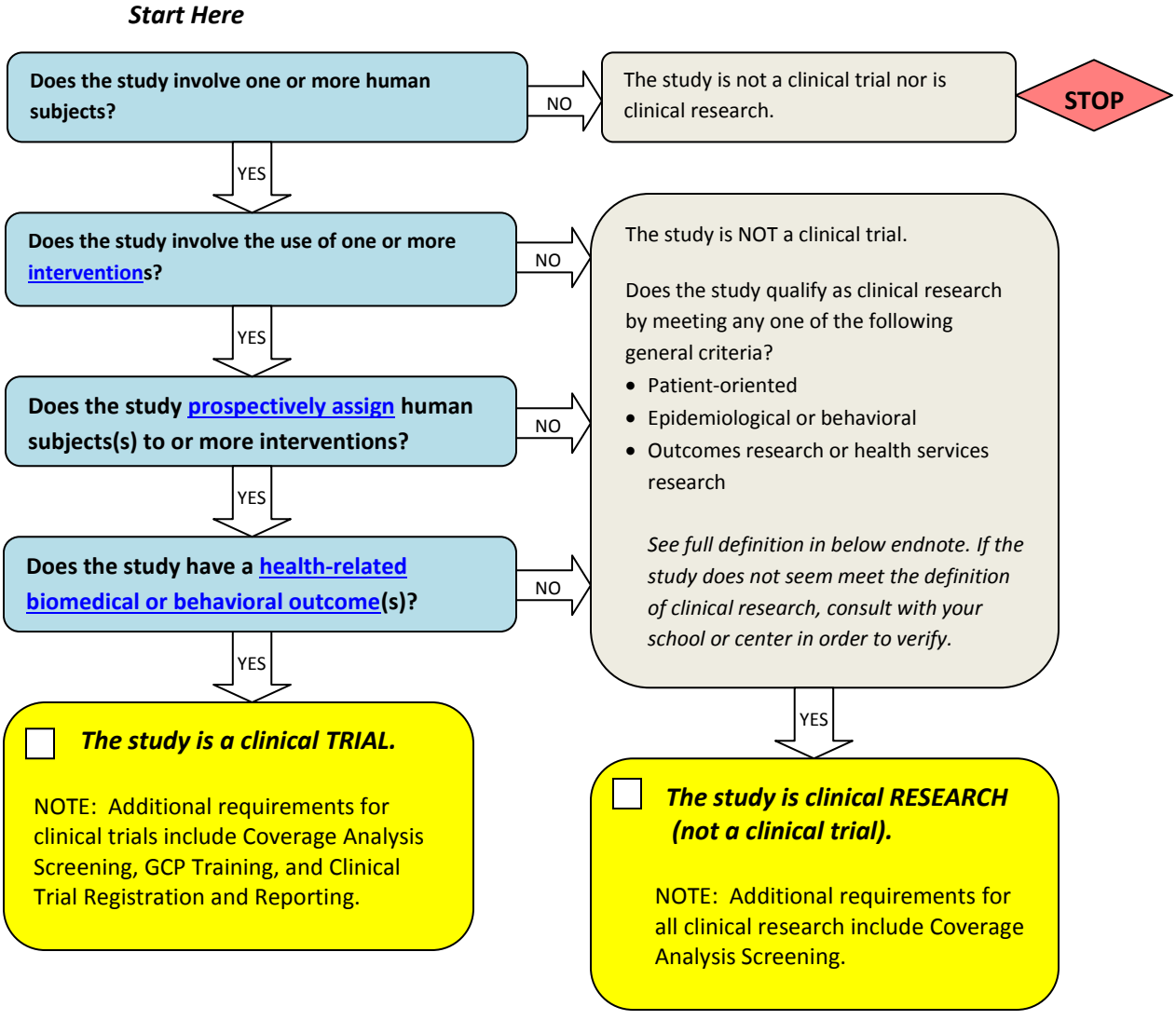
VCU Clinical Trial / Clinical Research – Decision Tree

VCU relies upon standard definitions for identifying clinical trials[i] as a subset of clinical research[ii] (See VCU Compliance Notice 14-003). Clinical trials involve additional compliance requirements; therefore, it is essential that these types of studies are correctly identified with the VCU IRB, OSP, and other administrative units. In support of compliance, all clinical research (including clinical trials) must also clearly identify if the study involves VCU Health System billable services and/or other resources of the VCU Health System.

The following flowchart helps identify these important features of human research studies conducted at VCU and should be reviewed as part of recording compliance features unique to clinical research as soon as possible in the study planning process.



[i] **Clinical Trial:** A clinical trial is a type of a clinical research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

[ii] **Clinical Research:** A human research study that is:

1. *Patient-oriented research.* Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes (a) mechanisms of human disease; (b) therapeutic interventions; (c) clinical trials; and (d) development of new technologies.
2. *Epidemiological and behavioral studies*.
3. *Outcomes research and health services research.*

   Note: Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Decision Tree Definitions:

Intervention: An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Prospectively Assigned: The term "*prospectively assigned"* refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

Health-Related Biomedical or Behavior Outcomes: Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Source: Notice of Revised NIH Definition of "Clinical Trial"