

Examples^{1,2}

The examples below are meant to assist researchers in understanding the types of activities that do and do not require IRB oversight based on whether they meet the federal definition [“Does your study require IRB Review”](#) of research involving human subjects. The scenarios must meet the definition for both research and human subjects in order to trigger the requirement for IRB review (i.e. If there is a ‘YES’ in both columns, IRB review is required).

Please submit a [Research and Engagement Determination Form](#) for a formal determination from the IRB, if you think that your study does **NOT** constitute research with human subjects.

ACTIVITIES	EXAMPLES	IS IT RESEARCH?	ARE THERE HUMAN SUBJECTS?
Data collection for internal, department, school, or other University administrative purposes	<ul style="list-style-type: none"> Teacher evaluations, customer service surveys or workshop evaluations where results will be used to facilitate improvements 	<p>NO</p> <p>The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>
Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about people as part of a class exercise or assignment that is not intended for use outside of the classroom	<ul style="list-style-type: none"> Research methods courses in which student assignments include interviews or surveys of individuals but results are not disseminated outside of the class. 	<p>NO</p> <p>The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>
Collecting and publishing personal or professional stories, without intent to draw conclusions or generalize findings	<ul style="list-style-type: none"> Oral histories Autobiography Photojournalism 	<p>NO</p> <p>The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>

¹ PRIM&R Webinar “Key Decision Points” Is it Research Involving Human Subjects? Is it Exempt? Is IRB Review Required?” Hale, Karen, RPh, MPH, CIP; Nelson, Daniel, MSc, CIP. February 28, 2013.

² Petty, Cheri. “You’ll Know it When You See It: Defining Human Subjects Research Under DHHS Regulations.” November 8, 2013. PRIM&R 2013 AER Conference. Boston, MA.

<p>Carrying out fee based services without the expectation of academic recognition or co-authorship or data ownership</p>	<ul style="list-style-type: none"> • Personnel studies • Cost-benefit analyses • Customer satisfaction studies • Biological sample processing 	<p>NO The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>Case studies (n=1) or outcomes of only one individual that is published or presented</p>	<ul style="list-style-type: none"> • Interviews or data collected from only one individual. 	<p>NO The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>Institutional research (research conducted about the institution) that involves data collection, analysis, or reporting about educational, administrative, or other aspects of OSU for either internal improvement or external reporting</p>	<ul style="list-style-type: none"> • Analysis of graduation rates by gender, age or race for reporting purposes • Analysis of student success in a specific department or course for program improvement purposes • Analysis of student tests or work samples to assess student outcomes for intra-departmental reporting • Analysis of institutional databases or archival materials to inform such issues as: <ul style="list-style-type: none"> ○ enrollment management ○ faculty or staff planning ○ space planning and utilization • Focus groups, surveys or interviews with faculty or students intended to evaluate and improve programs or services provided by the institution or to assess needs 	<p>NO The activity is not research. Involves a <i>systematic investigation</i> but no intent to contribute to <i>generalizable knowledge</i>.</p> <p>Institutional research is specific and applied. It is not intended to generate theory, provide results that will be <i>generalized</i> beyond OSU, or advance knowledge. It is intended to be of direct, practical value.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>Program improvement or evaluation projects where the use of results is</p>	<ul style="list-style-type: none"> • Internal reporting of assessments of community education or 	<p>NO The activity is not research.</p>	<p>NO There are no human subjects</p>

<p>restricted to informing the implementation or content of the program</p>	<p>programs, i.e.,</p> <ul style="list-style-type: none"> ○ survey results from senior center participants ○ physical activity levels of participants in a walking program <ul style="list-style-type: none"> ● Data collected to fulfill reporting requirements of a state agency funding a specific program or project ● Collection of information from individuals to inform decision making ● The collection and analysis of data used to assess and improve a program with the intent of , publishing the original analysis and results are presented as quality improvement, not research 	<p>Involves a <i>systematic investigation</i> but the findings are not <i>generalizable</i> beyond the program under study.</p>	<p>since this is not research.</p>
<p>Searches of existing literature</p>	<ul style="list-style-type: none"> ● Review of public meeting minutes ● Review of published journal or newspaper articles ● Review of historical records ● Review of public websites 	<p>YES</p> <p>The activity is research</p> <p>It is a systematic investigation designed to develop or contribute to generalizable knowledge.</p>	<p>NO</p> <p>There are no human subjects There is <i>no interaction or intervention</i> and the data are publically available rather than <i>private</i>.</p>
<p>Research projects that involve the use of publicly available data to analyze public figures</p>	<ul style="list-style-type: none"> ● Analysis of public meeting minutes ● Analysis of local crime or poverty statistics 	<p>YES</p> <p>The activity is research</p> <p>It is a systematic investigation designed to develop or contribute to generalizable knowledge.</p>	<p>NO</p> <p>There are no human subjects There is <i>no interaction or intervention</i> and the data are publically available rather than <i>private</i>.</p>

