Does the research *prospectively assign* participants to an intervention?

Is the research designed to evaluate an effect of the *intervention* on the participants?

Is the effect being evaluated a *health-related biomedical or behavioral* outcome?

Study meets the definition of clinical trial. COUHES will review research if the following criteria are met:

- The research does not involve significantly greater than minimal risk.
- MIT has the appropriate resources *necessary to facilitate the research.

Research that meets the criteria are required to follow policies and procedures set forth by the COUHES office. All other investigators should contact the COUHES office prior to proposal submission.

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i Prospectively assigned: 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.

ii Intervention: "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.

iii Health-related biomedical or behavioral outcome: A "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.

iv Significantly greater than minimal risk: to subjects means that there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events.

* See COUHES.MIT.EDU for list of available resources at MIT.