

Chart 1: Does an activity involve “human subjects”

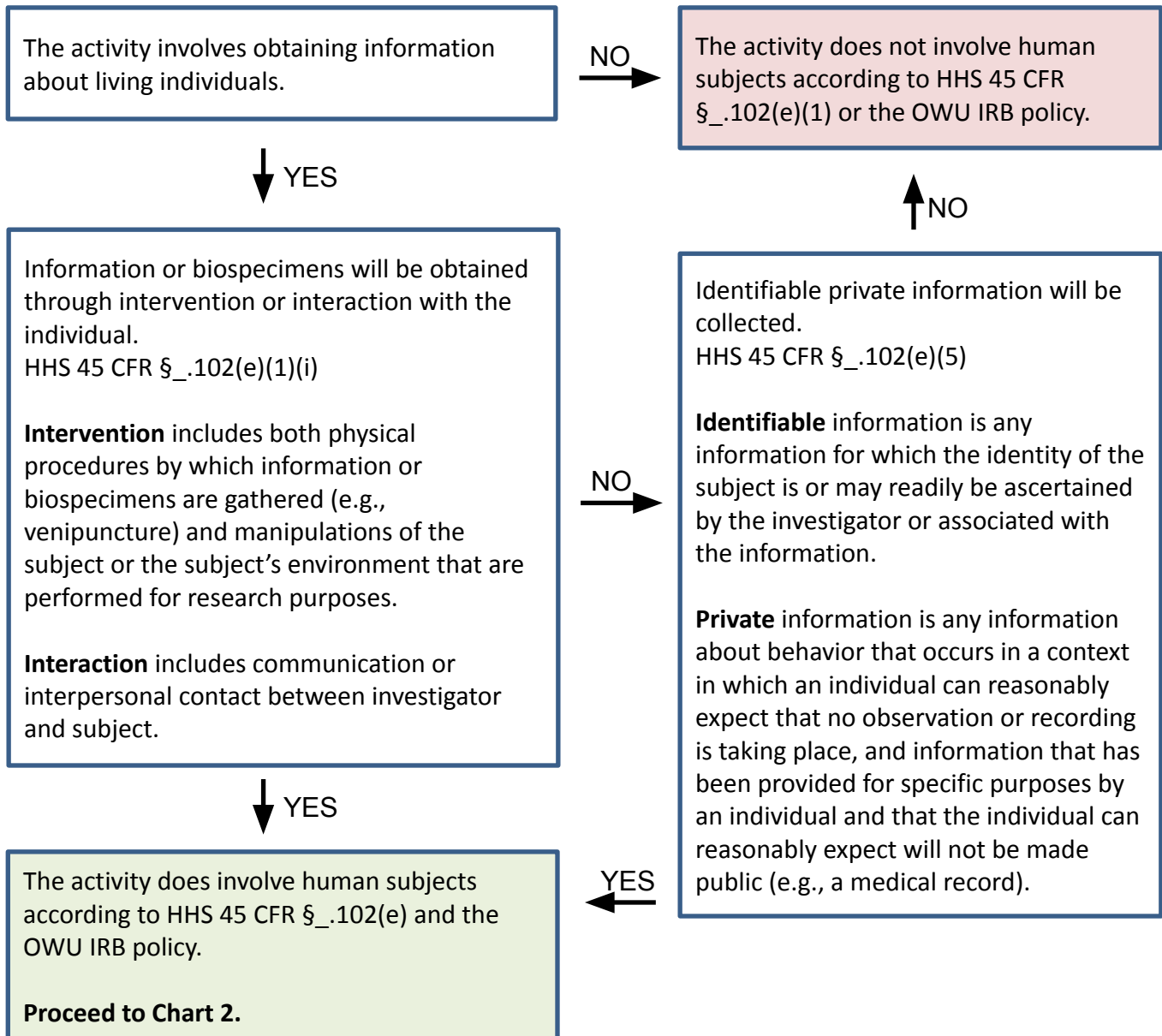


Chart 2: Is an activity “research”