Research involving data about or samples from deceased individuals	<ul style="list-style-type: none"> • Analysis of cadaveric tissue • Review of death certificates 	<p style="text-align: center;">YES</p> <p style="text-align: center;">The activity is research</p> <p style="text-align: center;">It is a systematic investigation designed to develop or contribute to generalizable knowledge.</p>	<p style="text-align: center;">NO</p> <p style="text-align: center;">There are no human subjects Not a living individual about whom data or private identifiable information is collected.</p>
Fact-collecting interviews of individuals where <u>all</u> questions focus on process, objects, products, or policies, rather than an individual's attitudes, behaviors, or perspectives	<ul style="list-style-type: none"> • Canvassing librarians to determine the differences between inter-library loan policies or rising journal costs • Interviewing farmers about their animals • Audit of the physical activity features in a community • Interviewing managers about their company's manufacturing processes 	<p style="text-align: center;">YES</p> <p style="text-align: center;">The activity is research</p> <p style="text-align: center;">It is a systematic investigation designed to develop or contribute to generalizable knowledge.</p>	<p style="text-align: center;">NO</p> <p style="text-align: center;">There are no human subjects</p> <p style="text-align: center;">Research questions are focused on objects, products or processes and not <i>about the individual</i> providing the information</p> <p style="text-align: center;">NOTE: Opinion based inquiry is considered to be <i>about the individual</i> and would require IRB review</p>

CASES

	IS IT RESEARCH?	ARE THERE HUMAN SUBJECTS?
<p>A faculty member helps a colleague at another institution develop a survey given to the colleague's students. Students are asked for feedback on the course content, assignments, and tests. (Providing names on the survey is optional.) The faculty member will also help to analyze the survey results; names (if any) will not be removed before surveys are sent to the faculty member. Results will be used only to improve the course.</p>	<p>NO</p> <p>The activity is not research. Results will only be used for program improvement.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>
<p>The director of the neonatal intensive care unit is concerned about the unit's efficiency, drug utilization, and quality of care. She is particularly interested in the use of an expensive treatment regimen. She conducted a 3-month study involving the unit's physicians, nurses, and staff, as well as the medical records of premature babies. Upon completion of the study, Dr. Bambino used the</p>	<p>NO</p> <p>The activity is not research. Findings are not disseminated outside of the institution.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>

<p>data to make improvements in the unit. She then presented the data during pediatric grand rounds.</p>		
<p>A graduate student who works part time at an art museum is helping the museum conduct a survey of people who viewed the new Impressionist exhibit. The student employee will interact with patrons to distribute the surveys and will also help to analyze the responses. Individuals who complete the survey and provide their name and address will be mailed a coupon good for \$10 off their next visit to the museum. The museum will use the results of the survey to design their new ad campaign, conduct fund-raising, and to plan future exhibits.</p>	<p>NO The activity is not research. Quality improvement projects are not typically generalizable.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>A graduate student intends to interview people about their experiences related to race and identity. She will conduct audio-recorded interviews with individuals from both rural and urban areas of the Middle East that the United States and will ask some basic demographic questions and open-ended questions about ethnicity, family, religion, defining experiences related to race (good and bad) and definitions/concepts of race.</p> <p>Data will be analyzed to look for similarities and differences among various participants as well as compelling stories. The information will be used to create a vignette-based fictional performance piece for the theater that reflects on the nature of race and the self. Interview data will not be used for any other purposes.</p>	<p>NO The activity is not research. The project is not intended to create, develop, or contribute to generalizable knowledge.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>A faculty member will conduct a federally-funded study to describe, compare, categorize and analyze the tobacco use policies/restrictions of the most heavily used public transportation systems in several countries and correlate results to local tobacco use rates. The goal is to develop or contribute to generalizable knowledge and results will be published/presented. Data will be collected from existing datasets, websites, policies, and from transit authority personnel (phone/email questionnaires).</p> <p>Publically available data will be collected from transit authority websites to</p>	<p>YES The activity is research It is a systematic investigation designed to develop or contribute to generalizable knowledge.</p>	<p>NO There are no human subjects. The information gathered via questionnaires is not <u>about</u> living individuals. All information is factual information about the organizations policies and procedures.</p>

document current policies/restrictions regarding tobacco usage. Online publically-available, aggregate data on tobacco use from the respective areas will also be obtained. Transit authority personnel will be contacted to obtain a written copy of any tobacco-related policies and to obtain factual information about how the policies are communicated. An email questionnaire will be sent first, followed by a phone call if no response. Only factual information about policies/organizations will be obtained.³

NOTE: If the researcher wanted to include questions about personal opinions on the policies/procedures or if additional personal data about the respondents and policy makers was collected, then it would be determined that data about living individuals was being collected and the research would include *human subjects*.

