## Chart 1: Does an activity involve "human subjects"

The activity involves obtaining information about living individuals.



The activity does not involve human subjects according to HHS 45 CFR §\_.102(e)(1) or the OWU IRB policy.





Information or biospecimens will be obtained through intervention or interaction with the individual.

HHS 45 CFR §\_.102(e)(1)(i)

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.



The activity does involve human subjects according to HHS 45 CFR §\_.102(e) and the OWU IRB policy.

Proceed to Chart 2.



collected.

HHS 45 CFR §\_.102(e)(5)

Identifiable information is any

Identifiable private information will be

**Identifiable** information is any information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Private information is any information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).



## Chart 2: Is an activity "research"

The activity is a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**, i.e., conclusions will be drawn about a larger entity (e.g., the population), not just the individuals being investigated.

NO.

The activity falls under one of the HHS 45 CFR § .102(I)(1-4) exclusions.

The activity is scholarly or journalistic in nature (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship). The collection and use of information will focus directly on the specific individuals about whom the information is collected.

NO v

HHS 45 CFR § .102(I)(1)



The activity is research according to HHS 45 CFR § .102(I) and the OWU IRB policy.

Proceed to Chart 3.

**V** 

YES

The activity is a **course project** in which there is

- 1) no more than minimal risk to the human subjects,
- 2) there is no involvement of vulnerable human subjects (e.g., pregnant women, children, prisoners, or cognitively impaired persons), and 3) the project is not part of a student independent project, honors thesis, or other individual student research experience.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

NO

YES

Review Table 1 and Examples of Research v. Non-research. Then revisit Chart 2 to determine whether your activity is or is not research. The activity is not research according to HHS 45 CFR §\_.102(I) and the OWU IRB policy.

Proceed to Chart 3.

**Table 1: Research vs. Nonresearch** 

**NONRESEARCH** 

entity (e.g., the population).

**COURSE PROJECTS** 

RESEARCH

	Covered by HSR policy	HSR policy does not apply	Involving Human Subjects
INTENT	HHS 45 CFR §46.102(I): Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge., i.e., data will be used to draw conclusions about a larger entity.	HHS 45 CFR §46.102(I)(1): Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.	Intent of project is to provide an educational experience about the research process or methods. Not covered by the HSR policy if no more than minimal risk, no subjects from vulnerable populations, and project is not an individual student project.
MOTIVATION FOR PROJECT	Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure, obtaining grants, completing an honors thesis).	Project occurs to portray the individuals involved.	Project occurs as part of assigned coursework in order to learn a new technique or fulfill an assignment.
DESIGN	Designed to develop or contribute to general scientific knowledge.	Designed to collect and use information about specific individuals themselves, and not generalizing to other individuals or the population.	NOT designed to develop or contribute to generalizable knowledge; design is often an example or template provided by a professor or course book.
SUBJECT POPULATION	HHS 45 CFR §46.102(e)(1): Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.	Individuals about whom the information is collected.	Individuals who are not part of vulnerable population, e.g., pregnant women, children, prisoners, or cognitively impaired persons.
BENEFITS	Participants may or may not benefit directly – benefit, if any, to individuals is likely to be incidental or delayed.	Individual benefit may or may not be anticipated.	Benefit is for the student conducting the project.
DISSEMINATION OF RESULTS	Results of the project will likely be disseminated outside the institution for the purpose of sharing the outcomes or implications of the project, not just the process.	Intent to publish or present generally presumed at the outset of the project; dissemination of information occurs to document a specific historical event or the experiences of individuals without intent to draw conclusions about a larger	Results and conclusions are not disseminated outside the University.

## **Chart 3: Next steps**

Your project meets the policy's definitions of Human Subject Research.



Complete human research ethics training and <u>submit your proposal</u> to the IRB.



Your project meets the Human Subject definition, but is a **course project**.



YES

Your project meets the Human Subject definition, but does **NOT** meet the policy's definition of research, i.e., is nonresearch.



Complete the <u>Scholarly Activities Involving Human Subjects form</u> to notify the IRB of your work. If the IRB has concerns about the nature of your project, we will contact you within one week (7 business days) of your submission. If you do not receive any follow-up communication from the IRB within one week (7 business days) of your submission, you may assume that we agree it meets the requirements of a course project and you may proceed with your scholarly work.

Complete the <u>Course Project form</u> to notify the IRB of your work. If the IRB has concerns about the nature of your project, we will contact you within one week (7 business days) of your submission. If you do not receive any follow-up communication from the IRB within one week (7 business days) of your submission, you may assume that we agree it meets the requirements of a course project and you may begin data collection.