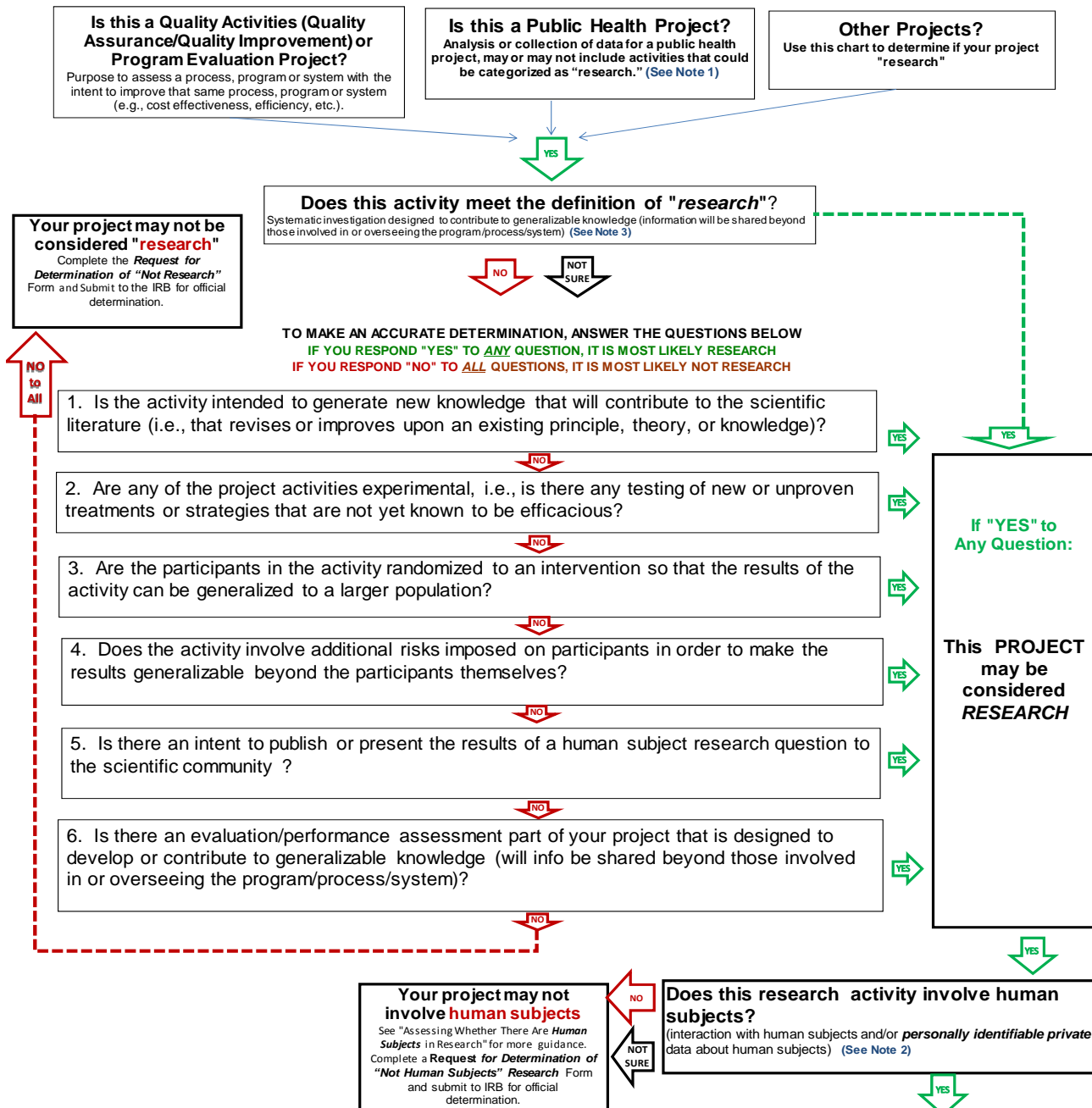


1. Is the activity in which you will be engaged RESEARCH?

ASSESSING WHETHER YOUR PROJECT IS "RESEARCH" REGULATED BY THE IRB

2/15/2011

For Assessing Projects Such As Program Evaluation, Quality Improvement, Quality Assurance, or Public Health Practice



NOTE 1: Examples: SAMHSA projects for which you are collecting required performance measures to monitor the effectiveness of the programs; projects where the primary intent is to identify and control a health problem; or projects where the primary intent is to directly benefit a population or group of individuals.

NOTE 2: Analysis of data that are not individually identifiable (i.e., permanently stripped of all patient identifiers by someone other than the investigator and not gathered by the research team) may be determined to not involve human subjects. SEE ALSO: "Assessing whether there are Human Subjects in Research"

NOTE 3: Intent to publish is an insufficient criterion alone for determining if a project is research. There are other purposes for publishing descriptions of non-research activities. For example, quality improvement projects are often disseminated outside the institution for the purpose of sharing the *process (the QA/QI methodology)* not the health care outcomes or implications. This would not be considered research.