Many times, it comes down to specific questions and/or data points. Collecting information *from* an individual does not necessarily equal collecting information *about* an individual.

A researcher is writing a grant and collects preliminary data about a subset of children to test a new measurement mechanism. The measures are noninvasive and occur in a context of typical educational practice. The intent of the data collection is to gather information for a grant proposal to support a rigorous evaluation of the measure. There is no intention to publish this data apart from including it in a grant proposal

YES

This activity is research.

Pilot testing, even if results are only used for grant proposals, is considered research because it is a systematic investigation that is used to *develop* generalizable knowledge.

YES

There are human subjects.

The data about the children are collected through intervention or interaction.

IRB Review is Required.

³ Petty, Cheri. "You'll Know it When You See It: Defining Human Subjects Research Under DHHS Regulations." November 8, 2013. PRIM&R 2013 AER Conference. Boston, MA.

SCENARIOS	IS IT RESEARCH?	ARE THERE HUMAN SUBJECTS?
<p>Original Scenario: The light bulbs in K-5 classrooms are changed from incandescent to florescent.</p>	<p>NO The activity is not research. No data are being collected.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>Evaluators are now interested in whether or not the change in light bulbs influence the behavior in the classroom. Students are asked to complete a pre- and post- survey intended to gauge their attitudes towards the lighting in the classroom. Teachers also complete a pre- and post-survey to rate the behavior changes in their students.</p>		
<p>Note: In these scenarios, “results” are defined as the individual participant data (survey responses from students and teachers) in either individual or aggregated form.</p>		
<p>Scenario 1: Researchers observe what type of light bulb is in each classroom and measure impacts on classroom behavior.</p> <p>Results will only be used to inform light decisions to improve classroom behavior within the school of study.</p>	<p>NO The activity is not research. Findings are not disseminated outside of the institution.</p>	<p>NO There are no human subjects since this is not research.</p>
<p>Scenario 2: Researchers observe what type of light bulb is in each classroom and measure impacts on classroom behavior.</p> <p>Results are used to inform light decisions to improve classroom behavior within the school of study but researchers also intend to publish on how the evaluation occurred, not on the results of the evaluation.</p>	<p>NO The activity is not research. Findings of the evaluation are not disseminated outside of the institution. The publication focuses on HOW the evaluation occurred, not on the results of the evaluation.</p>	<p>NO There are no human subjects since this is not research.</p>

<p>Scenario 3: Researchers observe what type of light bulb is in each classroom and measure impacts on classroom behavior.</p> <p>Results are intended for publication.</p>	<p>YES</p> <p>The activity is research. Findings will be used to contribute to generalizable knowledge</p>	<p>YES</p> <p>There are human subjects. Researchers are collecting information about the participants (through surveys).</p> <p>IRB review required.</p>
<p>Scenario 4: Classrooms are randomly assigned fluorescent or incandescent light bulbs and researchers measure the impacts on classroom behavior.</p> <p>Results will only be used for improving the behavior within the school of study.</p>	<p>NO</p> <p>The activity is not research. Findings are not disseminated outside of the institution.</p>	<p>NO</p> <p>There are no human subjects since this is not research.</p>
<p>Scenario 5: Classrooms are randomly assigned fluorescent or incandescent light bulbs and researchers measure the impacts on classroom behavior.</p> <p>Results are intended for publication.</p>	<p>YES</p> <p>The activity is research. Findings will be used to contribute to generalizable knowledge.</p>	<p>YES</p> <p>There are human subjects. Researchers are manipulating the environment of the subjects and collecting information about them (through surveys).</p> <p>IRB review required.</p>

Scenario 6: Classrooms are randomly assigned fluorescent or incandescent light bulbs and researchers measure the impacts on classroom behavior.

The initial intent was to use results only for improving the behavior within the school of study. Later, researchers decide they want to publish the results.

<p style="text-align: center;">YES</p> <p style="text-align: center;">The activity is research</p> <p style="text-align: center;">At the point that the intent changes, this became research.</p> <p style="text-align: center;">At this decision point, researchers should</p> <p style="text-align: center;">STOP—and contact the IRB.</p> <p style="text-align: center;">Researchers may be required to go back to the participants and seek consent for the new use of the data.</p>	<p style="text-align: center;">YES</p> <p style="text-align: center;">There are human subjects.</p> <p style="text-align: center;">Researchers are manipulating the environment of the subjects and collecting information about them (through surveys).</p> <p style="text-align: center;">IRB Review Required</p>
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