

NIH funding opportunities



NO Clinic<u>al</u>

Trial

NO

Clinical

Trial

Faculty of Medicine and Health Sciences: Research Development and Support 2 Nov 2017 (#40)

[Click on blue <u>hyperlink</u> for further information]

NIH Clinical Trials: Beginning with applications due on or after **25 January 2018**, NIH is implementing policy changes to the application and reporting requirements for awards that include clinical trials (CTs). Because of these changes, some studies that were not considered CTs in the past will be going forward. Deciding whether a study is or isn't a CT should not be the result of a scientific judgement call or even based on your prior experience. Rather, it should be determined using the **Decision Tree for NIH Clinical Trial Definition** (see link). The diagram below will also assist you making the correct decision.

Studies that involve **secondary research with biological specimens or health information** are NOT clinical trials.

1. Does the study involve human subjects?



2. Are the participants prospectively assigned to an intervention?

Prospectively assigned = a pre-defined process (e.g. randomized) 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.



3. Is the study designed to evaluate the effect of the *intervention* on the participants?

Intervention = manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical behavioural processes and/or endpoints. Examples: 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 behaviour (e.g., diet, cognitive therapy, exercise, development of new habits), treatment strategies, prevention strategies, and, diagnostic strategies.



Y E S

4. Is the effect that will be evaluated a health-related biomedical or behavioural outcome?

Health-related biomedical or behavioral outcome = 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: 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 behaviours, and, positive or negative changes to quality of life



See case studies: https://grants.nih.gov/policy/clinical-trials/case-studies.htm