groups (e.g., voters, prisoners, employees) as being representative of these institutions or social processes, is human subjects research.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. The researcher need not collect personal information in order for the work to qualify as an intervention that involves human subjects. For example, an experiment that tracks participants' eye movements across a screen would still involve human subjects, even if no personal information is recorded.

Individually identifiable private information means that the identity of the human subject is or may be readily ascertained by the investigator or associated with the information collected. This includes information about behavior that occurs in a context in which the subject can reasonably expect that no observation or recording is taking place, as well as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical/clinical records, academic records, social services records, new media forms of disclosure which are not made public but which you may have access to by accident or privilege).

☐ No → Continue to question #4.

☐ Yes, or Not Sure? The research requires review. Please read the section below "Human Subjects Research: Expectations for IRB Protocols" prior to submitting your research protocol to the Office of Research.

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. Please read the section below "Human Subjects Research: Expectations for IRB Protocols" prior to submitting your research protocol to the Office of Research.

☐ No → Continue to question #5.

5. Is there any possibility that the researcher or collaborators (e.g., student assistants, professional partners) could ascertain the identity of a living individual from the existing or secondary data utilized at any point during the course of the research?

☐ Yes, or Not Sure? The research requires review. Please read the section below "Human Subjects Research: Expectations for IRB Protocols" prior to submitting your research protocol to the Office of Research.

☐ No → STOP. A protocol submission is not required. Using non-identifiable information does not meet the federal regulatory criteria for oversight. If your research utilizes data which are irrevocably de-identified or have already been coded by a third party in such a way that the researcher and collaborators cannot ascertain the identity of a living individual, the project does not need to be reviewed by the IRB and is not subject to oversight by the Office of Research.

Not Human Subjects Research: Additional Information and Restrictions

Some activities, though they may be deemed "not human subjects research," **may still pose risks** if they:

- Involve protected or vulnerable populations
- May cause participants harm (e.g., psychological, physical, legal, educational, social and/or economic)
- Pose risk to *you* as the researcher.

Regardless of whether a project needs to be reviewed by the IRB, the rights and welfare of the participants involved in a project must be protected. Investigators may need to consult discipline specific guidance. The general principles of respect for persons, beneficence, and justice outlined in IRB educational materials posted on our website can also be applied to activities that do not meet the federal regulatory criteria for IRB review.

Student Research: Faculty members should engage their 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 research endeavor.
- A faculty member is still responsible for direct supervision of student projects and ensuring that the work is conducted ethically and follows best practices within the discipline.

Human Subjects Research: Expectations for IRB Protocols

If you have completed this worksheet and determined that your research requires submission of a protocol to the Office of Research, please visit the IRB website to view the steps for submitting a protocol. The basic expectations for all IRB protocols are as follows:

- The purpose of the study is clearly identified.
- A rationale is provided for the study that builds on previous research and includes appropriate citations.
- The research team has made every effort to optimize meaningful informed consent/assent and voluntary participation. Consent/assent language is simple; straightforward; appropriate for the level of literacy, education, developmental and cognitive capacity of the participants; and culturally appropriate.
- The protocol is well-written and has been proofread.

The review criteria that IRB members use provide more details about the expectations for each protocol.