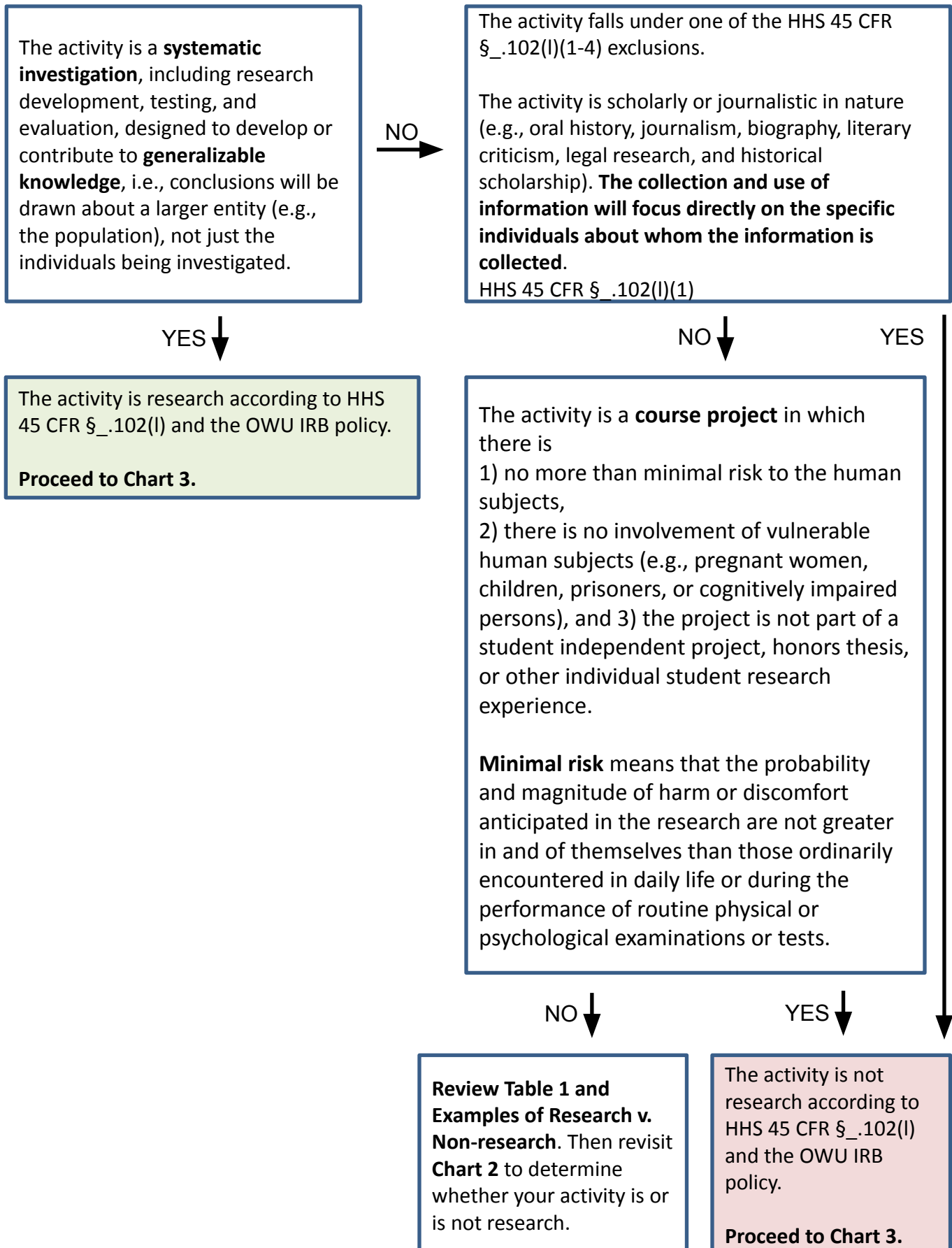


Table 1: Research vs. Nonresearch

	RESEARCH Covered by HSR policy	NONRESEARCH HSR policy does not apply	COURSE PROJECTS Involving Human Subjects
INTENT	HHS 45 CFR §46.102(l): 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(l)(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 entity (e.g., the population).	Results and conclusions are not disseminated outside the University.

Chart 3: Next steps

