

## Definition of Research Questions

Questions assist in the evaluation of whether an activity meets the definition of research according to the Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) definition.

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” DHHS, 45CFR

“Any experiment that involves a test article and one or more human subjects.” FDA

<b>1. Is the activity systematic?</b>	
Does the proposed study involve the prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization?	<b>No    Yes</b>
Does the proposed study involve a “control group” in whom the therapeutic or study intervention is intentionally withheld or an alternate intervention such as standard care, education only, or an intervention targeted at a different endpoint to allow an assessment of the efficacy of the target intervention?	<b>No    Yes</b>
Will the project be conducted using a research design that will lead to scientifically valid findings? Elements of a research design include a fixed protocol, goal, methodology, population, and time period as well as statistical tests.	<b>No    Yes</b>
<b>2. Is the activity intended to develop or contribute to generalizable knowledge?</b>	
Is the intent that the information learned from the project be generalizable beyond ANMC processes and practices?	<b>No    Yes</b>
Is the information or data collected about a given population used to describe, explain, interpret, or make predictions about other members of that population?	<b>No    Yes</b>
Does the project involve an untested clinical intervention and collecting information about patient outcomes for the purpose of establishing scientific evidence?	<b>No    Yes</b>

OR

<b>3. Does the activity involve an experiment with a test article?</b>	
Does the project involve testing the safety and efficacy of a drug or device in human subjects?	<b>No    Yes</b>
Is the intent to report the results to the FDA as a well-controlled study in support of a new indication for use or in support of a change of labeling or advertising for a drug or biologic?	<b>No    Yes</b>