

IRB Determination Worksheet -Does My Project Need IRB Review?

Instructions: Use this worksheet to determine if an IRB application is required for your research project. This worksheet is designed to help researchers determine if their project constitutes human subjects research, per definitions provided by [the federal regulations](#) for the protection of human subjects.

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 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. **NOTE:** Please review the section below "Not Human Subjects Research: Additional Information and Restrictions" prior to beginning your project.

2.

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

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 ~~use~~ 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 ~~reference~~ this section btt (u)-4 (t)6 (u)-4 tin

