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

ASSESSING WHETHER YOUR PROJECT IS "RESEARCH" 2/15/2011

REGULATED BY THE IRB

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

Is this a Quality Activities (Quality Assurance/Quality Improvement) or Program Evaluation Project?

Purpose to assess a process, program or system with the intent to improve that same process, program or system (e.g., cost effectiveness, efficiency, etc.).

Is this a Public Health Project?

Analysis or collection of data for a public health project, may or may not include activities that could be categorized as "research." (See Note 1)

Other Projects?

Use this chart to determine if your project "research"

TO MAKE AN ACCURATE DETERMINATION, ANSWER THE QUESTIONS BELOW

IF YOU RESPOND "YES" TO ANY QUESTION, IT IS MOST LIKELY RESEARCH.
IF YOU RESPOND "NO" TO ALL QUESTIONS, IT IS MOST LIKELY NOT RESEARCH

1. Is the activity intended to generate new knowledge that will contribute to the scientific literature (i.e., that revises or improves upon an existing principle, theory, or knowledge)?

2. Are any of the project activities experimental, i.e., is there any testing of new or unproven treatments or strategies that are not yet known to be efficacious?

3. Are the participants in the activity randomized to an intervention so that the results of the activity can be generalized to a larger population?

4. Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves?

5. Is there an intent to publish or present the results of a human subject research question to the scientific community?

6. Is there an evaluation/performance assessment part of your project that is designed to develop or contribute to generalizable knowledge (will info be shared beyond those involved in or overseeing the program/process/system)?

Your project may not be considered "research"

Complete the Request for Determination of "Not Research" Form and submit to the IRB for official determination.

Does this activity meet the definition of "research"?

Systematic investigation designed to contribute to generalizable knowledge (information will be shared beyond those involved in or overseeing the program/process/system). (See Note 3)

TO MAKE AN ACCURATE DETERMINATION, ANSWER THE QUESTIONS BELOW

IF YOU RESPOND "YES" TO ANY QUESTION, IT IS MOST LIKELY RESEARCH.
IF YOU RESPOND "NO" TO ALL QUESTIONS, IT IS MOST LIKELY NOT RESEARCH

If "YES" to Any Question:

This PROJECT may be considered RESEARCH

Does this research activity involve human subjects?

(Interaction with human subjects and/or personally identifiable private data about human subjects) (See Note 2)

Your project may not involve human subjects

See "Assessing Whether There Are Human Subjects in Research" for more guidance. Complete a Request for Determination of "Not Human Subjects" Research Form and submit to IRB for official determination.

SUBMIT PROJECT TO IRB AS RESEARCH INVOLVING HUMAN SUBJECTS

Submit applicable materials to IRB for appropriate level of review

See website for more info: http://www.uvm.edu/irb/

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.