

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 research involving human subjects. The scenerios 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 [Appendix E: IRB 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 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> |
| 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 The activity is not research. Involves a systematic investigation but no intent to contribute to <i>generalizable knowledge</i>.</p> | <p>NO 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 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> |
| Carrying out fee based services without the expectation of academic recognition or co-authorship or data ownership | <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 not 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

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| <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 DU 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 DU, 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 restricted to informing the implementation or content of the program</p> | <p>Internal reporting of assessments of community education or 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 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 | <p>NO The activity is not research. Involves a systematic investigation but the findings are not generalizable beyond the program under study.</p> | <p>NO There are no human subjects since this not research.</p> |

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| | <ul style="list-style-type: none"> 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 improved, not research | | |
| Searches of existing literature | <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 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 There is <i>no interaction or intervention</i> and the data are publically available rather than <i>private</i>.</p> |
| Research projects that involve the use of publicly available data to analyze public figures | <ul style="list-style-type: none"> Analysis of public meeting minutes Analysis of local crime or poverty statistics | <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. 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>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 Not a living individual about whom data or <i>private identifiable information</i> 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>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 Research questions are focused on objects, products or processes and not <i>about the individual</i> providing the information NOTE: Opinion based inquiry is considered to be <i>about the individual</i> and would require IRB review</p> |

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| 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 The activity is not research. Results will only be used for program improvement.</p> | <p>NO There are no human subjects since this is not research.</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. The project is not intended to create, develop, or contribute to generalizable knowledge.</p> | <p>NO There are not 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 document current policies/restrictions regarding tobacco usage. Online</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 about living individuals. All information is factual information about the organizations policies and procedures.</p> <p>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 <i>human subjects</i>.</p> |

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| <p>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.</p> | | <p>Many times, it comes down to specific questions and/or data points. Collecting information <i>from</i> an individual does not necessarily equal collecting information <i>about</i> an individual.</p> |
| <p>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.</p> | <p>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 <i>develop</i> generalizable knowledge.</p> | <p>YES There are human subjects. The data about the children are collected through intervention or interaction. IRB Review is Required.</p> |

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